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Abstract Mentors

The Abstract Mentor Programme provides an opportunity for early-career abstract submitters to receive feedback from experienced abstract submitters on their draft abstracts. The programme links participants to mentors within the same track to maximize the use of the mentors’ expertise. Mentoring support was complemented by an online e-course on conference abstract writing.

This year, 80 mentors reviewed 156 draft abstracts for 124 researchers, offering them an opportunity to improve their submissions. 116 mentees finally submitted an abstract for IAS 2015.

Of the 156 abstracts, 34 were accepted, with the following breakdown:
- poster discussion sessions: 2
- poster exhibition: 32

We would like to extend a special thank you to the volunteer abstract mentors, listed here, whose mentoring helped early career HIV researchers improve the quality of their abstracts:

Amit Achhra, Australia
Moses Adoga, Nigeria
Susannah Allison, United States
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International Abstract Review Committee

The 8th IAS Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2015) received more than 2,600 abstract submissions, which were put through a blind, peer-reviewed process carried out by an international panel of reviewers who play a critical role in designing a strong scientific programme.

More than 900 specialists from around the world volunteered their time and expertise to serve as peer reviewers, helping to ensure that the abstracts presented were selected on the basis of rigorous review and were of the highest scientific quality.

We extend our special thanks to these individuals for the time they dedicated to the success of the conference:

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### AIDS 2015 Conference Embargo Policy

The content of oral abstracts is embargoed until the start of the session in which the abstract is being presented, with the exception of oral abstracts included in an official IAS 2015 press conference. The embargo on those abstracts lifts at the start time of the press conference in which the oral abstract is featured or the start time of the scientific session in which the abstract is presented – whichever is earlier.

The content of poster discussion and poster exhibition abstracts is embargoed until 10:00 (PDT – Pacific Daylight Time) on Friday, 17 July 2015.

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### SESSION CODING FOR IAS 2015 PROGRAMME

**Example 1:** MOAA01 = MO (Weekday) – AA (Session type) – 01 (Session order)

**Example 2:** MOAA0105LB = MO (Weekday) – AA (Session type) – 01 (Session order) – 05 (abstract order) – LB (late breaker abstract)

**Example 3:** MOPEA001 = MO (poster presentation day) – PE (presentation type) – A (track) – 001 (abstract order)

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MOAA01 Persistently Seeking Virus

A murine viral outgrowth assay to detect HIV in patients with undetectable plasma viral loads

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Background: Sensitive assays are needed for detection of residual HIV in patients with undetectable plasma viral loads to determine if eradication strategies are effective. The gold standard quantitative viral outgrowth assay (QVOA) underestimates the magnitude of the viral reservoir, while sensitive PCR-based assays lack the ability to distinguish replication competent from defective virus. We sought to determine whether xenograft of leukocytes from HIV-1 infected patients with undetectable plasma viral loads into severely immunocompromised mice would result in viral amplification and measurable viral loads within the abscinate murine host.

Methods: We evaluated whether xenograft of 1 peripheral blood mononuclear cell (PBMC) from 5 HIV-1+ patients on suppressive anti retroviral therapy (ART), 2 PBMCs or purified resting CD4+ T cells from 5 HIV-1+ elite suppressors (ES), or 3 PBMCs from a SIV infected pigtailed macaque on suppressive ART, all with undetectable plasma viral loads, into NOD.Cg-PkdcsidId2Gdm1WjlsJ (NSG) mice resulted in viral amplification in the mouse. Successful xenograft of mice was confirmed by flow cytometry. Human CD4+ T cells were depleted in humanized mice with depleting antibody, and CD4+ T cells were a subset in a mouse with activating anti-CD3. Plasma viral loads in xenografted mice were quantified using ddPCR, and compared to plasma viral load and QVOA results from the human or macaque donor.

Results: With this murine viral outgrowth assay (MVOA), we amplified HIV-1 from all 10 HIV+ subjects with undetectable plasma viral load, including an ES from whom we were unable to recover virus by QVOA. We detected HIV in mice an average of 20 days after xenograft with PBMCs from patients on suppressive ART, and an average of 28 days after xenograft with PBMCs or resting CD4+ T cells from ES. For 2 of the mice xenografted with CD4+ T cells from ES, we detected HIV only after activation with anti-CD3. We similarly detected SIV in macaques in mice by 7 days post-xenograft.

Conclusions: The MVOA has the potential to serve as a powerful tool to identify residual HIV-1 in patients with undetectable viral loads, such as those who have undergone promising cure therapies.

MOAA0102

Virologic and immunologic correlates of viral control post-ART interruption in SIV-infected rhesus macaques

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Background: Antiretroviral therapy (ART) does not eradicate HIV and the virus rebounds upon treatment interruption. Recently, a sustained control of HIV replication in the absence of ART has been achieved in a subset of patients starting ART early after infection, defined as post-ART control treatment controllers (PTC). Unfortunately, the virologic and immunologic determinants of post-ART control of HIV replication are still unclear, particularly in tissues. Here, we used the well-established model of SIV-infection in rhesus macaques (RAM) to investigate the existence of PTC in this model and the features associated with post-ART SIV control.

Methods: 15 RMS (B10.BR and B117) were infected (i.v.) with SIVmac. All 15 animals initiated a 5 drug ART regimen 60 days after infection, which was maintained for seven months. ART was then interrupted and RAMs monitored for eight additional months. Blood (PB), lymph node (LN), and colostral (RB) biopsies were collected throughout the study. Quantitative assessment of total SIV-DNA and RNA was performed on purified blood CD4+ T cells and mucosal tissues by quantitative PCR. Immunological parameters were determined by flow cytometry.

Results: ART suppressed SIV RNA to <40 copies/mL in all RAMs. After ART interruption, 6 RAMs controlled SIV viremia at <10^3 copies/mL up to 8 months off-ART (PTC), while 9 RAMs rebounded to pre-ART levels (noncontrollers, NC). At pre-ART, PTC had significantly lower plasma viremia and SIV-DNA content, as well as higher CD4 T cell counts as compared to NC. Levels of intestinal CD4 T cells were similar, but PTC had higher frequencies of Th17 cells than NC. On-ART, PTC had significantly lower levels of residual plasma viremia (3 copies/mL, limit of detection) and SIV-DNA content (both in blood and colostrum). After ART interruption, SIV-DNA content rapidly increased in NC while it progressively decreased in PTC. Finally, in PTC control of SIV rebound associated with higher CD4 T cell levels and reduced immune activation in PB and RB during the entire off-ART period.

Conclusions: Lower set point viremia, reduced cell-associated SIV-DNA, and preserved Th17 cell homeostasis associated with improved virologic response to ART and sustained viral control post-ART interruption in SIV-infected RAMs.
Conclusions: Anti-HIV antibody responses correlate with quantifiable reservoir size during chronic ART-mediated suppression. Epitope location (envelope proteins and reverse transcriptase, an enzyme involved in the early steps of viral replication) may determine the strength of this association. Future studies are needed to evaluate whether viral RNA or proteins are produced in cells with defective proviruses.

MOAA0105LB
HIV-1 virological remission for more than 11 years after interruption of early initiated antiretroviral therapy in a perinatally-infected child

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Durable HIV-1 remission after interruption of combined antiretroviral therapy (cART) has been reported in some adults who started cART during early HIV-1 infection. The in utero HIV-1-infected “Mississippi chilid”, exhibited transient viral control after interrupting very early-initiated cART. However viremia rebounded 27 months later, leaving unclear the possibility of obtaining long-term post-treatment remission in vertically-infected children. Here we report the case of a perinatally-HIV-1-infected adolescent who shows unprecedented virological remission more than 11 years after cART discontinuation.

Methods: HIV-RNA and CD4+ T-cell counts have been monitored since birth. Ultrasensitive HIV-RNA, PBMC-associated HIV-DNA, flow-cytometry-assessed frequency of HIV-specific CD8+ T-cells, CD95 T-cell mediated HIV-suppression, reactivation of the CD4+ T-cell reservoir were evaluated after 10 and 11 years of control off therapy. Plasma concentrations of antiretrovirals were determined by tandem mass spectrometry.

Results: One infant born from a woman with uncontrolled HIV-1 viremia received zidovudine-based prophylaxis during 6 weeks. HIV-RNA and DNA were not detected 3 and 14 days after birth. HIV-RNA was detected at 4 weeks of age. HIV-RNA peaked at 2.1x10^6 copies/ml at 3 months of age when cART (zidovudine, lamivudine, didanosine, ritonavir) was initiated. HIV-RNA was undetectable one month later and remained below assay-detection limits while on cART, except at 15 and 21 months of age. Between 5.8 and 6.8 years of age cART was discontinued by the family. HIV-RNA was undetectable at 6.8 years of age and cART was not resumed. HIV-RNA has remained < 50 copies/ml from 18.3 years of age, except for one blip (cART interruptions). HIV-RNA was undetectable one month later and remained below assay-detection limits while on cART, except at 15 and 21 months of age. Between 5.8 and 6.8 years of age cART was discontinued by the family. HIV-RNA was undetectable at 6.8 years of age and cART was not resumed. HIV-RNA has remained < 50 copies/ml from 18.3 years of age, except for one blip (cART interruption). CD4+ T-cell counts remained stable. After 11 years of control off therapy (confirmed by undetectable plasma concentrations of antiretrovirals), HIV-RNA was below 4 copies/ml and HIV-DNA was 2.2 Log copies/10^6 PBMC. Low levels of HIV-RNA and p24 were detected upon activation of CD4+ T-cells with PHA. HLA genotype showed homozygosity at several loci (A*2301-;B*1503/4101;C*0210/0802;DRB1*1101-;DQB1*0602-). HIV-specific CD8+ T-cell responses and T-cell activation were very weak. HIV-1 western blot was positive with absence of antibodies against gp110 and p18.

Conclusions: This case provides first-time evidence that very long-term HIV-1 remission is possible in perinatally-early-treated children, with similar characteristics as reported in adult post-treatment controllers.
MOAA0106LB

Time associated changes in cell-associated HIV RNA in HIV-infected subjects on suppressive antiretroviral therapy - implications for clinical trials of cure interventions

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Background: Cell-associated unspliced (CA-US) HIV RNA is an important marker of the HIV reservoir and a common primary endpoint in clinical trials of latency reversing agents in HIV-infected subjects on antiretroviral therapy (ART). We observed large baseline variation in CA-US HIV RNA in a recent trial of disulfiram and hypothesised these changes were due to circadian-related alterations in CD4+ T-cell composition, gene regulation or anticipatory stress.

Methods: Blood was collected on three occasions (B1, B2 and B3) from HIV-infected subjects (n=30) on suppressive ART prior to any intervention. B3 was collected immediately prior to administration of disulfiram. We measured CA-US HIV RNA and DNA by real-time PCR and plasma viral loads using a single copy assay by droplet digital PCR. Plasma cortisol and thyroxine stimulating hormones (TSH) levels were quantified by ELISA. PMBC were stained with live-dead dye and antibodies to CD3, CD4, CD8, CD45RA, CC57, CD27, CD81, HLA-DR, acetylated lysine and acetylated histone-3 and were analysed by flow cytometry. Data were assessed for normality then analysed with Wilcoxon matched-pairs signed rank tests and paired-t-tests.

Results: CA-US RNA was higher in blood collected at B3 compared to B1 and B2 (median 85.63 vs. 28.14 and 34.87 copies/million CD4+ T-cell equivalents; both, p<0.001). There were little differences in HIV DNA or plasma HIV RNA at these times. B3 was collected earlier in the day compared to B1 and B2 (mean 8:28am vs. 11:38am and 10:2am; both, p<0.001). Other parameters that were significantly higher at B3 compared to B1 and B2 were cortisol (p=0.001 and 0.011), TSH (p=0.023 and 0.004), CD4+CD38+HLADR− T-cells (both, p<0.001) and CD4+CD38+HLADR+ T-cells, which were elevated at B3 compared to B2 (p=0.012). There were no significant differences in the percentage of T-cell subsets or histone acetylation in the blood collected at these time-points.

Conclusions: Time-associated variation in CA-US HIV RNA seen in HIV-infected subjects on suppressive ART was not associated with significant alterations in CD4+ T-cell subset composition and was suggestive of circadian changes in HIV RNA transcription. Diurnal changes in CA-US HIV RNA may need to be considered in the design of future cure intervention trials.

MOAA02 Microbiome: the Good and the Bad for HIV

MOAA0202

Treatment with anti-α4β7 integrin antibody reduces virus-mediated gastrointestinal pathology by targeting distinct mucosal tissues

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Background: Our laboratory has recently demonstrated that in vivo administration of a monoclonal antibody against α4β7 integrin (α4β7-mAb) reduces virus-mediated gastrointestinal pathology following infection, and results in both quantitative and qualitative differences in the levels of virion and tissue localization of the virus between the two groups.

Methods: Groups of 12-16 RM were administered a single i.v. dose of HIV-1 (500000 copies/ml) in CA-US HIV RNA may need to be considered in the design of future cure intervention trials.

Conclusions: The α4β7-mAb either protects or delays intravaginal SIV transmission, reduces gastrointestinal pathology following infection, and results in both quantitative and qualitative differences in the levels of virion and tissue localization of the virus.

Methods: Groups of 12-16 RM were administered a single dose of HIV-1 (500000 copies/ml) intrarectally. Each monkey was then repeatedly challenged with a low-dose SIVmac251 intra-vaginally or a single high-dose intrarectally.

Results: i.v. administration of α4β7-mAb blocked the detection of α4β7 on CD4+ T cells in the blood, cervicovaginal tissue, and GALT throughout the period of mAb administration. Viral RNA was reduced in GALT biopsies of the α4β7-mAb treated groups compared to those treated with control mAb (median 3.5 vs. 12.8 copies/mg DNA respectively, p<0.005). Furthermore, in-depth analysis performed on a subset of animals (n=4/group) indicated that proviral DNA was 5 to 25 fold more abundant in jejunum, ileum, or colon of control-treated groups compared to those treated with α4β7-mAb. In contrast, no difference in proviral loads in the spleen and lymph nodes from various sites was noted in the 2 groups.

Conclusions: The α4β7-mAb either protects or delays intravaginal SIV transmission, reduces gastrointestinal pathology following infection, and results in both quantitative and qualitative differences in the levels of virion and tissue localization of the virus.

MOAA0203

Oral microbiome in HIV-infected women: aging, disease progression and opportunistic infections increase the pathogenic profile

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Background: A recent marked increase in the proportion of HIV-infected individuals older than 50 highlights the need to study the impact of aging on HIV pathogenesis. HIV-Associated Non-AIDS (HANA) conditions, such as cardiovascular disease, diabetes, osteoporosis, and dementia are more prevalent in older HIV-infected populations than young adults. The microbiome in saliva and the oral cavity has been studied as a window into pathogenesis in aging populations. Although disruption of the oral microbiome (dysbiosis) has been linked to various human conditions and diseases associated with aging, the role of age-related dysbiosis in the development of opportunistic infections and HANA conditions in HIV patients is not well understood.

Methods: We utilize 16S RNA-based pyrosequencing to compare the salivary microbiome in 3 groups: Chronically HIV-infected women enrolled in the Women’s Intergroup HIV Study who are 1) >50 years old (aging), or 2) <35 years old (young adult), and 3) healthy age-matched uninfected women. We also examine correlations between dysbiosis of the salivary microbiome, disease progression, and opportunistic oral infections.

Results: HIV infection results in dysbiosis of the salivary microbiome that is enhanced in aging individuals, and characterized by increased abundance of pathogenic bacteria and a decline in healthy probiotic microbes. Higher proportions of Prevotella, Staphylococcus, Mororrea, Peplophastopoccocus, Ruminococcus, and Orbacterium were detected in both aging and young adult HIV infected women than in uninfected controls. Prevotella, Mororrea, and Orbacterium increases were higher in aging than in young HIV patients. HIV infection in older patients was associated with greater salivary shedding of Epstein Barr Virus (EBV). Increased EBV shedding, higher peripheral HIV burden, and reduced CD4+ T cell counts correlated with increases in Prevotella and decreases in probiotic Lactobacillus. Patients with opportunistic oral infections also showed enhanced salivary levels of Porphyromonas, Lachnospira, and Actinobacillus, and reduced Streptococcus.

Conclusions: Age, severity of disease progression, and emergence of opportunistic infections all contribute to various degrees in increasing the pathogenic footprint of the oral microbiome during chronic HIV infection. The study findings provide new insights into age-related dysbiosis of the salivary microbiome and its role in HIV pathogenesis and lay critical groundwork for future expanded investigations.
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**MOAA0204**

Serum-derived bovine immunoglobulin isolate increases peripheral and mucosal CD4 T cell count in patients with HIV enteropathy

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Background: A multi-center trial in HIV-enteropathy was conducted to evaluate the impact of serum-derived bovine immunoglobulin isolate (SBII) on markers of peripheral and mucosal immunity and gastrointestinal (GI) symptoms as previously reported.

Methods: Patients (n=15) on long-term suppressive ART with HIV-enteropathy were randomized to receive SBII 2.5 vs 5.0 grams (g) ID or placebo (PBO) during a 4-week lead-in phase followed by SBII 2.5 vs 5.0 g ID for 20 weeks. Evaluations included plasma biomarkers for inflammation, peripheral CD4 counts and pt-reported surveys on GI symptoms. Eight pts underwent duodenal biopsies to examine mucosal immunity.

Results: 103 pts (2 SBII 5 g; 73 ID; 30 PBO; n=125 confirmed 2.5 vs 5.0 g [p=15 each]) were randomized. Duodenal inflammation [Duodenal inflammation (p<0.001)] was significantly reduced from baseline (BL) to week 10 between groups (p=0.02). Moreover, at all taxonomic levels, there were differences between the positive and negative controls, and proliferation and cytokine expression measured using multicolor flow cytometry.

Conclusions: Several key species were significantly correlated with both proliferative and cytokine responses in HIV exposure groups via PCoA analysis. Several OTUs of the phylum Firmicutes were differentially regulated by Shannon index. Moreover, at all taxonomic levels, there were differences between the positive and negative controls, and proliferation and cytokine expression measured using multicolor flow cytometry.

**MOAA0205**

HIV-exposure, gut microbiome, and vaccine responses in South African infants


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Background: The gut microbiome is crucial for mucosal and systemic immune development. In mice, certain bacteria are required for induction of Treg and Th17 cell development in the gut. Likewise, gut microbiota enhance immune responses to influenza vaccination in the mouse model. HIV-infected women have altered vaginal and gut microbiome, and HIV-exposed infants (HEU) and their mothers receive antibiotics for Pneumocystis pneumonia prophylaxis, therefore HEU may have altered gut microbiota. HEU have higher morbidity and mortality than HIV-unexposed (HU) infants, and respond poorly to certain infant vaccinations. We hypothesized that the etiology of this relative immune deficiency is mediated by gut dysbiosis.

Methods: HEU and HU infants were recruited at birth from informal settlements of Cape Town. Blood and stool were collected after informed consent was obtained. Stool DNA was extracted using MoBio PowerFecal DNA kit and 454 or Illumina sequencing was performed. Data was preprocessed using QIMIE and UPARSE and imported into R for further analyses using phyloseq. Differential abundance testing was performed at Operational Taxonomic Unit (OTU) level using the R metagenomeSeq package. Whole blood was incubated with BCG, positive and negative controls, and proliferation and cytokine expression measured using multi-parameter flow cytometry.

Results: We found substantial differences in bacterial diversity between HEU and HU infants by Shannon index. Moreover, at all taxonomic levels, there were differences between the HIV exposure groups via PCoA analysis. Several OTUs of the phylum Firmicutes were differentially abundant between HEU and HU infants, three of which were of the genus Veillonella. Several key species were significantly correlated with both proliferative and cytokine responses to BCG. For example, at 6 weeks of age, significantly decreased abundance of Bacteroides species, and in particular B. fragilis, were present in infants with high CD4+IL-2+, CD8+IL-17+ and CD8+HLA-DR+ responses to BCG vaccination at 6 weeks of age.

Conclusions: Gut microbial composition could explain the immunological differences between HU and HEU infants. These differences should be considered in development of HIV vaccines for exposed neonates.

**MOAA0206LB**

SIV-induced translocation of bacterial products in the liver mobilizes myeloid dendritic and natural killer cells associated with liver damage

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Background: Disruption of the mucosal epithelium during immunodeficiency kentivirus infections permits translocation of microbial products into the circulation, causing systemic immune activation and driving disease progression. However, the specific effects of microbial products in liver, as a blood-filtering organ, are unclear.

Methods: In this study we investigated the effects of simian immunodeficiency virus (SIV) infection of rhesus macaques on microbial translocation in the liver by immunohistochemistry. We also compared liver infiltration by myeloid dendritic cells (mDCs), trafficking to the liver by lymphocytes, and liver-resident natural killer (NK) cell frequencies, phenotypes, and functions in naive and chronically SIVmac251+ or SIVmac251-infected rhesus macaques using flow cytometry.

Results: In livers of normal rhesus macaques very low levels of bacteria and LPS were detectable, but increased up to 20-fold in chronically SIV-infected animals. Increased microbial products in the liver of infected macaques was associated with production of the chemotactant, CXCL16, by mDCs. Subsequently, lymphocytes expressing the CXCL16 receptor, CXCR6, were mobilized in blood and hypercytotoxic NK cells were recruited to the liver. Microbial accumulation, mDC activation and hepatic cytotoxic NK cell frequency were all significantly correlated with markers of liver damage.

Conclusions: Collectively, these data indicate that SIV-associated accumulation of microbial products in the liver initiates a cascade of innate immune activation resulting liver damage. These findings have implications for the liver pathology associated with HIV, especially in instances of coinfection with HCV.

**MOAB0101**

Field evaluation of point-of-care testing for early infant diagnosis in Cape Town, South Africa

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Background: Provision of rapid early infant HIV diagnosis (EID) service remains a challenge for prevention of mother-to-child transmission programmes globally. Point-of-care (POC) EID testing may improve access and turnaround times, but while several POC technologies are in development there are few data on implementation.

Methods: We conducted an implementation study of the Alere q Detect POC system for EID at two public sector health facilities. At a maternity hospital the POC device was used to test HIV-exposed neonates soon after birth; at a primary care clinic the device was used for routine six-week EID testing. At each site infants undergoing laboratory-based HIV PCR testing per local protocols were tested on the POC device by doctors or nurses with results available within 1 hour. Analysis examined the performance of POC versus laboratory testing of the same specimen, and semi-structured interviews with providers to assess implementation issues and acceptability.

Results: Overall 476 tests were conducted: 291 birth tests in the maternity hospital (mean child age, <1 day) and 195 six-week tests in primary care (mean child age, 51 days). 12% of all tests resulted in an error with no differences by site; most error results resolved with retesting. POC EID was more sensitive (100%, lower confidence limit, 40%) and specific (100%, lower confidence limit, 56%) among older children tested in primary care compared birth testing in hospital (92%, [95% CI, 62-100%] and 99% [95% CI, 99-100%], respectively), though test performance improved with repeated lab testing and negative predictive value was high (>99%) at both sites. In interviews, providers felt that the ease of use of the device coupled with the
High rates of baseline NNRTI-resistance and virologic failure among ART naive HIV-1-infected children in Mali


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Background: Limited data exist on drug resistance and antiretroviral treatment (ART) outcomes in HIV-1 infected children in West Africa. We determined the prevalence of baseline resistance, and correlates of virologic failure (VF) and ART failure in children receiving ART in Mali.

Methods: Prospective observational study of HIV-infected children <10 years of age initiating first-line ART in Bamako, Mali. Assessments occurred at baseline and after 6 months of ART. Genotypic resistance testing on stored baseline and 6-month samples occurred at study end. Reverse transcriptase and protease genes were sequenced using in-house methods. Resistance was defined as intermediate or high-level according to the Stanford HIV Genotypic Resistance Algorithm v7.0. VF was defined as viral load (VL) ≥10,000 copies/mL. Clinical and immunological failure were based on WHO criteria. Logistic regression was used to evaluate factors associated with VF and resistance.

Results: 150 children were enrolled. 60% male and mean age 3.4 years. 94% reported no PMTCT exposure. Median baseline CD4 count and VL were 633 cells/mm3 (IQR: 381-1039) and 675,651 copies/mL (IQR: 40,000-1,583,200). Initial ART regimens were lopinavir/ritonavir-based (43%) or NNRTI (efavirenz or nevirapine)-based (57%). Of 141 children with amplifiable baseline samples, 28 (19.8%) had NNRTI resistance, only 2 of whom had PMTCT exposure, and none had PI resistance. Mean age of children with baseline NNRTI resistance was 2.3 years. By 6 months of ART, 11 died, 8 were lost to follow-up and 6 had missing VL data. Among 125 remaining children, 41 (33%) had VF, 24 of whom (58%) had drug resistance (23 with NNRTI and one with PI mutations). 93% of children with VF did not meet criteria for clinical or immunological failure.

In multivariate analyses adjusting for age, gender, adherence, and ART regimen, baseline NNRTI resistance was strongly associated with VF and 6-month resistance (OR: 6.7, p=0.001; OR: 20, p<0.001). Baseline NNRTI resistance was common in Malian children without prior NNRTI exposure and was associated with VF and a high resistance rate during ART. Clinical and immunologic criteria rarely detected VF. Our findings support WHO recommendations of PI-based regimens in all children <3 years, and virological monitoring.

T cell activation and treatment outcomes among infants receiving early ART

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MOAB0105

Treatment and resistance outcomes of Asian children on second-line antiretroviral therapy

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Background: Treatment failure occurs in 30% of children on first-line antiretroviral therapy (ART), with limited options for second-line treatment. Resistance outcomes of Asian children on second-line ART are needed to guide future management.

Methods: We retrospectively reviewed medical records of children <18 years old who were taking or switching to second-line ART from HIV-infected children from Thailand, Vietnam, and Indonesia. We included children with available first-line failure resistance information, second-line ART regimen, and at least one follow-up visit. The primary endpoint was virologic suppression (<50 copies/mL) at Week 48. Cox proportional hazards regression was used to evaluate factors predicting post-switch virologic failure.

Results: Of 277 children enrolled, 41% were female. Baseline values included median (interquartile range; IQR) age 7.5 (5.3-10.3) years, CD4 count 300 (146-562) cells/mm3, and HIV-RNA 5 (4.4-5.5) log10 copies/mL. The median duration of first-line ART was 2.7 (1.7-4.2) years. Resistance mutations at first-line failure were available for 156 (56%) children. VF occurred in 73 (27%; incidence 7 per 100 person-years) children. VF occurred in 31 (43%) children taking EFV, 16 (52%) taking NNRTIs, and 1 (6%) taking PI-based regimens. Factors significantly associated with increased risk of VF were CD4% <13 (7-20%); HIV-RNA >5 log10 copies/mL (HR 2.4; 95% CI 1.27-4.59) at second-line switch; and ≥1 NNRTI mutation (92%). Current second-line regimens contained lamivudine (90%) and included ≥4 thymidine analogue mutations (TAMs; 18%), Q151M (8%), M184V (82%), and ≥1 NNRTI mutation (92%).

Conclusions: Virologic failure occurred in 27% of children on second-line ART overall and in 43% of children taking EFV. Factors significantly associated with increased risk of VF were CD4% <13 (7-20%); HIV-RNA >5 log10 copies/mL; and ≥1 NNRTI mutation. Second-line regimens contained lamivudine and ≥4 TAMs in 90% of children. Resistance outcomes of Asian children on second-line ART are needed to improve virologic outcomes and guide future management.

MOAB0106

Week 48 safety and efficacy of a rilpivirine (TMC278)-based regimen in HIV-infected treatment-naïve adolescents: PAINT phase II trial

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Background: Rilpivirine 25mg gd exposure was similar in adults and adolescents (Week 4 2015 pharmacokinetic analysis). Week 4 safety and efficacy results are reported here.

Methods: PAINT (NCT01998644) is a Phase II, ongoing, open-label, single-arm trial of rilpivirine plus two investigator-selected NNRTIs in treatment-naïve HIV-1-infected adolescents (n=12 to < 18 years, from sites in India, Thailand, Uganda, South Africa, USA). After the adult approved indication, only patients with viral load (VL) ≤100,000 copies/mL were enrolled. Vi- rologic response was defined as VL < 50 copies/mL at time-to-loss of virologic response (TLOVR) algorithm.

Results: Of 36 patients, 20 (56%) were female, 18 (50%) aged 13-15 years and 32 (89%) Black/African American. 28 (78%) had baseline (BL) VL ≤100,000 copies/mL, 4/8 (50%) had VL >100,000 copies/mL, achieved virologic response. Of the ten non-responders (28%), eight were virologic failures (VFs); one was dosed without a protocol-violating screening NNRTI RAM) and withdrawn and one withdrew due to an AE (pulmonary tuberculosis). CD4+ count increased by median (range) 250.5 (-135 to 740) cells/mm3. For 218 VFs, overall adherence (pill count) was > 95% (one of these also had BLVL >100,000 copies/mL). Of eight VFs developed rilpivirine RAMs, mostly E138K (n=4), K101E (n=2) and M230L (n=4): 4/5 developed NRTI RAMs, mostly M184V (n=3).

Conclusions: This 48-week analysis supports use of rilpivirine 25mg gd combined with other antiretroviral inhibitors in treatment-naïve HIV-1-infected adolescents (n=12 to < 18 years) with VL ≤100,000 copies/mL. Rilpivirine safety, virological and pharmacokinetic results were similar to those observed in adults.

MOAB0107LB

In utero tenofovir exposure is not associated with fetal long bone growth

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Background: Despite widespread use of tenofovir (TDF) in pregnant and breastfeeding women, few data have been published on fetal bone development or child growth after in utero TDF exposure.

Methods: We evaluated fetal long bone measurements in HIV-infected pregnant women’s fetuses delivered in Cape Town, South Africa. Measurements were conducted by a trained research sonographer using high-resolution ultrasound. Fetal femur (FL) and humerus (HL) length z-scores were compared by duration of in utero TDF exposure in three categories: 1) TDF-exposed since conception (TDF-C); vs. 2) TDF-exposed for ≥4 weeks and initiated after 1st trimester (TDF-E), vs. 3) TDF-exposed for <4 weeks or TDF-unexposed (TDF-U). Ultrasound performed at <10 weeks gestational age (GA), twin pregnancies, and those resulting in intrauterine fetal demise were excluded. Linear mixed effects models were used to assess the effect of duration of TDF exposure category on FLZ and HLZ.

Results: A total of 1957 fetal ultrasounds (408 TDF-C, 581 TDF-E, 968 TDF-U) in 1030 women were included (73% of whom had ≥2 ultrasounds) were available for analysis. Women in the TDF-C group were older and had lower CD4 cell counts than women in the other categories but did not differ in anemia or history of low birthweight deliveries (Table). Median duration of TDF exposure was 26.9, 13.0 and 0 weeks, respectively, in the TDF-C, TDF-E and TDF-U groups. Mean FLZ and HLZ did not differ by TDF exposure category (FLZ: 0.321 vs. 0.330 vs. 0.333,
MOAB02 HIV and TB: Gaps and Opportunities

MOAB0201 The durability of isoniazid preventive therapy for tuberculosis: long-term follow-up from a prospective cohort of HIV-infected adults in South Africa

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Background: Isoniazid preventive therapy (IPT) has been demonstrated to reduce the risk of active tuberculosis (TB) in HIV-infected adults, but the effectiveness of shorter IPT regimens (6-9 months) rapidly wanes in high TB burden settings. We examined the long-term durability of 6 months of IPT among HIV-infected adults in South Africa.

Methods: We analyzed the experience of a prospective clinical cohort of HIV-infected adults at one urban and one rural hospital in South Africa. In 2003-2010, 3,465 HIV-infected adults were followed for 9,908 person-years (PY).

Results: From 2003-2010, 3,465 HIV-infected adults were followed for 9,908 person-years (PY) during which 372 incident TB cases were diagnosed (incidence rate [IR]: 3.8/100PY; 95% CI: 3.5-4.1). During 9,908 PY, 318 incident TB cases were diagnosed (IR:4.0/100 PY; 95% CI:3.6-4.4) and during 8,022 PY without IPT, 209 incident cases of TB were diagnosed (IR: 2.9/100 PY; 95% CI: 2.2-3.7).

Conclusions: In this prospective cohort of HIV-infected adults in South Africa, receipt of 6 months of IPT resulted in a marked (40%) reduction in risk for TB during the first year following IPT initiation, independent of ART status. No reduction in risk was noted in those who were initiated beyond one year, confirming similar findings in settings of high TB burden. We demonstrate that IPT remains an important intervention for HIV-infected individuals, and that even a short regimen can provide crucial protection from TB of up to one year for those not yet initiated on highly active antiretroviral therapy.

MOAB0202 Treatment outcomes of drug-resistant TB patients in South Africa, disaggregated by HIV status, as reported in a national electronic drug-resistant TB register

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Background: South Africa reports the third highest number of drug-resistant TB (DR-TB) cases and the largest population living with HIV in the world. We describe treatment outcomes of patients from the South African Electronic Drug Resistant Tuberculosis Register (EDRWeb), the national database of all DR-TB cases, after January 2009.

Methods: Retrospective, de-identified descriptive analysis of all patients with multidrug resistant (MDR) TB who initiated DR-TB treatment in South Africa between 01/01/09-30/09/11. During this period, guidelines specified all MDR-TB patients were admitted to specialized referral hospitals for the 6 month intensive phase of treatment or until culture conversion, then followed as outpatients for 12-18 months. Treatment outcomes included success (cured and treatment completed), failed, lost to follow-up, and died. Person-time accrued from treatment initiation until the earliest of outcome date recorded or 24 months on treatment. Cox hazard models were used to evaluate the relationship between HIV status and all-cause mortality.

Conclusions: Among those with an outcome reported (8,465/13,692; 62%), overall mortality and success rates were 24.6% [95% CI 23.7-25.5] and 42.4% [41.3-43.4], respectively. Success was similar between HIV negative patients (42.9% [41.0-44.8]) and those co-infected with HIV (42.5% [41.0-43.9]; 15.5/100 pys). Mortality was substantially higher in HIV positive patients (27.3% [26.0-28.6]; 60.1/100 pys) than the HIV negative (17.3% [15.9-18.7]; 8.1/100 pys) group (adjusted hazard ratio 1.45 [1.30-1.62]). Fewer HIV positive patients were lost to follow-up or failed treatment compared to HIV negatives (21.6% and 8.6% vs. 29.0% and 10.8%).
**MOAB0204**

**Missed opportunities in the TB/HIV cascade of care in 14 high burden TB/HIV African countries, 2012**

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**Background:** Despite being preventable and curable, tuberculosis (TB) remains the leading cause of morbidity and mortality of people living with HIV (PLHIV). The past decade has seen considerable scale-up of collaborative TB/HIV activities, however, implementation remains suboptimal. Closer inspection at each stage of the cascade of TB/HIV care is warranted to assess the gaps and to identify opportunities for strengthened service delivery in order to eliminate HIV-associated TB mortality.

**Methods:** Data were downloaded from the Global TB Programme Database on 22/01/2015 on the latest available TB treatment outcomes (2012 cohort), disaggregated by HIV status, from reporting high TB/HIV burden countries in the WHO African Region, along with related data on the implementation of collaborative TB/HIV activities. Data were analysed and missed opportunities identified.

**Results:** 14 countries reported the required outcome data, accounting for some 570,000 HIV-positive incident TB cases, (Table 1), or 63% of the African burden and 49% of the global burden in 2012. More than 50,000 reported HIV-TB positive cases died or were lost to follow-up, representing 16% of evaluated cases, compared with 11% of evaluated HIV-negative TB cases (Figure 1).

**Figure 1. TB-related death among HIV-positive patients according to the number of active drugs used as part of empiric TB therapy**

**Conclusions:** There is an elevated risk of death from TB in HIV patients managed in EE compared to WE and LA. This is partly explained by modifiable risk factors including low rates of DST, hampering the optimized choice of TB drugs in a setting of high MDR-TB prevalence. Our data call for urgent action to improve the care of HIV/TB patients in EE.

**Authors Index**

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Conclusions: This analysis highlights some considerable gaps in the care cascade, resulting from suboptimal implementation and/or recording and reporting. In order to prevent disproportionate TB mortality among PLHIV, countries are encouraged to scrutinize weaknesses in the care cascade at every level to enhance early detection of HIV-associated TB, timely ART initiation and scaled-up TB prevention.

MOABO205LB
Empiric TB therapy does not decrease early mortality compared to isoniazid preventive therapy in adults with advanced HIV initiating ART: results of ACTG A5274 (REMEMBER study)

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Background: Strategies for reducing the high early mortality seen among patients initiating ART in resource-limited settings (RLS) are urgently needed. We hypothesized that the high burden of tuberculosis (TB) in these settings, empiric TB treatment among patients at high risk for death would reduce early mortality.

Methods: REMEMBER (Reducing Early Mortality and Early Morbidity by Empiric Tuberculosis Treatment Regimens) is a multi-country randomized clinical trial comparing 2 management strategies: ART + empiric 4 drug TB therapy (Empiric) vs. ART+ isoniazid preventive therapy (IPT) in HIV infected individuals with CD4 count < 50 cells/mm3. Participants were screened for TB prior to entry using symptom screen, locally available diagnostics per standard of care, and GeneXpert when available. The study was stratified according to CD4 count (< 25 cells/mm3) and poor prognostic factors (body mass index < 18.5, Hemoglobin < 8g/dl, recent hospitalization). The primary endpoint was survival (death or unknown status) at 24 weeks post randomization, and Kaplan Meier estimates of the endpoint rates across arms were compared by the z-test.

Results: Of 1368 participants screened, 850 (62%) were randomized; 53% were male, 9% were black, and median (quartiles) age was 36 (30-42) years. The median (quartiles) CD4 count at study entry was 18 cells/mm3 (9, 32). At week 24, both arms had the same primary endpoint rate of 5.2% (95% CI: 3.5% to 7.8% for Empiric and 3.4% to 7.8% for IPT) with an absolute risk difference of -0.6% (95% CI: -3.0% to 2.9%). Primary endpoint rates were similar across arms for the stratification factors and for other secondary outcomes: Viral load < 400 copies/ml was achieved in 84% Empiric and 85% IPT; Grade 3 or 4 symptoms occurred in 12 % Empiric and 11% IPT, Grade 3 or 4 laboratory abnormalities in 23% both arms; and new clinical events in 49% Empiric and 51% IPT.

Conclusions: Among highly TB screened participants with advanced HIV in RLS, empiric TB therapy did not reduce mortality at 24 weeks compared to IPT. The low mortality seen in both arms supports enhanced screening for TB prior to ART initiation and the routine use of IPT.

MOAC0101LB
Final results of the HPTN 052 randomized controlled trial: antiretroviral therapy prevents HIV transmission

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Background: The HPTN 052 trial was designed to evaluate whether antiretroviral therapy (ART) reduces sexual transmission of HIV. The trial started in April 2005 and ended in May 2010. The HPTN 052 trial was designed to evaluate whether antiretroviral therapy (ART) reduces sexual transmission of HIV. The trial started in April 2005 and ended in May 2010. The trial included 14,998 HIV-positive adult men and women in 7 countries (Africa, Botswana, Kenya, Thailand, India, Brazil and the US) (97% heterosexual). HIV-infected index participants had CD4 cell counts between 350-550 cells/mm3 at enrollment. Index participants were randomized to receive ART at enrollment (early arm) or when their CD4 cell count fell to ≤250 cells/mm3 or they developed an AIDS-defining illness (delayed arm). The primary analysis was based on genetically-linked viral transmission events. When interim analysis in May 2011 demonstrated the benefits of early ART, ART was offered
MOAC0102
Level of viral suppression and cascade of HIV care in a South African semi-urban setting in 2012 (ANRS-12126 -12285)
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Background: For antiretroviral treatment (ART) programs to have a preventive impact, the proportion of HIV-infected people being treated should be high. In 2012, seven years after the beginning of ART programs in the South-African township of Orange Farm, we measured the proportion of HIV+ who were virally suppressed, especially among age groups highly exposed to HIV (women 18-29y and men 25-34y).

Methods: A community-based cross-sectional representative survey conducted in 2012 among 3293 men and 3473 women. Study procedures included a face-to-face questionnaire and collection of blood samples that were tested for HIV, 10 antiretroviral drugs (ARVs) and HIV-Viral Load (VL).

Results: HIV prevalence was 17.0% [95% Confidence Interval: 15.7-18.3%] among men and 30.1% [28.5-31.6%] among women. Overall, 59.1% [57.4-60.8%] of men and 79.5% [78.2-80.9%] of women reported having ever been tested for HIV. When controlling for age, circumcision was not associated with ever being tested (66.1% vs 53.6%; p<0.001). Among HIV+ individuals, 21.0% [17.7-24.6%] of men and 30.5% [27.7-33.3%] of women tested positive for any ARV. The ratio of ARV+ people over those HIV+ was 0.084. Using basic calculations, we found that if ART programs were actually treating all eligible patients since 2005, this would be 170% more HIV infections and 50% more treatment costs over 15 years.

Conclusions: In Orange Farm, in the 2005-2012 period, ART programs were sub-optimal, and, among HIV+, proportion of viral suppression was low, especially among the highly-exposed age groups. This suggests that, up to 2012, ART programs may not have substantially impacted HIV incidence. However, our study showed at community level that, when effectively taken, ARVs present a high effectiveness in suppressing VL.

MOAC0103
A mathematical model to determine potential costs and benefits of increasing antiretroviral therapy coverage in female sex workers: the case of Panama
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Background: Panama adopted Treatment as Prevention (TasP) in February 2014 and is now seeking efficient and effective ways to expand antiretroviral therapy (ART) coverage in key populations. We developed a mathematical model to determine the ART coverage and associated costs required to meet HIV incidence reduction targets for the female sex worker (FSW) population, which has a 1.6% HIV prevalence.

Methods: The Government of Panama, British Columbia Centre for Excellence in HIV/AIDS and Simon Fraser University are collaborating to develop mathematical models for informing Panama’s TasP strategy. Quantitative and qualitative Information was collected from national reports, key informant interviews and focus groups with civil society to inform a community-based HIV transmission model incorporating disease progression and treatment. The model was calibrated and validated for 2013. Estimated FSW population size is 17,000 and according to the GARP report, current ART coverage for both FSW and the hard-to-reach client population is about 47%. Annual ART cost/Individual is US$625. Simulation scenarios for meeting 50%, 70% or 90% reduction in HIV incidence in FSW in 15 years assumed ART expansion either for FSW and their clients (Scenario 1) or for FSW only (Scenario 2).

Results: ART expansion for FSW costs slightly more in Scenario 1 than 2. However, overall for both populations of FSW and clients, more infections are averted and treatment program costs are lower for the strategy targeting FSW only (see table). Furthermore, initial aggressive expansion of ART coverage leads to overall cost savings and a more effective means of averting new infections (see figure). The ratio of no action compared to the 90% Scenario 2 strategy would be 170% more HIV infections and 50% more treatment costs over 15 years.

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[Outcomes and Costs of TasP Expansion Scenarios]

[Annual Treatment Cost for FSW Population]
Conclusions: Rapid expansion of Tasp for female sex workers in Panama would avert infections and treatment costs already within 15 years. Initial short-term investment to increase ART coverage would be offset by long-term savings. Since Panama adopted Tasp, UNAIDS has announced the 50-50-50 targets for HIV diagnosis, treatment and suppression, which calls for an even more rapid reduction in incidence. Ongoing analyses are evaluating costs and outcomes of reaching the new targets by 2020.

**MOAC0104**

**Does a universal test and treat strategy impact ART adherence in rural South Africa? ANRS 12249 Tasp cluster-randomized trial**

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Presenting author email: ciwuji@yahoo.com

**Background:** HIV treatment guidelines are recommending ART at increasingly higher CD4 counts for maximizing individual and population benefits. However, the expansion of ART use may be at the expense of optimal adherence. We report on adherence and virological suppression when initiating ART at different CD4 thresholds within the Treatment as Prevention (ANRS 12249) trial of universal home-based testing and immediate ART initiation in rural KwaZulu-Natal.

**Methods:** Using data of a cluster-randomised trial of immediate ART vs. initiation according to current national guidelines (CD4≥500cells/mm³), we compared adherence levels (≥95% vs. <95%), measured using a visual analogue scale (VAS) and pill count (PC) and virological suppression at 6 months (<400 c/mL) according to CD4 count at ART initiation through logistic regression models, adjusting for possible confounders (age, sex, marital status, education and employment).

**Results:** During March 2012-May 2014, 601 participants who were not on ART entered care in trial clinics. 392 initiated ART. 254 completed 6 months ART on CD4 of whom 6 months HIV RNA data were included in analyses. 169 were women; median (IQR) age and CD4 at ART initiation were 35 years (28, 46) and 313cells/mm³ (206, 513). Adherence ≥95% at 6 months was high (88% and 83% by PC and VAS, respectively) with no evidence that this may be independent of the presence of symptomatic HIV disease.

**Conclusions:** Treatment as prevention is a potential delivery platform for combination HIV prevention strategies that reduce the susceptibility of uninfected persons and the infectiosity of infected persons is needed. Community-based HIV testing and counseling, with linkage to care and prevention, is a potential delivery platform for combination HIV prevention.

**MOAC0105LB**

**Community-based HIV testing and linkage effectively delivers combination HIV prevention: results from a multisite randomized trial**

1University of Zimbabwe, Harare, Zimbabwe, 2Univ. of North Carolina at Chapel Hill, Dept. of Pathology, Baltimore, United States, 3UCSF Methods in Medical Research Center, University of North Carolina at Chapel Hill, Chapel Hill, United States, 4Nagasaki University, Department of Applied Chemistry, Nagasaki, Japan, 5National Institute of Health Sciences, Chiang Mai, Thailand, 6Hospital Nossa Senhora da Conceição, Porto Alegre RS, Brazil, 7Instituto de Enfermedades Infecciosas y Research Center, Cáceres, Spain

Presenting author email: sesheM@yahoo.com

**Background:** To have a population impact in generalized HIV epidemics in Africa, high coverage of combination HIV prevention strategies that reduce the susceptibility of uninfected persons and the infectiosity of infected persons is needed. Community-based HIV testing and counseling, with linkage to care and prevention, is a potential delivery platform for combination HIV prevention.

**Methods:** We conducted a multisite program of community-based HIV testing and counseling, linkage to HIV care, and demand creation for voluntary medical male circumcision (VMMC) in rural communities in KwaZulu-Natal, South Africa and Sheema district, Uganda. HIV testing was done at home or through mobile units. HIV-positive persons were randomly allocated to linkage to care strategies: lay-counselor facilitation at the initial clinic visit, lay-counselor follow-up visits at home, or standard clinic referral. HIV-negative uncircumcised men were randomized to VMMC demand creation strategies: lay-counselor follow-up visits at home, SMS reminders, or standard VMMC promotion at the time of testing.

**Results:** Between June 2013 and February 2015, 15,332 persons received HIV testing and counseling. Among 1,325 HIV-positive persons randomized to linkage strategies, overall clinic linkage was high (93%). Compared to standard linkage, lay counselor clinic facilitation increased linkage to care (RR=1.09, 95% CI: 1.05-1.13), and home follow-up visits increased ART initiation (RR=1.23, 95% CI: 1.01-1.57). In all arms, ART initiation was limited by bottle-necks in service-delivery at the clinics, although 87% of those eligible initiated ART by 6 months. Overall, 82% of persons initiating ART achieved viral suppression without significant difference between study arms.

**Conclusions:** Community-based HIV testing and linkage to care and prevention effectively delivers combination HIV prevention. Simple strategies, such as SMS reminders or lay-counselor visits, increase linkage for ART initiation and male circumcision. Community-based strategies require integration with efficient clinical services, and additional strategies are needed to address clinic delays that are barriers to ART delivery.

**MOAC0106LB**

**Treatment as prevention: characterization of partner infections in the HIV Prevention Trials Network 052 trial**

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Presenting author email: sesheM@yahoo.com

**Background:** In 2011, results from an interim analysis of the HPTN 052 trial demonstrated that early antiretroviral therapy (ART) was highly effective for prevention of HIV transmission from HIV-infected adults (index participants) to their HIV-uninfected sexual partners. All index participants were offered ART after May, 2011; the trial ended May, 2015. This report describes the analysis of partner infections in HPTN 052.

**Methods:** HIV from index-partner pairs was analyzed. Phylogenetic methods were used to compare HIV pol sequences from index-partner pairs and controls. Linkage probability was further assessed by comparing the genetic distances between pol sequences (Bayesian analysis). Selected samples were also analyzed using next generation sequencing (env region). Three infections that occurred close to the time of index ART initiation were analyzed by BEAST and serologic methods to determine the probable timing of HIV transmission. This abstract presents provisional findings based on data available as of May, 2015.

**Results:** Seven-five partner infections were confirmed (64 in Africa, 6 in Asia, 5 in the Americas), including 39 described previously (JID 2011; 204:1918-26). Linkage status was determined for 70 cases (5 cases failed analysis). Of these 70 cases, 26 (37%) were classified as uninfected if the partner was most likely infected from someone other than the index participant), and 44 (63%) were classified as linked (the index was most likely the source of the partner’s HIV infection). In 7 of the 44 linked cases, the partner seroconverted while the index was receiving study ART. In 4 of these 7 cases, the partner seroconverted shortly after the index started ART, likely before the index was virally suppressed. In the remaining 3 cases, the partner seroconverted when the index was not virally suppressed due to ART failure.
Post prevention of mother-to-child-transmission: 30-months outcomes in the Malawian “Option B+ programme”


University of Bern, Institute of Social and Preventive Medicine, Bern, Switzerland, 2University of Washington, International Training and Education Centre for Health, Seattle, United States, 3Ministry of Health, Department of HIV and AIDS, Lilongwe, Malawi, 4Baobab Health Trust, Lilongwe, Malawi, 5Dignitas International, Zomba, Malawi

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Background: Under the Option B+ PMTCT strategy HIV-infected pregnant and breastfeeding women initiate lifelong ART. Long-term retention after weaning is unknown. We examined treatment outcomes for up to 30-months after ART initiation.

Methods: We examined cumulative incidence of mortality, no follow-up after ART initiation, loss to follow-up after the first follow-up visit (LTF), treatment discontinuation and retention in the Malawian “Option B+ programme”. We analysed 24-months aggregated facility-level data (65,749 patients, 654 facilities) and 30-months individual-level data (3,225 patients; 6 large facilities) from Option B+ patients who initiated ART during 2011-2014. We excluded patients who transferred to another facility.

Results: In facility-level data 79.9% (52,525/65,749) and 75.0% (40,509/54,029) of all patients were still in care 6 and 12 months after ART initiation. After 24 months 70.6% (17,257/24,245) were retained, 26.8% were LTF, 1.5% had died and 0.6% stopped ART.

In six large facilities with individual-level data, slightly more patients defaulted or discontinued treatment: 24 and 30 months after ART initiation retention was 67.2% and 62.6%. Most patients were lost early and many did not return after the first visit (Figure 1), but after 18 months, further LTF was low. Of those who started ART during pregnancy 15.8% (95%-CI: 14.4-17.4%) had no follow-up, 18.0% (95%-CI: 16.0-20.0%) were LTF, 6.8% (95%-CI: 5.1-8.3%) stopped ART and 0.5% (95%-CI: 0.3-1.5%) died 30 months after follow-up. Of those who initiated ART while breastfeeding 8.5% (95%-CI: 6.8-10.4%) had no follow-up, 18.6% (95%-CI: 15.7-21.7%) were LTF, 1.9% (95%-CI: 1.0-3.5%) stopped ART and 0.6% died (95%-CI: 0.2-1.3%) (Figure 1).

Patients who collected < 85% of the prescribed drugs during the first year of ART were at higher risk of LTF between 13-30 months compared to patients who collected >85% of the prescribed drugs (aHR: 3.92; 95%-CI: 1.99-4.59).

Conclusions: Suboptimal long-term retention in care (87-70% after 2 years) needs to be addressed. Attrition rates are higher in those starting ART during pregnancy vs. breastfeeding. Poor early drug adherence predicts later LTF. If women stay in care throughout breastfeeding, retention after weaning is likely.

Recruiting male partners for couple HIV counseling and testing in Malawi’s Option B+ program: a randomized controlled trial

N. Rosenberg1, T. Mandel, F. Saidi2, C. Stanley1, E. Jere1, L. Mwangomba1, K. Kumwenda1, I. Molobi1, M. Mawe1, A. Chauma1, W.C. Miller1, I. Hoffman1, M.C. Hosseinipour1,2

1UNC Project, Lilongwe, Malawi, 2University of North Carolina, Chapel Hill, United States, 3District Health Office, Lilongwe, Malawi

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Background: In Malawi’s antenatal program, HIV counseling and testing (HCT) for pregnant women is nearly universal, but couple HCT (cHCT) is uncommon, even though it is included in the Option B+ guidelines. CHCT is critical for HIV-infected women: many have HIV-infected partners in need of HIV diagnosis and treatment or HIV-uninfected partners in need of HIV prevention. CHCT may also increase Option B+ retention. Two partner recruitment strategies were assessed for cHCT uptake, male HIV status, female Option B+ retention, and consistent condom use.

Methods: Newly diagnosed HIV-infected pregnant women ≥16 years with male partners in Lilongwe were recruited from Gwaila District Hospital Antenatal Unit from March-October 2014 to participate in a randomized controlled trial. Women in the “invitation only” arm received an invitation inviting male partners to antenatal care; women in the “invitation plus tracing” arm received the same invitation but male partners were traced by phone and/or home visit if they failed to present within one week. Women were assessed one month later. Analyses were conducted using Chi-squared tests.

Results: Of 220 eligible women, 200 (90%) consented and enrolled. CHCT uptake was 52% in the invitation only arm and 74% in the invitation plus tracing arm (p<0.001). Among the 126 men who presented for cHCT, 25% already knew they were HIV-infected, 47% learned they were HIV-infected for the first time, and 25% were HIV-uninfected with no difference by arm (p=0.8). There was a trend towards greater one-month retention among women in the invitation plus tracing arm (81%) compared to the invitation only arm (83%) (p=0.09). Among HIV-discordant couples, unprotected sex declined from 94% to 23% (p<0.001) following cHCT. Participation did not lead to intimate partner violence in either arm.

Conclusions: The invitation plus tracing strategy was extremely effective for recruiting male partners for cHCT and substantially more effective than the invitation only strategy. Both strategies identified many HIV-infected men and HIV-discordant couples. CHCT resulted in higher ART retention, declines in unprotected sex in HIV-discordant couples, and no intimate partner violence. Scaling up an invitation plus tracing strategy within the Option B+ program would have substantial public health benefits.

Zimbabwe approaching virtual elimination of mother to child transmission of HIV following implementation of Option A

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Background: We evaluated the impact of Option A, rolled out in August-December 2011, on HIV-free infant survival and mother-to-child transmission (MTCT) in Zimbabwe.

Methods: In 2012 and 2014 we conducted cross-sectional community-based surveys of mother-infants pairs residing in the catchment areas of 157 health facilities randomly selected from 5 of 10 provinces in Zimbabwe. Eligible infants (alive or deceased) were born 9-18 months before each survey to mothers ≥18 years old. We randomly selected mother-infant pairs and conducted questionnaires and verbal autopsies and collected blood samples. The impact analysis was limited to 113 catchment areas unexposed to Option A activities at baseline according to facility records; we estimated the HIV-free infant survival and MTCT rate within each catchment area and compared the 2012 and 2014 estimates using a paired t-test.
Results: We enrolled 8568 mother-infant pairs with viable maternal specimens in 2012 and 9619 in 2014, of whom 1107 (12.9%) and 1176 (12.2%) mothers respectively were HIV-infected. Among infants born to HIV-infected mothers, 50.6% (95% confidence interval CI: 88.8, 92.3) of infants were alive and HIV-uninfected at 9-18 months in 2012, compared to 94.7% (95% CI: 93.4, 96.0) of infants in 2014 (p=0.001); MTCT was 9% (95% CI: 7.3, 10.7) in 2012 and 5.3% (95% CI: 4.0, 6.6) in 2014. In the 113 catchment areas where Option A was implemented after the infants surveyed in 2012 were born, there was a 6.5 percentage point (95% CI: 3.3, 9.7) mean increase in HIV-free infant survival (88.1% to 98.3%, p<0.001), and 6.2 percentage point (95% CI: 3.5, 9.4) mean decrease in MTCT (9.9% to 3.7%, p<0.001).

Conclusions: We found a substantial and statistically significant increase in HIV-free infant survival and decrease in MTCT among infants aged 9-18 months following the implementation of Option A in Zimbabwe. Our estimates capture transmissions during pregnancy, delivery and the first 9-18 months of breastfeeding. Notably, 72% of HIV-exposed infants were still breastfeeding at baseline and 78% at endline, so additional infections may occur. The 2014 survey also provides a baseline for evaluating Option B+, which has been recently rolled out in Zimbabwe and should further accelerate efforts to eliminate MTCT.

MOAC0204
Antiretroviral intensification to prevent intrapartum HIV transmission in late comers

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Background: Infants born to HIV-infected pregnant women presenting late are at high risk of intrapartum infection. Mother infant antiretroviral (ARV) intensification may substantially reduce this risk.

Methods: In a multicenter, phase 3, adaptive single-arm trial in Thailand, pregnant women with <8 weeks of standard ARVs [zidovudine (ZDV)+lamivudine (3TC)+lopinavir/ritonavir] and their infants received ‘ARV intensification’ to prevent transmission at delivery: women took a single nevirapine (NVP) dose in labor and continued ARVs for 4 weeks; formula-fed neonates received 2 weeks AZT+3TC+NVP followed by 2 weeks AZT+3TC, instead of standard 1-week ZDV. Infants were tested for HIV at birth, 1, 2, 4, 6 months. A negative DNA PCR < 48 hours, followed by a confirmed positive PCR defined intrapartum transmission.

Data from 3,965 mother/infant pairs (84 intrapartum transmissions) in 3 PHTP randomized perinatal HIV prevention trials (NCT00386230, NCT00398684, NCT00409591) conducted in Thailand. Enrolled women were 22-35 years, median CD4 count 370 cells/mm3, mean VL 3.5 log10 copies/ml. Intrapartum transmission was predicted through a logistic model with VL, maternal/infant ARVs, delivery mode and prematurity status as covariates. The Bayesian estimation of the risks of intrapartum transmission was predicted through a logistic model with VL, maternal/infant ARVs, delivery mode and prematurity status as covariates. The Bayesian estimation of the risks of intrapartum transmission was predicted through a logistic model with VL, maternal/infant ARVs, delivery mode and prematurity status as covariates. The Bayesian estimation of the risks of intrapartum transmission with/without intensification used all historical information and decision rules to stop for futility or superiority of ARV intensification over standard of care (risk ratio RR<1) were determined for 3 interim analyses. Prior intrapartum transmission probabilities were subsequently updated using the results of the intensification trial to derive posterior probabilities (Credibility Interval, CI) as well as probability distributions of RR< 1 and RR< 0.5.

Results: At first interim analysis, the DSMB recommended stopping enrollment and reporting intensification efficacy. Overall 88 mother/infant pairs received intensification without any intrapartum transmission.

Conclusions: ARV intensification is very effective in preventing intrapartum transmission in pregnant women receiving a short course antepartum ARVs before delivery.

MOAC0205LB
Costs of Zimbabwe’s accelerated prevention of mother-to-child transmission of HIV program

I. Ochoa-Moreno1, C. Mangenah2, R. Buzdugan3, N.S. Padian3, S.I. McCoy4, F.M. Cowan2, B. Musha-Chirumoto5

In 2010 and 2013, World Health Organization issued revised guidelines on the recommended approaches for prevention of mother-to-child transmission of HIV (PMTCT) (Options A, B, B+). Estimating the cost of these PMTCT regimes is essential. We estimated the cost of Option A in Zimbabwe, which was rolled out in 2011. These data also represent baseline estimates to assess the cost-effectiveness of Option B+, rolled out in Zimbabwe in late 2013.

Methods: We conducted a cross-sectional survey of 157 randomly selected health facilities offering PMTCT services in 5 of 10 provinces in Zimbabwe. In each facility we collected data on the output and cost of PMTCT services, including staff and supplies for the whole year and for each month of 2013. We also assessed the time allocation of staff providing these services. We estimated the average cost of PMTCT services per facility and for specific services in the PMTCT cascade such as HIV testing and antiretroviral prophylaxis. We also examined the variation in costs by the type of provider.

Results: We estimated that the average cost of PMTCT services is approximately US$3,000 (median US$987) per facility-year, which varies widely by facility size and type. On average, 80% of the overall cost corresponds to staff (US$1,900) and the remaining 20% to supplies (US$2,100). The average cost per pregnant woman tested was US$75 (median US$44) and the average cost per HIV-infected pregnant woman on antiretroviral prophylaxis or treatment was US$1,040 (median US$527) per year. Scale was associated with cost; 40% of the variation in the cost per pregnant woman tested can be explained by number of HIV+ women on ART/ARV, as was 50% of the variation in prophylaxis and treatment costs (see figure).

Conclusions: These findings are the first empirical estimations of PMTCT programs costs in Zimbabwe. Given limited resources, calls for the elimination of MTCT have challenged the international community to optimize the use of resources to increase coverage of PMTCT priority services. Information about costs is essential to determine the highest possible quality HIV services at the lowest feasible cost and thus maximize efficiency.
MOAC0301LB

Increasing uptake of voluntary medical male circumcision (VMMC) among men aged 20-34 years in Njombe & Tabora regions, Tanzania: a cluster randomised controlled trial


VMMC Tanzania Study Group

Backgrounds: Tanzania introduced voluntary medical male circumcision (VMMC) in 2009 as part of its national HIV prevention strategy. Reaching men aged 20-34 years with circumcision may affect the immediate reduction in HIV incidence. However, approximately 80% of VMMC clients in Tabora and Njombe regions are aged 10-19 years. This study evaluated the effect of a strategy to increase VMMC uptake among men aged 20-34 years in Njombe and Tabora.

Methods: A cluster-randomized controlled trial at 20 VMMC outreach sites was conducted in Njombe and Tabora, focusing on increasing VMMC uptake. The intervention, which was informed by formative research, included i) additional demand-creation messages (non-HIV benefits of VMMC, voluntary nature of HIV testing) ii) involvement of recently circumcised men as auxiliary peer promoters, iii) separate waiting and education areas for men aged >20 years, and iv) sessions on wound healing and post-circumcision abstinence targeting female partners. Analysis was based on cluster-level summary measures.

Results: Overall, 6251 men were enrolled in 10 intervention sites (1809 Njombe, 4442 Tabora) and 3968 men in the 10 control sites (1036 Njombe, 2932 Tabora). The proportion of clients aged 20-34 was greater in intervention sites compared to control sites (17.7% vs. 13.0%; RR=1.4; 95% CI: 0.9-2.0; p=0.11). The effect of the intervention varied by region: in Njombe, there was little difference in attendance between control and intervention sites (11.3% vs 14.7%; RR=0.77, 95% CI: 0.4-1.8; p=0.43) while in Tabora there was a two-fold difference (27.5% vs 11.5%; RR=2.39, 95% CI: 1.7-3.4; p<0.001). Similarly, the mean number of clients aged 20-34 was greater in intervention facilities in Tabora (mean difference=182; 95% CI 5-359; p=0.05) and there was little difference in Njombe (mean difference=12; 95% CI:-13-36; p=0.31).

Conclusions: The intervention was associated with a significant increase in the proportion of VMMC clients aged 20-34 years in Tabora but not in Njombe. The lack of the intervention effect in Njombe may be due to saturation, as VMMC has been available for longer. The results suggest the intervention may be more likely to be effective in areas newly targeted for VMMC.

MOAC0302LB

Acceptability and feasibility of a novel approach to promote HIV testing in sexual and social networks using HIV self-tests


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Backgrounds: Identifying interventions to increase men’s uptake of HIV testing in sub-Saharan Africa is essential for the success of combination prevention strategies, including treatment as prevention. HIV self-testing is an emerging approach with high acceptability, but limited evidence exists on optimal strategies for distributing self-tests and reaching men in particular. This study explored a novel approach of providing multiple self-tests to women with high HIV incidence in order to promote HIV testing among their sexual partners.

Methods: HIV-uninfected women aged 18-39 years were recruited at two sites in Kisumu, Kenya between January-March 2015: a drop-in center for female sex workers (FSWs) and a health facility with antenatal and postpartum clinics. Following informed consent and instructions on the testing process, self-tests were provided at enrollment were either used by the IP or given to other persons (mean 2.7% [90% CI: 1.8-3.6%]).

Results: A total of 278 IPs were enrolled (101 FSWs, 81 antenatal, 116 postpartum). Follow-up interviews were completed with 262 IPs (94.2%) by May 9, 2015. Most self-tests provided at enrollment were either used by the IP or given to other persons (mean 2.7% [90% CI: 1.8-3.6%]).

Conclusions: This outbreak highlights the vulnerability of rural, resource-poor populations to drug use, misuse, and addiction; the importance of timely HIV surveillance activities and rapid response to interrupt disease transmission; and the need for expanded mental health and substance use treatment programs in medically underserved rural areas.
MOAC0304LB
HIV-1 and HCV molecular epidemiology of a large community outbreak of HIV-1 infection linked to injection drug use of oxy-morphone - Indiana, 2015

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Background: In January 2015, a cluster of HIV-1 infections was detected in a rural county in southeastern Indiana among persons who reported injection of the prescription opioid oxymorphone. As of May 13, 2015, HIV-1 infection has been diagnosed in 153 individuals. We compare molecular analyses of HIV-1 and HCV sequences among a subset of individuals in this outbreak to infer the timing of HIV transmission relative to HCV.

Methods: Serum and plasma samples were collected from November 2014 - April 2015. HIV polymerase (pol) gene sequences from persons with newly diagnosed HIV infection were phylogenetically analyzed. Phylogenetic trees were defined when HIV-1 pol sequences were highly genetically related (>95% nucleotide identity) and a statistical evidence supporting relatedness was high (Shimodaira-Hasegawa probabilities >0.99). Recency of HIV infection was determined by avidity testing using a modified Bio-Rad HIV 1/2 plus O assay (BRAI). HCV NS5B gene sequences were phylogenetically analyzed to determine the number of clusters of independent HCV strains within this population.

Results: The pol gene was sequenced for 57 HIV-1-infected persons. Two clusters of HIV-1 subtype B infection were identified (Cluster 1, n=55; Cluster 2, n=2; figure panel A). Among 49 specimens available for BRAI testing, 45 (91.8%) were recent infections. Of 36 HIV-infected persons, 38 (94%) were HCV co-infected. The NS5B gene was high (Shimodaira-Hasegawa probabilities >0.99). Recency of HIV infection was determined by avidity testing using a modified Bio-Rad HIV 1/2 plus O assay (BRAI). HCV NS5B gene sequences were phylogenetically analyzed to determine the number of clusters of independent HCV strains within this population.

Conclusions: In this prescription opioid injection-associated outbreak, a single strain of HIV-1 was introduced into a population infected with multiple HCV strains. In contrast to the homogeneity of HIV strains observed in this cohort, the heterogeneity of HCV strains (cluster- ing and non-clustering) suggests earlier introduction of HCV compared with HIV. These data demonstrate the outbreak potential with introduction of HIV-1 into a community where HCV prevalence is high among persons who inject prescription opioids.

MOAC0305LB
HPTN 067/ADAPT study: a comparison of daily and intermittent pre-exposure prophylaxis (PrEP) dosing for HIV prevention in men who have sex with men and transgender women in New York City

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Background: Daily oral FTC/TDF (Truvada) is US FDA-approved for HIV pre-exposure prophylaxis (PrEP). HPTN 067/ADAPT, a phase II randomized, open-label PrEP trial, assessed the feasibility of intermittent FTC/TDF-based PrEP for HIV prevention among men who have sex with men (MSM) and transgender women (TGW) in New York City (NYC).

Methods: MSM and TGW were eligible if male at birth, and reported intercoarsual and >1 other HIV risk factor in the past 6 months. Exclusion criteria included HIV infection, hepatitis B infection, acute HIV symptoms, and abnormal renal function. Following 6 weeks of once-weekly direct observed dosing, participants were randomly assigned 1:1 to 24 weeks of PrEP dosing: daily (D), twice weekly plus one post- sex dose (time-driven [T]), or one pre- and one post-sex dose (event-driven [E]). Regimens were compared for prophylactic coverage (PrEP within 4 days pre- and 24 hours post-sex) of sex events, pills taken, side effects, and plasma drug levels. Adherence and coverage were assessed using electronic monitoring adjusted by self-reported sex and pill taking behavior collected in daily weighed interviews.

Results: 178 participants were randomized: 176 MSM, 3 TGW; median age 30 years, 70% black, 13% white, 25% Hispanic. D arm participants had significantly higher complete coverage of sex acts (66%; D, 47%; T, 52%; P<0.03; Table 1) and highest adherence to regimen (85% D, 40% T, 41% E; p<0.001). Significantly fewer pills were used with intermittent (T and E) regimens than daily PrEP (p<0.001). Side effects were similar across arms, with gastrointestinal and neurologic symptoms most common. Participants reporting recent sex in all PrEP dosing arms achieved similar rates of detectable plasma tenofovir levels and of concentrations associated with effective PrEP dose frequency.

Conclusions: While this cohort of mostly black MSM in NYC reported higher prophylactic coverage of sex acts and higher adherence to daily PrEP, non-daily PrEP users who reported recent sex achieved comparable rates of effective tenofovir plasma concentrations. Intermittent PrEP required substantially fewer pills, although side effects were similar. This study demonstrates the feasibility of intermittent PrEP, a potentially more cost-effective alternative to daily PrEP, among US black MSM.
**MOAC0306LB**

**HPTN 067/ADAPT study: a comparison of daily and non-daily pre-exposure prophylaxis dosing in Thai men who have sex with men, Bangkok, Thailand**

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**Background:** Oral FTC/TDF PrEP is effective for preventing sexual HIV acquisition when used daily. An alternate dosing (non-daily) regimen was effective in the IPERGAY trial. Daily and non-daily regimens have not been compared directly with respect to pharmacokinetic properties for sexual exposure.

**Methods:** We enrolled men who have sex with men (MSM) in a phase 2, randomized, open-label trial of oral FTC/TDF PrEP in Bangkok, Thailand. We randomly assigned participants to one of three self-administered dosing regimens for 24 weeks: daily (D); time-driven twice weekly with a post-sex dose (T); or event-driven before and after sex (E). We contacted participants weekly to collect dates/times of PrEP use (monitored electronically by Wisepill™) and sex events. We defined adherence as the proportion of tablets taken as recommended, and coverage as taking ≥1 tablet the four days before sex and ≥1 tablet within 24 hours after sex.

**Results:** We randomized 178 MSM (median age 31 years). PrEP coverages were similar in arms D and T (85% vs 84%; p=0.79) and both were greater than in arm E (74%) (p<0.05). Adherence was greater in D (85%) compared with T (79%) or E (65%) (p<0.001). Compared with D, the number of doses required for full adherence was reduced by 57% in T and by 80% in E (p<0.001).

**Characteristics**

<table>
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<th>Characteristic</th>
<th>Daily (D)</th>
<th>Time-driven (T)</th>
<th>Event-driven (E)</th>
<th>Total</th>
<th>p value</th>
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<tr>
<td>N</td>
<td>60</td>
<td>59</td>
<td>59</td>
<td>178</td>
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<tr>
<td>Median age</td>
<td>31</td>
<td>28</td>
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<tr>
<td>Number of sex events over full study, not including oral sex</td>
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<td>1337</td>
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<tr>
<td>% total events fully covered</td>
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<td>84</td>
<td>74</td>
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<tr>
<td>Total required tablets actually taken</td>
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<td>3272</td>
<td>1255</td>
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<tr>
<td>Total tablets required</td>
<td>9420</td>
<td>4121</td>
<td>1928</td>
<td>--</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total % adherence</td>
<td>85</td>
<td>79</td>
<td>65</td>
<td>--</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% detectable (≥9.1 fmol/million cells) in PBMCs when reporting sex in last 7 days (at 10 weeks of follow up; at 30 weeks of follow up)</td>
<td>100; 91.3</td>
<td>96.6; 94.7</td>
<td>93.3; 85.7</td>
<td>96.7; 91.1</td>
<td>0.54</td>
</tr>
<tr>
<td>Median drug concentration in PBMCs (fmol/million cells) when reporting sex in last 7 days (at 10 weeks of follow up; at 30 weeks of follow up)</td>
<td>81.1; 102.0</td>
<td>35.3; 32.9</td>
<td>26.4; 23.9</td>
<td>45.6; 40.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Conclusions:** Compared with the daily regimen, the time-driven dosing regimens offered comparably high PrEP coverage for sex acts for Thai MSM, despite slightly less adherence, while requiring fewer tablets. However, since non-daily dosing results in significantly lower PBMC drug concentrations, stricter adherence is required under these regimens to maintain pharmacokinetic drug concentrations.

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**MOAD0101**

**Rapid uptake and adoption of the WHO 2013 Consolidated ARV guideline recommendations: paving the way to achieving the 90/90/90 global target**

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**Background:** Progress towards the ending the AIDS epidemic by 2030 critically depends on adoption of global guidelines that address evidenced based proven approaches to optimally treat all people living with HIV (PLWHIV) and to how best deliver interventions. With the 2013 Consolidated ARV Guidelines, WHO successfully launched new policy recommendations on the clinical, operational, programmatic and M&E aspects of HIV treatment and care.

**Methods:** WHO HQ with regional and country offices, held 9 capacity building and dissemination consultations for >100 countries from 2013-2014. Through triangulation of baseline surveys, e-surveys with the country MoH HIV focal point and data compiled from the 2014 Global AIDS Response Progress Reporting (GARPR), we have documented the adoption of priority HIV treatment policies within the 58 WHO focal countries. Data is presented through end 2014.

**Results:** Within 18 months of the launch of the 2013 consolidated ARV guidelines, 44 of 58 (76%) of focus countries adopted at least one of the major recommendations; globally another 25 countries were in the process of adopting, 60% of focus countries adopted a CD4 count initiation of ≤500 cells/mm3, while Brazil, Thailand and Yemen offer treatment to all adults regardless of CD4 cell count. 71% adopted a policy to treat all children with HIV <5 years; Ethiopia treats all children <15 years. More than 90% of countries adopted PMTCT Option B+/B+: 59% adopted treatment for all HIV serodiscordant couples; and 86% adopted the use of TDF + 3TC (or FTC) + EFV as the preferred first-line therapy, granting more people access to better treatment regimens; and 69% planned to implement routine viral load monitoring. Adoption varied by WHO region (Figure 1).

An update on the country implementation of these policies will be available in April 2015.

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**WHO 2013 Consolidated ARV Guidelines**

Policy uptake in 58 WHO focus countries end 2014 (% responding yes, by region)

[WHO ARV Guidelines Adoption by region]

**Conclusions:** With the 2013 Consolidated ARV Guidelines, WHO brought together 56 new recommendations across the continuum of HIV treatment and care, and supported countries to more rapidly adopt new policies than ever before; if fully implemented, countries can achieve the 90/90/90 global target.
MOAD0102
Can the UNAIDS 90-90-90 target be reached? Analysis of 12 national level HIV treatment cascades

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Background: UNAIDS has set the “90-90-90” target for all countries: to diagnose 90% of all HIV-positive people, provide antiretrovirals for 90% of those diagnosed and achieve undetectable HIV RNA for 90% of those treated, in every country worldwide by 2020. This translates to at least 73% of all HIV-positive people achieving undetectable HIV RNA in every country. We used national level HIV treatment cascades to analyse whether countries have achieved these targets.

Methods: We compared published estimates of HIV treatment cascades across 12 countries in Western and Eastern Europe, North and South America, Australia and sub-Saharan Africa. Cascades were selected based on reliable, generalizable, recently published results from large cross-sectional and longitudinal study cohorts. Data were analysed in six stages: 1-HIV positive people, 2-Diagnosed, 3-Linked to care, 4-Retained in care, 5-On antiretroviral treatment, 6-Undetectable HIV RNA. Each country level cascade was analysed to identify whether each stage of the 90-90-90 target was met.

Results: The percentage of HIV-positive people who both received antiretroviral treatment and achieved undetectable HIV-RNA ranged from 9% (Russia) to 73% (Switzerland). None of the 12 countries met the UNAIDS target of 90% of HIV-positive people diagnosed. One country (Switzerland) met the target of 90% of diagnosed people on antiretroviral treatment. Five countries (Switzerland, Australia, UK, Denmark, Netherlands) met the target of 90% of treated people with undetectable HIV RNA. While five Western European countries achieved >50% undetectable HIV RNA, three Eastern European countries achieved under < 20%. USA achieved undetectable HIV RNA for 30% overall, the lowest amongst high-income countries, comparable to sub-Saharan Africa (29%). The largest fall between stages in the treatment cascades was from 153 to 517 cells/mm^3 copies/mL (Haiti excluded because VL not regularly measured) and median CD4 increased 8% in active care at 10 years (Figure). At the end of follow up, 85% for the same periods were 2.4%, 6.8%, 9.0%, 10.8%, and 13.6% respectively. LTFU rates overall were 4.2%, 6.8%, 9.0%, 10.8%, and 13.6% respectively. LTFU rates for the same periods were 2.4%, 6.8%, 10.9%, 14.8%, and 24.2% respectively; 62% remained in active care at 10 years (Figure). At the end of follow up, 85% of active patients had VL <400 copies/mL. (Haiti excluded because VL was not regularly measured) and median CD4 increased from 153 to 517 cells/mm^3. After 10 years, only 11% of patients remained active and on their first HAART regimen or not on HAART were also measured.

Results: 4,975 patients (66% male) met inclusion criteria. At HAART initiation the median age was 35 years, 23% had AIDS, and 45% were not ART-naive. At 1, 3, 5, 7 and 10 years, overall rates of mortality were 4.2%, 6.8%, 9.0%, 10.8%, and 13.6% respectively. LTFU rates for the same periods were 2.4%, 6.8%, 10.9%, 14.8%, and 24.2% respectively; 62% remained in active care at 10 years (Figure). At the end of follow up, 85% of active patients had VL <400 copies/mL. (Haiti excluded because VL was not regularly measured) and median CD4 increased from 153 to 517 cells/mm^3. After 10 years, only 11% of patients remained active and on their first HAART regimen, 13% were on their second, 12% were on their third, and 22% were on their fourth or more regime. Heterogeneity in outcomes between sites was substantial.

Conclusions: Despite advanced disease and use of mostly old antiretrovirals, a large proportion of first HAART initiators in these Latin American cohorts were alive, in active control, with substantial immune recovery and virologic suppression after 10 years. Early death was a problem as well as persistent LTFU and frequent change of therapy.

MOAD0103
Major outcomes of early HAART programs at CCASAnet sites: “First Wave of HAART” study

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Background: Expanded access to HAART in Latin America began slowly in the late 1990s and faster in early 2000s; many antiretrovirals used then, are now outdated and most patients presented with advanced disease stages. Characterizing these patients’ major outcomes (death, loss to follow-up [LTFU], viral suppression, CD4+ cell [CD4] count evolution, and regimen changes) after a decade of HAART- not well defined at present- may provide insights into their present and future situation, and provide information relevant for the management of patients who initiated HAART more recently.

Methods: The study included adults from 8 CCASAnet sites: Argentina, Brazil, Chile, Haiti, Honduras and Mexico who initiated HAART before 2004, without exclusion of non-ART-naive. Status (active, LTFU, or dead) for each patient was registered at 6-month intervals for up to 10 years, as well as CD4 and viral load (VL) in active patients. The proportions of patients in first, second, third or further HAART regimen or not on HAART were also measured.

Results: 4,975 patients (66% male) met inclusion criteria. At HAART initiation the median age was 35 years, 23% had AIDS, and 45% were not ART-naive. At 1, 3, 5, 7 and 10 years, overall rates of mortality were 4.2%, 6.8%, 9.0%, 10.8%, and 13.6% respectively. LTFU rates for the same periods were 2.4%, 6.8%, 10.9%, 14.8%, and 24.2% respectively; 62% remained in active care at 10 years (Figure). At the end of follow up, 85% of active patients had VL <400 copies/mL. (Haiti excluded because VL was not regularly measured) and median CD4 increased from 153 to 517 cells/mm^3. After 10 years, only 11% of patients remained active and on their first HAART regimen, 13% were on their second, 12% were on their third, and 22% were on their fourth or more regime. Heterogeneity in outcomes between sites was substantial.

Conclusions: Despite advanced disease and use of mostly old antiretrovirals, a large proportion of first HAART initiators in these Latin American cohorts were alive, in active control, with substantial immune recovery and virologic suppression after 10 years. Early death was a problem as well as persistent LTFU and frequent change of therapy.

Country % Diagnosed % On ART % Undetectable HIV RNA Country % Diagnosed % On ART % Undetectable HIV RNA

UNAIDS 90-90-90 Targets for 2020

Country % Diagnosed % On ART % Undetectable HIV RNA

United Kingdom (2013) 76% 68% 61% Sub-Saharan Africa (2013) 45% 39% 29%

France (2010) 81% 60% 52% Russia (2013) 49% 41% 19%

Country-level cascades versus 90-90-90 target

Conclusions: Only one of the 12 countries analysed achieved the UNAIDS 90-90-90 coverage target of 73% of HIV-positive people with undetectable HIV RNA. There were disparities between countries. A standardized reporting method should be implemented to facilitate comparisons between countries to better identify gaps and inform policy.
MOAD0104

Integrating HIV-care into primary care clinics improved access to treatment and did not compromise primary health care: province-wide trend analysis over four years during implementation in Free State, South Africa

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Backgrounds: The integration of HIV-care into primary health care (PHC) clinics is a strategy to expand access to antiretroviral therapy (ART). However, integration may compromise PHC service delivery within weak health systems. We designed a study to examine changes in PHC service provision (pre and post-integration) in public-sector PHC clinics in Free State, South Africa.

Methods: We analysed administrative data on 15 PHC indicators. The data were collected monthly over a critical four year period as integration was implemented into 131 PHC clinics representing a catchment population of 1.5 million. We defined integration as the month and year the PHC clinic provided comprehensive HIV-care, from testing to treatment to follow-up. We utilisedinterrupted time series analysis at ±18 and ±30 months from HIV integration in each clinic to identify changes in PHC services post-integration. We conducted sensitivity analyses with linear mixed effect models to study the relationship between HIV service indicators and the PHC indicators.

Results: The number of patients receiving ART in the 131 PHC clinics studied increased from 121 (April 2009) to 57,958 (March 2013). We did not observe any changes in service indicators for 11 of the 15 PHC indicators we examined. However, we did observe decreases in population-level immunisation coverage after integration by 0.98% (SE=0.25, p< 0.001) at ±18 months and by 1.31% (SE=0.16, p< 0.001) at ±30 months. Clinic level immunisation coverage also decreased by 33 infants per 100,000 patients (SE=0.16, p< 0.001) at ±30 months. None of these changes were associated with the number of HIV patients at the clinics. We also observed decreases in total clinic visits per year for adults and children under 5 years old.

Conclusions: Despite an extraordinary increase in patients accessing ART in PHC clinics during our study period, the vast majority of PHC indicators remained unchanged. Our findings suggest that the integration of HIV-care into public-sector PHC clinics is a viable strategy through which to expand access to ART. However, further research is needed to understand how immunisation coverage is affected.

MOAD0105LB

Implementation scale up of the Adherence Club model of care to 30,000 stable antiretroviral therapy patients in the Cape Metro: 2011-2014

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Backgrounds: The Adherence Club (AC) model of care was piloted by Médecins Sans Frontières starting in 2007. Adherence Clubs are groups of ~30 stable antiretroviral therapy (ART) patients who meet every 8 weeks for group support, brief symptom screen and collection of pre-packed ART facilitated by a lay healthcare worker. Following good pilot outcomes, from 2011 the Cape Metro health district in turn piloted, using a collaborative quality improvement approach and then adopted the model of care.

Few data on large-scale implementation of novel models of care exist. We describe the implementation scale up across the district highlighting key efficiencies and context specific adaptations to the model.

Methods: We describe the scale-up from January 2011 - December 2014. Data from routine electronic monitoring of the ART programme provides the total number of ART patients retained in care (RIC) while monitoring of Adherence Club participation is reported monthly by each Adherence Club.

Results: AC implementation expanded over the 4-year period with the number of patients retained in AC care increasing annually from 5,675 in December 2011 to 30,790 in December 2014 (Figure 1). By December 2014, ACs were offered at 78.1% of ART facilities (51/76) with only 7.5% of ART patients in care at a facility where ACs were not operating. The proportion of patients receiving ART within an AC grew from 7.5% in 2011 to 25.0% by the end of 2014 (Figure 1).

[Figure 1. Number of patients receiving care within an Adherence Club and the proportion of all ART patients in the Cape Metro health district receiving care within an Adherence Club, January 2011 - December 2014]

Conclusions: Over a 4-year period, the AC model of care was widely accepted and expanded to support a quarter of all patients receiving ART in the district. Adaptations to the model of care supported implementation within the various facility contexts. Some facilities offered ACs at the facility while others decentralized the model to outreach, community and home venues. Most used various lay cadres of staff, while some used nurses to facilitate the groups. The model offered efficiencies both to patients and the health system. For ACs to expand to provide quality care to a greater proportion of ART patients, appropriate resources are required. Further research is needed to evaluate the outcomes of AC patients.
Evaluation of a putative transmission pair revealed by phylogenetic reconstruction of deep-sequence data

**Results:** Donor plasma env-V3 sequences were the lowest in the cohort (mean 0.06), identifying them as a putative transmission pair. The estimated transmission date (ETD), calculated as the midpoint of the recipient’s last HIV-negative and first positive tests, was August 01. Donor plasma/PBM C env-V3 sequences were +5, +6, +12 months from ETD. Environment-v3 from plasma-RNA and PBM C DNA were tripaclcoped, pooled equally and deep-sequenced (Roche 454). BEAST and HyPhy were used to reconstruct phylogenies, estimate multiplication of infection and reconstruct transmitted/bourder (T/F) viruses from plasma-derived deep sequences from donor and recipient.

**Conclusions:** Results highlight the utility of phylogenetic reconstruction applied to deep-sequence data to characterize T/F viruses and intra-host evolution in transmission pairs. Differences in CD4 depletion and V3 evolution in these individuals, despite acquisition of a near-identical X4 strain, underscores the critical role of host genetics on HIV evolution/pathogenesis.

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**MOPDA0103**

**Dasatinib preserves SAMHD1 antiviral activity in CD4+ T cells treated with IL-7**

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**Background:** HIV-1 post-integration latency in quiescent CD4+ T cells is responsible for viral persistence despite antiretroviral treatment. It was proposed that the increase in proviral load in HIV-infected patients after IL-7 treatment was due to homotypic proliferation of memory CD4+ T cells. We determined previously that IL-7 increased HIV-1 infection through phosphorylation and subsequent inactivation of the restriction factor SAMHD1. Now we examined SAMHD1 phosphorylation in PBMC from patients enrolled in ACTG 5214 study (NCT00099671), in order to elucidate the role of IL-7 in HIV-1 proviral integration and persistence and whether this could be related to SAMHD1 inactivation. In addition, we determined that the tyrosine-kinase inhibitor Dasatinib preserved SAMHD1 antiviral activity, avoiding IL-7-mediated HIV-1 infection.

**Methods:** PBMC samples obtained from 10 patients enrolled in ACTG 5214 study (NCT00099671), collected before (day 0) and 4 after administration of IL-7. PBMCs obtained from 2 patients diagnosed with chronic myeloid leukemia (CML), on chronic treatment with Dasatinib. Resting CD4+ T cells from healthy donors obtained by negative selection from PBMCs. Phosphorylation of SAMHD1 at Y1592 was determined by immunoblotting and flow cytometry. Proviral integration was analyzed by TaqMan qPCR. Dasatinib (BMS-354825, Sprycel) was provided by Bristol-Meyers Squibb.

**Results:** 1) IL-7 (1nM) induced SAMHD1 phosphorylation, interfering with its antiviral activity. 2) IL-7-mediated SAMHD1 phosphorylation greatly increased HIV-1 infection in purified CD4+ T cells, increasing early and late retronfection, as well as proviral integration. 3) A significant increase in pSAMHD1 was observed in central memory CD4+ T cells from HIV-infected patients treated with IL-7 (ACTG 5214). 4) Dasatinib completely inhibited SAMHD1 phosphorylation at 75nM, interfering with HIV-1 retronfection and consequently, with proviral integration. 5) CD4+ T cells from patients with CML treated with Dasatinib showed lower expression of SAMHD1 phosphorylated.

**Conclusions:** By inducing SAMHD1 phosphorylation, IL-7 increases susceptibility of resting CD4+ T lymphocytes to infection, leading to HIV persistence. SAMHD1 regulation plays a central role in the establishment of HIV-1 reservoirs and represents a major target for therapeutic intervention. Dasatinib is the first compound currently used in clinic that has been described to preserve the antiviral function of an innate factor such as SAMHD1.

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**MOPDA0104**

**HIV-specific latency reversing therapies that exploit novel pathways for suboptimal Tat protein expression**

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**Background:** We have identified a footprint of Tat protein expression in latent HIV-infected cells. Suboptimal levels of Tat are often associated with indeterminate HIV-eRNA transcripts from cellular promoters adjacent to latent integrated proviruses. To simulate the role of RNA-processing pathways in HIV latency we recapitulated the low level Tat-expression from cellular-provirus read-through transcripts present in HIV latency reporter cells that express low-level Tat using the native
**MOPDA0105**

**HIV rebound and meningoencephalitis following ART interruption after allogeneic hematopoietic stem cell transplant: an investigation of the source of HIV rebound**

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**Background:** Allogeneic hematopoietic stem cell transplant (alloHSCT) with uninterrupted antiretroviral therapy (ART) is being investigated as a component of HIV eradication strategies. In the two “Boston patients”, alloHSCT resulted in the disappearance of HIV in peripheral blood. However, after analytical ART interruption, viral rebound occurred. Proposed sources of HIV rebound include the latent reservoir in resting CD4+ T cells and tissue macrophages. We also identified new drug combinations that synergistically activate expression from the latent HIV-1LTR.

**Methods:** We screened 5,600 compounds in a known drug library and a library comprising of 114,000 drug-like compounds using a 293IRES HIV-specific reporter cell line that contained CMV-CBG/LTR-CBR luciferase reporter system. Hits were identified that activated the LTR-CBR while having a minimal effect on the DMR/CRG reporter. A rigorous selection verification included 11-point titration in the normal and counter-screen assay cell lines, in dsRED-expressing J-Lat cells, and activity in primary cell models of latent HIV.

**Results:** From this screening cascade two known BET bromodomain and four HDAC inhibitors were found to significantly and specifically activate LTR promoter whereas compounds such as Vorinostat exhibited non-specific activity and increased global transcription. Several drug combinations that target different mechanisms implicated in HIV-1 latency were found to synergistically reactivate the virus with high potency. Importantly, seven novel compound classes were identified in the 114,000 compound library screen. Analogues of these seven classes were obtained and examined in 11-point assay with CMV-CBG/LTR-CBR reporter cell lines and 106 compounds gave a clear indication of early structure-activity relationships.

**Conclusions:** Seven novel classes of HIV-specific latency purging drugs were found that activate HIV provirus in synergy with a low intrinsic expression of HIV RNA and Tat. These novel small molecule leads warrant further development to iteratively enhance their HIV-1 specificity and potency. We present the case of an HIV-infected patient who received alloHSCT for leukemia and experienced a unique scenario of HIV rebound.

**Results:** The patient had undetectable plasma HIV and achieved 100% donor chimerism at week 12 post-alloHSCT, but then became non-adherent with ART. At 5 months, the patient presented with fever and meningoencephalitis. Plasma and CSF HIV levels were 25,500 and 17,000 copies/ml, respectively. Before alloHSCT, 31 sequences were isolated from the VOA. At rebound, 14,645 and 5,003 sequence reads were obtained from CSF and blood respectively, and were combined into consensus sequences using a cut-off of >2.5% of total sequence reads. An identical sequence found at both pre-alloHSCT timepoints accounted for 93/1 (99%) of independent VOA sequences. This sequence grouped with the plasma and CSF viral rebound sequences in a monophyletic clade with high sequence homology.

**Conclusions:** Despite 100% donor chimerism in peripheral blood, ART interruption led to HIV rebound in plasma and CSF. Rebound virus was identical to a pre-alloHSCT isolate which compromised nearly 1/3 of the latent CD4+ T-cell reservoir sampled. This unique case suggests that recipient cells persist at early time-points after alloHSCT and that a single viral population latent in resting memory CD4+ T cells can re-establish infection.

**MOPDB0101**

**Bacterial vaginosis, intravaginal practices and HIV genital shedding: implications for HIV transmission**

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**Background:** Bacterial vaginosis (BV) is associated with an increased risk of HIV transmission and intravaginal practices (IVP), the practice of cleansing the vagina for hygienic, health or sexuality reasons, is the primary risk factor for developing BV. This study examines the relationship between BV, IVP and lower genital HIV shedding in HIV infected women in Zambia.

**Methods:** Participants were HIV-1 infected women, older than 15 years, and living in Luza, Zambia. Participants completed audio computer administered self-interviews questionnaires assessing demographic, sexual risk factors and IVP. BV was diagnosed by gram stain microscopy followed by Nugent scoring. IVP were coded from 1 to 4: no IVP, 1=3, 2, 4=5, respectively. Vaginal samples from the cervix and posterior fornix were obtained using the Copan Collection System (Copan Diagnostics). Bacterial vaginosis was defined using the Amsel criteria.

**Results:** A total of 446 female participants were enrolled. A higher percentage of women with BV had positive HIV RNA in their cervical (12.8% vs. 4.6%) and vaginal (9.4% vs. 2.6%) samples compared to women without BV. BV and IVP were positively correlated with HIV vaginal shedding. The prevalence of IVP was higher in women with BV in their cervical samples compared to women with BV in their vaginal samples. IVP was associated with increased odds of HIV vaginal shedding (OR 3.1 (95% CI 1.3, 7.1)) in women with BV cervix and OR 2.9 (95% CI 1.1, 7.3) in women with BV posterior fornix. The use of vaginal douches or tampons was also associated with increased odds of HIV vaginal shedding in women with BV cervix (OR 2.9 (95% CI 1.0, 8.2)).

**Conclusions:** Our findings support a potential role of BV in HIV transmission. BV may contribute to HIV shedding in women with BV by promoting genital inflammation. Further research is required to determine whether the impact of BV on HIV shedding is related to the inflammatory profile or to the presence of BV-associated species. The prevalence of BV was close to 50% in our population, indicating a high risk for HIV transmission among these women.
of vaginal secretions using Nugent criteria. HIV-1 plasma viremia and genital shedding was assessed by measuring HIV-1 RNA plasma and cervico vaginal lavages using real-time PCR.

Results: One hundred and twenty eight HIV-1 infected women were enrolled. Mean age was 37 years (range 24-60). Most had a stable male sex partner (125/98%), and the majority of male partners had HIV infection (86.6%). About one third (44.3%) reported more than one partner in the prior year. All participants had engaged in IV use in the prior month, and over 90% used IV daily. Ninety eight participants (76%) had abnormal vaginal flora (Nugent score of 4-10), and 82 (62%) had BV (Nugent score 7-10). HIV-1 plasma viremia was detected in 26 participants (26%) (median=6.4 log copies/ml, range=3.3-14.5). HIV-1 genital shedding was detected in 18 participants (14%) (median=6.7 log copies/ml, range=3.6-12.7). In multivariate analysis, daily IV use was associated with BV (OR=7.9, CI=1.54-40.8, p<0.01) and plasma viremia was associated with HIV-1 genital shedding (OR=7.23, CI=2.43-21.37, p<0.01). Demographic, sexual-risk factors, IV or BV were not associated with HIV genital shedding.

Conclusions: BV was common in this sample of women with HIV infection and occurred in women engaging in frequent IV use. Neither BV nor BV increased HIV genital shedding in women on suppressive antiretrovirals. Effective antiretroviral therapy remains the main strategy to prevent HIV female genital shedding and risk of subsequent HIV transmission. Further research in men with detectable plasma viremia is needed to examine how IVP and BV affect the vaginal mucosa and increase HIV transmission.

MOPDB0102
IUD use in HIV-positive women
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Background: 80% of HIV-positive (HIV+) women are of childbearing age, therefore access to effective, safe contraception is essential. Generally, IUDs provide safe, effective contraception but historically, IUDs were contraindicated in HIV+ women due to concerns regarding infection. Data in HIV+ women is scarce. The goal was to assess rate of complications for IUS insertions in HIV+ women. Access to effective, safe contraception is essential. Generally, IUDs provide safe, effective contraception should remain an option for HIV+ women if close follow up of short and long-term complications can be followed.

Methods: IUD insertions in HIV+ women were offered at Oak Tree Clinic (the provincial referral center for HIV+ women and children) since 2009, following strict clinical evaluations for eligibility. Criteria used for insertion were: not planning a pregnancy for at least one year; requesting a reversible contraceptive, wanted/needed to avoid estrogen-based methods, and CD4 > 150. STD screening was done in all cases. Demographic information collected included: age, CD4, ART at insertion, and purpose of IUD (contraception vs cycle control).

Results: Data was reviewed from 44 sequential women given IUDs from 2009 to 2014 with ages 17-48. CD4 count=1023 (median 950); 32/44 (73%) had viral loads <40 c/ml. 7 were not on ART. We found no statistical evidence that ART use reduced the risk of pregnancy by more than 90%, both among women on ART (aHR 0.06, 95% CI 0.01-0.45) and not on ART (aHR 0.05, 95% CI 0.28-0.47). We also analyzed data from 7 longitudinal studies (1, 2, 3, 4, 5, 6, 7) of ART efficacy. The goal was to assess rate of complications for IUS insertion in HIV+ women.

Conclusions: BV was common in this sample of women with HIV infection and occurred in women engaging in frequent IV use. Neither BV nor BV increased HIV genital shedding in women on suppressive antiretrovirals. Effective antiretroviral therapy remains the main strategy to prevent HIV female genital shedding and risk of subsequent HIV transmission. Further research in men with detectable plasma viremia is needed to examine how IVP and BV affect the vaginal mucosa and increase HIV transmission.

MOPDB0103
Effectiveness of contraception for HIV-infected women using antiretroviral therapy: combined data from 3 longitudinal studies
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Background: Ensuring safe, effective contraception for women with HIV-1 is a public health imperative. Some data suggest that antiretroviral therapy (ART) may diminish the effectiveness of certain contraceptive methods, particularly implants.

Methods: Combining data from 582 HIV-infected women participating in three longitudinal studies (Partners in Prevention HSV/HIV Transmission Study, Couples Observation Study, and Partners PrEP Study) from seven countries in Africa between 2004-2012, we calculated incident pregnancy rates among women using different contraceptive methods (implant, injectable, oral) and compared those to rates among women using no contraception. Multivariable Cox regression models controlled for confounding factors, and the interaction between each contraceptive method and ART use was tested to assess if ART diminished contraceptive effectiveness.

Results: During follow-up (median 1.8 years, IQR 1.2-2.3), 9% of women ever used implant, 41% used injectables (primarily DMPA), 15% used oral pills, and 47% never used hormonal contraception. Additionally, 31% of women ever used IVP during follow-up, including 23% using nevirapine and 5% using efavirenz. Among women not using contraception, pregnancy rates were 13.2 and 22.5 per 100 women-years for those on and not on ART, respectively.

Conclusions: In this large prospective evaluation of three studies, modern contraceptive methods were highly effective in reducing pregnancy risk in HIV-infected women, including those concurrently using ART. While limited evidence from other studies suggests that some ART agents could diminish the effectiveness of contraceptive implants, these data emphasize that implantable contraception is highly effective compared to no contraception and more so than shorter-acting methods such as injectables and oral pills.
### MOPDB0104

**Importance of programmatic longitudinal surveillance for identification of congenital anomalies among infants exposed to HIV-1 and antiretrovirals: findings from the Mpepu Study, Botswana**


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4. Massachusetts General Hospital, Department of Pediatrics, Boston, United States.
5. Bennett Statistical Consulting, Baltimore, United States.
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7. Massachusetts General Hospital, Department of Internal Medicine, Boston, United States.

**Background:** A large and increasing number of HIV-infected women are conceiving while taking antiretrovirals (ARVs) globally. In resource-limited settings, surveillance systems, if present, often are limited to the initial birth exam.

**Methods:** We used pre-randomization data from May 2011-Dec 2014 from an ongoing clinical trial of infant cotrimoxazole prophylaxis in Botswana. Enrollments of live-born infants of HIV-infected women occurred after delivery, so long as the mother consented to infant participation and no infant-life threatening conditions were identified at birth. Infants were examined by study staff at delivery, and monthly in the first 3 months of life, and congenital anomalies were documented. We present a descriptive analysis of anomalies identified after the initial birth exam.

**Results:** Of 2,935 HIV-infected women enrolled in the Mpepu study who delivered live-born infants, newborn exams were documented on 2,900 (99%) infants. ART from conception was documented for 1088 (38%) women, 1147 (40%) started ARVs during pregnancy; 442 (15%) women received AZT monotherapy, and 223 (7%) received no ARVs during pregnancy. A total of 28 congenital anomalies were identified, and 29 (29%) were first diagnosed at a visit after the initial birth exam (Table 1). No differences were identified in the number of infants with or without congenital anomalies by ARV exposure group in pregnancy, but the study was underpowered to detect differences in rare outcomes. Identification of congenital anomalies after the birth exam occurred either because the anomaly was not readily apparent at birth (e.g. biliary atresia), or because an externally-identifiable anomaly was overlooked at birth but subsequent parental concern led to documentation and management of the anomaly.

**Conclusions:** ARV use in pregnancy warrants ongoing surveillance monitoring for teratogenicity, particularly for regimens such as EFV/FTC/TDF with insufficient safety data in pregnancy. Nearly one third of birth anomalies detected in this cohort of well children were diagnosed after the initial birth exam. Our findings highlight the importance of incorporating, where possible, longitudinal assessment and reporting for detection of congenital anomalies that may not be identifiable at the birth exam.

<table>
<thead>
<tr>
<th>Case #</th>
<th>Description of Congenital Anomaly</th>
<th>Presenting symptom</th>
<th>Timing of Diagnosis from Birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anovestibular Fistula</td>
<td>Stool in urine</td>
<td>42 days</td>
</tr>
<tr>
<td>2</td>
<td>Bilary Atresia</td>
<td>Jaundice at birth</td>
<td>48 days</td>
</tr>
<tr>
<td>3</td>
<td>Bilary Atresia</td>
<td>Jaundice at birth</td>
<td>38 days</td>
</tr>
<tr>
<td>4</td>
<td>Congenital Lymphedema</td>
<td>Bilateral leg swelling</td>
<td>15 days</td>
</tr>
<tr>
<td>5</td>
<td>Jeyanal Atresia</td>
<td>Failure to pass stool with abdominal distension and vomiting</td>
<td>5 days</td>
</tr>
<tr>
<td>6</td>
<td>Macrocephaly</td>
<td>Widening of fontanelle and increasing head size</td>
<td>85 days</td>
</tr>
<tr>
<td>7</td>
<td>Pyloric Stenosis</td>
<td>Projectile vomiting</td>
<td>25 days</td>
</tr>
<tr>
<td>8</td>
<td>Talipes Equino Valgus</td>
<td>Concan expressed by mother about position of foot</td>
<td>60 days</td>
</tr>
</tbody>
</table>

(Table 1 - Congenital Anomalies)

### MOPDC0101

**Communities can mobilize to test: findings from a community randomized trial of a theory-based community mobilization (CM) intervention in South Africa**


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**Background:** While community mobilization (CM) is a powerful tool to increase and sustain demand for HIV testing services, few rigorous trials of CM interventions have been conducted. We implemented a theory-driven CM intervention in order to improve HIV outcomes in 22 communities participating in a community randomized trial (CRT) in a rural area of Mopumalanga Province, South Africa. The mobilization activities were designed to improve community collaboration to address HIV and inequitable gender norms.

**Methods:** Cross-sectional surveys were conducted with 50-55 residents ages 18-35 in each village prior to (n=1181, 2012) and following (n=1174, 2014) two years of intensive intervention activities in half of the villages. Intervention activities mapped onto six domains of CM: 1) shared concern around HIV, 2) community consciousness, 3) organizational structures, 4) leadership, 5) community cohesion, and 6) collective action. Validated domain measures were included in the surveys and mean CM scores were computed and used to predict HIV testing in the past year for each domain and for total CM scores. We used GEE logistic regression analysis to assess the effect of village level CM domain scores on individual-level testing outcomes and included interaction terms to assess intervention effects at follow-up.

**Results:** The overall CM score as well as three of six CM domains, including consciousness, concerns, collective action, were significantly associated with HIV testing following the intervention and interacted with intervention assignment. For example, for every standard deviation increase in community consciousness, the odds of HIV testing increased for intervention village participants (OR:1.36, p< .01) but not for control village participants. Similar findings for total CM score (OR: 1.51), shared concerns (OR:1.82), and collective action (OR:1.45) indicate that the intervention successfully improved HIV testing. Leadership, presence of organizations, and community cohesion were not significantly associated with HIV testing at baseline.

**Conclusions:** To our knowledge this is the first CRT assessing a theory-based CM intervention including quantitative measures of CM domains over time. While not all of the six domains were associated with HIV testing uptake, we found clear evidence that communities can be mobilized and that CM measures are associated with improved engagement in HIV testing.

### MOPDC0102

**Reducing stigma and increasing HIV testing with a health information intervention, a cluster-randomized trial from Malawi**

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**Background:** Despite widespread availability of antiretroviral therapy (ART), demand for HIV testing remains low across southern Africa. HIV testing may be viewed as a signal of HIV status. Those who seek an HIV test may be rejected by potential sexual partners who fear contracting HIV. This could discourage HIV testing, and encourage travel far from home for HIV testing to avoid being seen. Such stigma may be exacerbated by unawareness of the public benefit of ART, i.e. its capacity to reduce HIV transmission by 96%. We evaluated an information intervention designed to increase HIV testing rates by reducing stigma.

**Methods:** We conducted a cluster-randomized controlled trial in Malawi. We held community health information meetings in all villages. In control villages (n=62), we provided information on the private benefits of ART, including its potential to prolong life and reverse AIDS symptoms. In intervention villages (n=60), the public benefit of ART was discussed in addition to the control message.
Results: Among those aged 15-49, there was a significantly larger uptake of HIV testing in the intervention villages (intervention 2.6% vs. control 1.6%; p<0.0035), according to routinely collected data from 18 health facilities over a period of 3 months after the intervention. This effect was significant for men and women, and larger when corrected for spill-over. The intervention led to a large shift in beliefs about ART, as measured by a survey five months after the intervention. Respondents in intervention villages were more likely to report accepting attitudes towards sexual partners on ART. High beliefs about the public benefit of ART were associated with significantly more tests at nearby clinics. HIV testing decisions were predicted by a respondent's perception of her/his community's beliefs about ART. These observations strongly suggest that the effect of the intervention on HIV testing uptake is mediated by a reduction in stigma.

Conclusions: The results demonstrate that stigma between sexual partners is a significant barrier to HIV testing, and that providing new information on the effect of ART on HIV transmission can increase testing uptake.

MOPDC0103
HIV self-testing increases HIV testing frequency among high-risk men who have sex with men: a randomized controlled trial

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Background: HIV self-testing has the potential to increase HIV testing and thereby decrease the time persons living with HIV are unaware of their status, but the absence of counseling may result in increased risk of HIV acquisition.

Methods: In Seattle, Washington, we randomly assigned 230 HIV-negative men who have sex with men (MSM) at high risk for HIV acquisition in a 1:1 ratio to have access to HIV self-testing using the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test on oral fluids or to testing as usual for 15 months. Men randomized to self-testing were trained to use the test and provided a self-test at baseline; they could contact the study for additional tests as needed up to once a month. All participants were advised to test quarterly, offered testing reminders, and could test anywhere through any existing HIV testing source. The primary outcome was self-reported number of HIV tests during follow-up. To evaluate potential adverse effects of self-testing, we compared the following between two arms: non-concordant condomless anal intercourse (CAI) and number of CAI partners in the last 3 months (measured at 9 and 15 months) and diagnosis with a bacterial sexually transmitted infection (STI) at the final study visit (15 months).

Results: Men randomized to self-testing reported significantly more HIV tests during follow-up (mean=5.3, 95%CI=4.7-6.0) than those in the control arm (3.8, 3.2-4.0; p<0.001), representing an average increase of 1.7 tests per participant over 15 months. Men randomized to self-testing reported using an average of 3.8 self-tests during follow-up. Self-testing was non-inferior to clinic-based testing with respect to markers of HIV acquisition risk. At the final study visit, 5.4% of MSM randomized to self-testing were diagnosed with a bacterial STI compared with 12.2% of control participants (risk difference=-6.8%; 95%CI=-16 to +1.8%). There were no significant differences between the two arms in the proportion of men reporting non-concordant CAI or the reported number of male CAI partners in the last 3 months at 9 and 15 months.

Conclusions: Access to free HIV self-testing increased testing frequency among high risk MSM and did not impact sexual risk behavior or STI acquisition.

MOPDC0104
Home HIV testing among transgender women in San Francisco: a pilot feasibility and acceptability study

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Background: Transgender women are the population most impacted by HIV in the United States, with prevalence approximately 40 times higher than the general population. The rates of HIV antibody testing in the transgender community are not commensurate with risk. Development of alternative testing strategies to ensure early detection, care, and prevention of infection is critical.

Methods: We conducted a pilot study to explore feasibility and acceptability of offering home-based, self-conducted HIV testing for transwomen. Fifty HIV-negative transwomen in San Francisco were provided with OraQuick oral HIV self-test kits and asked to utilize the tests once a month for three months. Survey data were collected at baseline, 1 month, and 3 months. In-depth-interviews (IDIs) were conducted with 11 participants at their final visit to learn more about self-testing experiences, barriers to self-testing, and how the self-test might fit into an expanded pool of testing options.

Results: Self-testing was both feasible and acceptable: following the first test 94% reported the test easy to use; 93% said the results were easy to read; and 91% said they would recommend the self-test to others. Acceptability remained high at three months. Approximately 25% used the test with others present and 68% reported preference for self-tests vs. clinic-based testing. IDIs revealed tension between a desire for the privacy afforded by self-testing and a desire for the social and resource support offered at health facilities. While most participants were comfortable accessing services and had been tested recently (88% in the past year), IDIs revealed apprehension about being seen at HIV-testing clinics. Qualitative data also indicated that partner testing was of interest and that the cost of the kits could discourage future utilization.

Conclusions: The home-based, self-conducted HIV test provides a viable option for populations who prefer to avoid the clinic environment. To increase acceptability, enhanced linkage strategies to social and resource support should be considered. The current price point is inaccessible for populations that experience disproportionate economic marginalization. Interest in partner testing could represent an opportunity to package tests in pairs and an expanded opportunity for testing uptake. Additional research should focus on expanding delivery options and implementation strategies.

MOPDC0105
Supervised HIV self-testing to inform implementation and scale up of self-testing in Zimbabwe

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Presenting author email: smavedzenge@rti.org

Background: HIV self-testing (HIVST) can potentially increase uptake of testing in a low-cost, confidential and non-stigmatizing manner. Rigorous evaluation of implementation materials for accurate self-testing has rarely been conducted. In preparation for implementation and scale-up of HIVST in Zimbabwe, we have adapted and iteratively refined instructional materials to support self-testing. Here we present results from our evaluation of these materials through supervised self-testing.

Methods: Participants were recruited at an HIV testing clinic using convenience sampling. They were given the instructional materials and left alone to complete their self-test and record the result. Confirmatory rapid testing after HIVST, and pre- and post-test questionnaires to evaluate their experience were conducted. The testing process was video recorded and videos analyzed using checklists. Data were evaluated weekly and IEC materials iteratively refined according to optimizing accuracy.

Results: We conducted 172 supervised self-tests among participants in urban Harare, with mean age of 30 (range 18-70), 53% female and 20% first-time testers. Overall 93% read their result accurately, in some cases despite failing to follow instructions as determined by video. Six percent were unable to determine their result. 1% got inaccurate results, including one HIV+ individual on ART who followed instructions correctly as determined by video. While most (88%) reported the test was not hard to use, 23% said some instructions were unclear, resulting in modifications to the materials. Common sources of confusion were in interpreting results, the purpose of the test kit desiccant, and unclear images/language. Low literacy was associated with unsure/invalid results, prompting revision of the materials for a rural, less literate setting.

Conclusion: Access to free HIV self-testing increased testing frequency among high risk MSM and did not impact sexual risk behavior or STI acquisition.
There, among 29 participants, 3% were unable to determine their results and 31% got an inaccurate result. Materials have been further revised making them almost entirely pictorial, and supervised self-testing is on-going.

Conclusions: Though there is little published research on optimizing HVST materials, we found that thorough evaluation of materials through supervised self-testing has been critical to optimizing accuracy. Numerous revisions were required, and evaluation in different settings yielded differing results. Rigorous development and testing of HVST supportive materials appropriate to country and setting is recommended prior to implementation of HVST programs.

### MOPDC0106

**Integrating partner notification services into PMTCT (Option B+) services in the northwest and southwest regions of Cameroon**


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**Background:** Partner notification (PN) for control of sexually transmitted infections (STIs) is a public health strategy which notifies the partners of infected individuals of their possible exposure to disease. PN has rarely been used in sub-Saharan Africa as an HIV prevention strategy. In Cameroon, patients newly diagnosed with HIV do not usually receive assistance in notifying their sex partners of their possible exposure to disease. PN has rarely been used in sub-Saharan Africa as an HIV prevention strategy.

**Methods:** In 2012, the World Health Organization issued new guidelines in PMTCT including Option B+ which recommends that all HIV positive pregnant women (PW) be placed on antiretroviral treatment for life irrespective of CD4 count. PN was integrated into PMTCT at 22 sites in Cameroon.

**Results:** During the 18 months, uptake was monitored monthly and 823 PW tested HIV positive at the 22 option B+ sites (Figure 1). Of the 840 partners they identified, 693(82.5%) were traced and notified of their exposure to HIV. Of the 935 notified, 421(45.8%) did their HIV test and received results. A total of 136(33.0%) of those tested were HIV positive and 138(99.3%) were linked to appropriate C&T services. HIV negative partners (67.0% of those tested) were counseled on risk reduction. Male partner involvement increased greatly at seven of ten sites monitored.

**Conclusions:** PN is a feasible HIV prevention strategy in resource-limited settings which can identify and test many partners of HIV positive PW. PN can be integrated into Option B+ PMTCT programs to identify HIV positive partners who are placed on treatment alongside the HIV positive PW.

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### MOPDD001 Implementation Challenges among People Who Inject Drugs

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**Background:** Eastern Europe and Central Asia face a rapidly escalating HIV epidemic driven by injection drug use (IDU). We evaluate the role of OST in engaging HIV-infected PWID in care and the effect of OST on utilization of medical services.

**Methods:** Cross-sectional study of healthcare utilization in the past six months among 296 randomly sampled HIV-infected opioid-dependent PWID conducted in healthcare clinics in Ukraine in 2010 across Ukraine. Participants categorized as therapeutic on OST if on OST for at least three consecutive months prior to the past six months or as not taking OST if not on any OST in the past nine months. Based on this criterion, 24 individuals were excluded.

**Results:** The 65% on OST (177/272) were less likely to be below the poverty line or live alone and more likely to be married or have gone to prison (p<0.05). The two groups did not differ significantly in terms of age, gender, or education. Those on OST had more years of opioid injection but were less likely to have injected in the past 30 days, to have engaged in polysubstance abuse, or to have ever overdosed on drugs (p<0.01). In the past 6 months, those on OST were less likely to seek emergency care (72% vs 84%, p<0.05) and had fewer mean emergency care visits (2.77 vs 4.57, p<0.01) with no significant differences in mean ambulatory care visits (1.78 vs 0.59, p=0.11) or hospitalizations (0.53 vs 0.34, p=0.36). Those on OST were more likely to be engaged in HIV care, as evidenced by higher rates of ART (37% vs 26%, p<0.08), recent CD4 testing (82% vs 60%, p<0.01), and recent TB testing (95% vs 71%, p<0.01). Number of self-reported symptoms was higher in the non-OST group compared to those on OST (10.46 vs 7.75, p<0.01). Limitations include cross-sectional design and potential for recall and social desirability biases.

**Conclusions:** Despite higher rates of incarceration and more years of opioid injection, those therapeutic on OST were less likely to seek emergency care than those not on OST and more likely to be engaged in HIV care with fewer overall symptoms.
**MOPDD0102**

The effects of opioid substitution therapy and highly active antiretroviral therapy on the cause-specific risk of mortality among injection drug using people living with HIV/AIDS

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**Background:** Prior studies indicate that opioid substitution treatment (OST) reduces the risk of mortality and improves the odds of accessing highly active antiretroviral therapy (HAART), however the relative effects of these treatments for injection drug using people living with HIV/AIDS (PHLV) are unclear. We aim to determine the independent and joint effects of OST and HAART on mortality, by cause, within a population of injection drug using PHLV initiating HAART.

**Methods:** We used a linked population-level administrative database for British Columbia, Canada (1996-2010) to form a cohort of injection drug using PHLV. We selected all individu-
als identified as HIV-positive and either having a history of OST at initial HAART receipt, as indicated by methadone or buprenorphine dispensation records in the BC PharmaNet database or having an indication of injection drug use before HIV infection, as indicated in the HIV test-
ing database. We employed time-to-event analytic methods, including comparing risk models, proportional hazards models with time-variant covariates, and marginal structural models, to identify the independent and joint effects of OST and HAART on all-cause mortality, as well as drug- and HIV-related mortality, controlling for covariates.

**Results:** Among 1,727 injection drug using PHLV, 403 (28.5%) died during a median 5.1 years (interquartile range 2.1-9.1) of follow-up. 178 (9.2%) died due to drug-related causes, 55.4% due to HIV-related causes, and 25.6% due to other causes. Standardized mortality ratios were 12.2 (95%CI 9.8, 15.0) during OST, and 30.2 (97.1, 13.1) during periods out of OST. Both OST (ad-
justed hazard 0.34; 95%CI (0.23,0.48)) and HAART (0.39; 95%CI (0.31, 0.48)) decreased the hazard of all-cause mortality, however individuals were at lowest risk of death when these medications were used jointly (0.16 (0.10,0.26)). Both OST and HAART independently protected against not only HIV-related death, but also drug-related death and death due to other causes.

**Conclusions:** While both OST and HAART are life-saving treatments, there is an urgency to ensure joint administration to protect against both drug and HIV-related mortality.

**MOPDD0103**

Assessing the HIV prevention potential of Mexico’s “narcomenudeo” drug law reform: implementation challenges among people who inject drugs

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**Background:** Mexico’s innovative 2009 “narcomenudeo” law decriminalized small-scale drug possession, mandating drug treatment diversion in lieu of incarceration and reframing drug policy to facilitate HIV prevention. However, the US-Mexico border region continues to experience elevated HIV risk related to syringe sharing, while evidence-based addiction treatment and other prevention services targeting people who inject drugs (PWID) remain critically under-resourced.

We designed a longitudinal cohort study to assess the implementation of this structural inter-
vention among at-risk PWID in Tijuana.

**Methods:** This mixed-methods research program integrated a structured questionnaire and laboratory testing with qualitative interviews assessing legal knowledge, police encour-
ers, drug and sex risk behaviors, and infectious disease status. At baseline, 737 PWID were recruited in Tijuana; 32 participated in qualitative interviews.

**Results:** Between 2010-2013, only 11% of PWID respondents reported being aware of drug decriminalization; virtually none experienced drug treatment diversion or the law’s other operational components. Interviews underscored the law’s irrelevance to PWID; 699 (98%) characterized police practices as typically inconsistent with formal law. Instead of diversion to addiction treatment, multivariate modeling suggested that police encounters are independently associated with increased HIV risk behaviors such as syringe sharing (OR=1.26; 95%CI 1.09, 1.48) and poly-drug use (OR=2.11; 95%CI 1.38, 3.22). Qualitative data underscored the dissonance between the formal legal standards for drug and syringe possession, treatment diversion, and other public health-oriented legal provisions on the one hand, and the lived experience of drug users on the other. Interviews mapped out a number of pathways by which arbitrary police enforcement severely undermine drug users’ ability to engage in protective HIV behaviors. Mixed-methods findings reveal that, just as housing instability can aggravate HIV risk, the lack of predictability in one’s legal environment—also known as a “weak rule of law”—can compound HIV risk.

**Conclusions:** Formal drug policy reform may be necessary in many settings to reduce HIV risk among PWID, but appears insufficient as a stand-alone intervention. As policy inter-
ventions intended to facilitate HIV prevention gain global momentum, ancillary structural re-
forms such as police training to improve the rule of law are needed to unlock their public health potential. Operational partnerships with law enforcement are discussed.

**MOPDD0104**

Low threshold services for females who inject drugs: reducing gender inequities in methadone enrollment

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**Background:** In 2011, the government of Tanzania established methadone assisted therapy (MAT) to combat the dual epidemic of HIV and injection drug use. However, enrollment of females who inject drugs into MAT has lagged behind that of males. To address this inequity, the methadone clinic at Mwananyamala Regional Referral Hospital (MRRH) introduced low threshold services for females in January 2013, allowing women to bypass the historically re-
quired attendance at community-based organizations prior to enrollment. Furthermore, existing female clients were encouraged to recruit their peers and one-day of the week was set aside for enrolling female clients only.

**Methods:** We conducted an interrupted time-series study to evaluate the impact of imple-
menting low threshold low services for females enrolling into MAT, using de-identified, routinely col-
lected data from November 2012 to October 2014 at MRRH. Prais-winsten regression models were utilized to estimate the mean change in the proportion of clients that were female and the weekly number of females enrolling, adjusting for male enrollment and a period of MAT enroll-
ment interruption form July-November 2013.

**Results:** Overall, 759 clients enrolled into the methadone clinic during the study period. Of those enrolling, the mean age was 34 years. The mean number of people enrolling into methadone during the study period was 8 clients (95%CI 7.9) per week. After implementation of low threshold services, the proportion of female clients increased from 14% (95%CI 13,15%) to 24% (95%CI 23.25%,p<0.001), but after the enrollment interruption, the proportion of female methadone clients decreased slightly to 22% (21-22%).

[Figure 1. Lowess Smooth of the Percentage of Female Methadone Clients]
**MOPDD0105**

Increasing rates of earlier antiretroviral treatment associated with elevated levels of optimal virologic response among HIV-positive illicit drug users during a treatment-as-prevention-based initiative in a Canadian setting

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**Background:** Among illicit drug users, renewed efforts to reduce high levels HIV/AIDS-related morbidity and mortality and curb rates of viral transmission rely, in part, on earlier initiation of antiretroviral therapy (ART). However, there are concerns that starting treatment prior to immunosuppression for members of harder-to-treat groups could contribute to lower levels of treatment adherence and lead to impaired virologic response. Thus, we sought to evaluate trends in CD4 cell count at ART initiation over time and rates of subsequent virologic response among HIV-positive illicit drug users during a community-wide Treatment-as-Prevention campaign in Vancouver, Canada.

**Methods:** We used data from the ACCESS study, an ongoing longitudinal cohort of HIV-positive illicit drug users linked to comprehensive HIV clinical monitoring and pharmacy dispensation records. In this retrospective study we included all individuals who initiated ART from 2005 onwards. We used multivariable logistic regression to evaluate differences in mean CD4+ cell count at initiation by year of initiation. To estimate time to plasma HIV-1 RNA viral load < 50 copies/mL by CD4 cell count at ART initiation we used Kaplan-Meier and Cox proportional hazards methods.

**Results:** Between 2005 and 2013, 357 individuals initiated ART. Median CD4 at initiation increased from 130 cells/mL (Inter-Quartile Range [IQR]: 60 - 205) in 2005 to 330 (205 - 430) in 2013. In a linear regression analysis adjusted for age, gender and ancestry, year of initiation was positively associated with CD4 cell count at initiation (β = 30.82 cells per year increase, p < 0.001). Among 357 initiates, 184 (52%) reached non-detectable plasma VL within 360 days. In an adjusted Cox proportional hazards model, CD4 cell count at initiation was positively associated with time to viral suppression (Adjusted Hazard Ratio: 1.21 per 100 cell/mL increase; 95% Confidence Interval: 1.13 - 1.29)

**Conclusions:** We observed substantial increases in CD4 cell count at initiation over time coincident with a community-wide TasP-based initiative. Individuals initiating ART earlier in the disease course exhibited higher rates of optimal virologic response. These findings support earlier initiation of ART among illicit drug users in order to reduce levels of HIV/AIDS-associated morbidity and mortality and rates of viral transmission.
**MOPEA001**

Monoclonal antibodies using IgG-V regions from cows vaccinated with HIV gp140 require cysteine and tryptophan for high affinity Env trimer-specific binding

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**Background:** Cows vaccinated with HIV AD8 Env gp140 trimer develop a vast quantity of high titre polyclonal antibody with broad neutralising activity in colloidal gold. We studied the molecular characteristics of this response by isolating the IgV-region genes from bovine memory B cells binding HIV-1 Env gp140 trimer and constructing monoclonal antibodies (mAbs).

**Methods:** PBMC from a cow vaccinated over 4 years with HIV-1 AD8 Env gp140 trimer were stained for CD27+ IgG memory B-cells and those binding PE-labeled gp140 were isolated using FACS single-cell sorting. The bovine Ig heavy (H) and light (L) chain variable (V) regions of 33 rearranged immunoglobulin (lg)-genes were amplified from cDNA by nested PCR, and V regions of H and L were subconected into expression vectors containing human IgG constant regions. Codons for Cys and aromatic amino acids in CDRH3 were changed to Ala by site-directed mutagenesis. Chimeric bovine-human (BH) IgG mAbs were produced using paired H and L chain plasmid transfection in 293T cells and tested against various Env in ELISA, directed mutagenesis. Chimeric bovine-human (BH) IgG mAbs were produced using paired H and L chain plasmid transfection in 293T cells and tested against various Env in ELISA, directed mutagenesis.

**Results:** HIV-specific memory B cells were found at a frequency of 0.96% of IgG+ CD21+ memory B cells from peripheral blood. From these 33 matched chimeric BH H and L chains binding Env gp140 immunogen were cloned and their CDR3 size ranged from 12 to 64 amino acids with a high Cys and aromatic aa frequency. Of these, 2 mAbs, 6A and 8C, displayed strong binding to HIV-1 Env unclaved trimer, but not monomer, and bound a subset of cleavage-avtive HIV-1 SOS-SF gp140. The VH somatic mutation rate for 8C and 6A was 27% and 28% respectively and their 21 and 14aa CDR3 domains were 57% and 53% mutated from their DH3 and DH8 germline genes. The HIV-specific binding characteristics of both 6A and 8C mAbs were eliminated when CDR3 Cys or Thr/Ala were changed to Ala. These mAb’s didn’t have broad neutralising activity.

**Conclusions:** The 8A and 8C mAbs target conformation-dependent epitopes on uncleaved Env gp140; but these don’t account for the potent neutralising activity of the polyclonal response. However, highly evolved IgV-regions resulted from vaccination with Env gp140 trimer.

**MOPEA002**

B cells and alterations in subsets

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**Background:** HIV-infected women were enrolled during pregnancy and they and their children were followed prospectively. Detailed phenotyping of the peripheral B cell compartment was performed by multiparametric flow cytometry (CD3+CD19/CD14+CD15/CD20+CD21/ CD27/CD45RA) using samples of HEU umbilical cord blood (UCB; n=8) or venous blood (n=4) obtained at 4-6 months of age. The magnitude of the antigen-specific B cell responses elicited by immunization with hexavalent acellular diphtheria-tetanus-poliomyelitis (DTP) vaccine (administered at 2 and 4 months of age) was estimated by staining with fluorescent tetanus toxoid (TT) oligomers.

**Results:** Total B cells numbers decreased between UCB and 4-6 months of age (70.5%±6.1% vs. 64.3%±5.4%) and increased frequencies of activated memory B cells (0.2%±0.3% vs. 2.3%±1.2%) and plasmablasts (0.1%±0.4% vs. 0.7%±0.2%) were observed. Conversely, atypical memory B cell (CD19+CD10-CD27-CD45RA) frequencies were unchanged. TT-specific B cells were detected at 4-6 months of age, where they represented 0.075% of class-switched plasmablasts, 0.082% of class-switched classical memory B cells, and 0.106% of class-switched activated memory B cells.

**Conclusions:** Preliminary results from this ongoing prospective study provide a high-resolution portrait of the global and antigen-specific B cell compartment and are suggestive of the presence of modest vaccine-elicited B cell responses in HEU children. Further studies will be required to validate whether these responses are associated with virologic and/or immunologic parameters in the mother, and to determine the short and long-term clinical impact of these findings.
T-cell immune responses (CD4 and CD8)

MOPEA004
Control of HIV-1 by cytotoxic T cells specific for multiple conserved epitopes
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Backgrounds: HIV-1-specific cytotoxic T lymphocytes (CTLs) play a critical role to suppress HIV-1 replication. It is well known that HLA-B*27-restricted and HLA-B*57-restricted CTLs play a key role in the control of HIV-1 in Caucasians and Africans. However, these alleles are very rare in Japan, indicating that HIV-1 is not controlled by these alleles-restricted CTLs in HIV-1-infected Japanese individuals. In the present study, we sought to identify HIV-1-specific CD8+ T cells controlling HIV-1 in HIV-1-infected Japanese individuals by employing exhaustive and comprehensive strategies.

Methods: We analyzed CD8+ T cell responses to 11-mer overlapping HIV-1 Gag, Pol, and Nef peptides in 461 chronically HIV-1-infected Japanese individuals to identify candidates of CD8+ T cells responses controlling HIV-1. Following re-evaluation for the role of the identified specific CTLs in the control of HIV-1, we characterized the cross-reactivity of their escape mutants.

Results: We identified 19 CTL epitope candidates significantly associated with low plasma viral load (pVL) and high CD4+ counts in the Japanese individuals. After re-evaluating the correlation between these epitope-specific CTLs and the clinical outcome, we identified 8 Gag and 5 Pol epitope-specific CTLs controlling HIV-1. The breadth of the responses to these 13 epitopes was negatively correlated with pVL (p = 2.1×10^-4) and positively with CD4+ counts (p = 5.3×10^-4), indicating strong synergistic effects of these T cells on HIV-1 control in vivo. Nine of these epitopes were conserved among HIV-1 subtype B-infected individuals, whereas three out of 4 non-conserved epitopes were cross-reacted by the specific T cells.

Conclusions: These results suggest that AIDS vaccines inducing CTLs specific for these 12 epitopes would be effective for protection against HIV-1.

Mucosal immunity

MOPEA005
Bacterial vaginosis is associated with loss of gamma delta T cells in the female reproductive tract
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Background: The most common female reproductive tract infection, Bacterial Vaginosis (BV), is characterized by a reduction in vaginal lactobacilli and an increase in gram negative anaerobic bacteria. BV is associated with increased risk of acquiring and transmitting HIV. Gamma delta (GD) T cells are essential components of the adaptive and innate immune system and play an important role in epithelial barrier protection. The majority of tissue-associated GD cells are gamma delta (GD) T cells and increase of the naïve/memory CD8+ T cell density decline, greater normalization of mucosal immune abnormalities, decrease inflammatory markers and reduce the viral reservoir.

Methods: We included 12 HIV- controls and 43 ART-naïve HIV patients who were randomized to elvitegravir, maraviroc (MRV) or MRV+ritonavir (MRV+RAL), each in combination with tenofovir/emtricitabine. Cohort and duodenal biopsies were obtained at baseline and at 9 months of ART. We performed a comprehensive assay of T cell subsets by flow cytometry, T cell density in duodenal biopsies, plasma and tissue concentrations of antiretroviral drugs by high-performance liquid chromatography. Plasma interleukin-6 (IL-6), lipoteichoic acid (LTA), soluble CD14 (sCD14) and zonulin-1 were measured by ELISA. Total cell-associated HIV DNA was measured in PBMC and mucosal mononuclear cells. Linear mixed models were computed to estimate the mean change of each parameter in plasma, PBMC colon and duodenum.

Results: Twenty-six HIV-infected patients completed the follow-up. In duodenum, the quadripulse regimen resulted in greater CD8+ T cell density decline, greater normalization of mucosal CCR5/CD4+ T cells and increase of the naïve/memory CD8+ T cell ratio, and induced a greater decline of sCD14 levels and duodenal HIV DNA levels (p=0.004 and p=0.087, respectively). MRV showed the highest drug distribution to the gut tissue, and duodenal concentrations correlated well with with a number of markers of the adaptive immunity in duodenum, i.e., %CD4+ and %CD8+ T cells (Rho 0.671, p=0.006 and Rho -0.518, p=0.048, respectively), CD4/CD8 ratio (Rho 0.679, P=0.005), and %CD4+ and %CD8+ HLA-DR+CD38+ T cells (Rho 0.625, p=0.013 and Rho 0.607, p=0.016, respectively). MRV elicited greater activation of the mucosal naïve CD8+ T cell subset, ameliorated the distribution of the CD8+ T maturational subsets and induced higher improvement of zonulin-1 levels.

Conclusions: Current knowledge of the immune dynamics at the female reproductive tract is limited and new tools to address mucosal vulnerability to HIV are needed. Changes in the vaginal flora occurring with BV are associated with diminished regulatory CD1 T cells suggesting disruption of the vaginal mucosa. We propose to use GD T cell responses as a marker of female genital tract vulnerability to HIV infection. Funded by WHIS (U01 AI103397) and Miami CAFR (P30AI073961).

MOPEA006
Effects of quadruple first-line ART on mucosal immunity and HIV persistence
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Background: It is unclear whether initiation of antiretroviral therapy (ART) with regimens aimed at achieving greater concentrations within lymphatic tissues may help to reconstitute mucosal immune abnormalities, decrease inflammatory markers and reduce the viral reservoir.

Methods: We included 12 HIV- controls and 43 ART-naïve HIV patients who were randomized to elvitegravir, maraviroc (MRV) or MRV+ritonavir (MRV+RAL), each in combination with tenofovir/emtricitabine. Cohort and duodenal biopsies were obtained at baseline and at 9 months of ART. We performed a comprehensive assay of T cell subsets by flow cytometry, T cell density in duodenal biopsies, plasma and tissue concentrations of antiretroviral drugs by high-performance liquid chromatography. Plasma interleukin-6 (IL-6), lipoteichoic acid (LTA), soluble CD14 (sCD14) and zonulin-1 were measured by ELISA. Total cell-associated HIV DNA was measured in PBMC and mucosal mononuclear cells. Linear mixed models were computed to estimate the mean change of each parameter in plasma, PBMC colon and duodenum.

Results: Twenty-six HIV-infected patients completed the follow-up. In duodenum, the quadripulse regimen resulted in greater CD8+ T cell density decline, greater normalization of mucosal CCR5/CD4+ T cells and increase of the naïve/memory CD8+ T cell ratio, and induced a greater decline of sCD14 levels and duodenal HIV DNA levels (p=0.004 and p=0.087, respectively). MRV showed the highest drug distribution to the gut tissue, and duodenal concentrations correlated well with with a number of markers of the adaptive immunity in duodenum, i.e., %CD4+ and %CD8+ T cells (Rho 0.671, p=0.006 and Rho -0.518, p=0.048, respectively), CD4/CD8 ratio (Rho 0.679, P=0.005), and %CD4+ and %CD8+ HLA-DR+CD38+ T cells (Rho 0.625, p=0.013 and Rho 0.607, p=0.016, respectively). MRV elicited greater activation of the mucosal naïve CD8+ T cell subset, ameliorated the distribution of the CD8+ T maturational subsets and induced higher improvement of zonulin-1 levels.

Conclusions: These data suggest that initiating ART with four drugs might more effectively reconstitute duodenal immunity, decrease inflammatory markers and impact on HIV persistence, and show unique effects of MRV in duodenal immunity driven by higher drug tissue penetration and possibly by class-dependent effects.
**MOPEA007**

Hormonal contraception and cervical immunity before and after HIV acquisition

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**Background:** We previously reported in a large prospective cohort study - the Hormonal Contraception (HC) and HIV study conducted in Uganda and Zimbabwe - that HIV serocconversion was associated with DMMPA use and both were associated with higher cervical RANTES levels 3 months prior to detected seroconversion. Here we evaluate HC use and cervical immunity longitudinally - before and after HIV acquisition.

**Methods:** We measured levels of inflammatory proteins in 3721 longitudinal cervical samples from 216 HIV seroconverters and 727 matched uninfected women in the HC-HIV study at two quarterly visits prior to HIV seroconversion (t-2, t-1), the seroconversion visit (t0), and two quarterly visits following seroconversion (t+1, t+2) and corresponding visits for HIV-negative women. We used Box-Cox power transformations to normalize protein concentrations and generalized linear models to compare biomarker levels by HIV status and HC use.

**Results:** Biomarkers remained relatively stable across visits for women remaining HIV-negative. In contrast, among seroconverters, IL-1β, IL-6, IL-8, MIP-2, VEGF, IL-1RA, BLR and BD-2 decreased while RANTES and ICAM-1 increased from t-2 to t+2. While no significant differences were observed at t-2, HIV seroconverters had higher levels of RANTES and lower levels of SLPI by t-1, and these differences continued throughout post-seroconversion visits. Compared with the no HC group, DMMPA users had higher levels of RANTES and lower BD-2 levels at both t-2 and t-1 visits. Higher RANTES levels continued at all post-seroconversion visits and lower BD-2 levels continued through t+4 for DMMPA users.

**Conclusions:** Changes in the immunoinflammatory environment of the female genital tract possibly related to mucosal susceptibility to HIV occurred within 6 months of, but prior to, seroconversion and continued post-seroconversion. Levels of several immunoinflammatory markers were related to HC use. DMMPA, in particular, was consistently associated with higher levels of RANTES, which in turn was associated with subsequent HIV seroconversion.

**MOPEA008**

Reporter assay to measure HIV-1 Nef-mediated evasion from T cells

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**Background:** HIV-1 Nef promotes persistent infection by downregulating Human Leukocyte Antigen class I (HLA) expression, thus evading recognition by cytotoxic T lymphocytes (CTL). To investigate this activity in greater detail, we have developed a quantitative reporter cell assay to measure the effect of Nef-mediated HLA class I down-regulation on epitope-specific T cell recognition.

**Methods:** Jurkat "effector" T cells were transfected with a TCRα/β restricted by the HLA-A*0201/Gag (FLK5GWPSFK) epitope, CD8β, and NFAT-driven luciferase reporter plasmid. CEM "target" cells stably expressing A*0202 were transfected with positive and negative Nef controls (NefΔ1-4, GFP and Δnef-GFP, respectively) and mutant variants defective for CD4 and HLA class I downregulation (AXαAAXα, ΔGFP and M20A-GFP, respectively). Transfected target cells were isolated by FACS based on high GFP and low Annexin V expression, pulsed with PK10 peptide and co-cultured with TCR+ effector cells at a 1:1 ratio. To examine endogenous HLA context, CEM-derived GFP-reporter-A*0202 "target" cells were infected with HIV-1 NL4.3 and NFAT mutant M20A and co-cultured with TCR+ effector cells. Surface A*0202 expression on target cells was analyzed by flow cytometry to assess Nef function. Effector T cell activation was measured by luminescence 6 hours following co-culture.

**Results:** Effector T cells generated a robust NFAT-driven luciferase signal following co-culture with PK10-pulsed target cells. Nef-mediated HLA downregulation on target cells resulted in lower luciferase activity, consistent with decreased TCR recognition. As expected, luciferase signal positivity correlated with A*0202 levels when target cells expressed different Nef mutants (Spearmann's R=0.95, P<0.001). Luciferase signal emitted by A*0202-specific effector cells upon co-culture with wild-type HIV-1 NL4.3 nef was nearly twofold lower than for cells infected with the HIV-1 NL4.3 Δvecmutant defective for HLA class I downregulation.

**Conclusions:** This in vitro reporter cell assay provides a new tool to study the immunological interaction between TCR and peptide-HLA on target cells. The assay is quantitative and scalable, which will allow larger studies to more directly assess the impact of patient-derived Nef sequences on antiviral T cell responses in the context of multiple HLA alleles that may contribute to vaccine effects.

**MOPEA009**

Nef and Vpu accessory proteins from primary HIV-1 isolates protect infected cells from ADCC

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**Background:** Recent studies have linked antibody Fc-mediated effector functions with control of human immunodeficiency type 1 (HIV-1) and simian immunodeficiency (SIV) infections. Interestingly, the presence of antibodies with potent antibody-dependent cellular cytotoxicity (ADCC) activity in the Th1 HIV-1 vaccine trial correlated inversely with the HIV-1 acquisition risk. These antibodies were recently found to recognize HIV envelope (Env) epitopes exposed upon Env-CD4 interaction. CD4 downregulation by Nef and Vpu, as well as Vpu-mediated BST-2/heatin antigen, were reported to modulate exposure of CD4-induced (CD4) Env epitopes and were proposed to reduce the susceptibility of infected cells to ADCC mediated by CD4 antibodies or sera from HIV-1-infected individuals.

**Methods:** In most previous studies, lab-adapted HIV-1 strains were used. Here, we tested if the modulation of ADCC responses by Nef and Vpu accessory proteins is conserved among primary HIV-1 isolates. To this end, we evaluated the ability of CD4 antibodies and sera from HIV-1-infected individuals to mediate ADCC on infected primary CD4+ T cells with a panel of patient-derived infectious molecular clones (IMCs) of HIV-1 that contained intact or defective nef and/or vpu genes, using a FACS-based ADCC assay.

**Results:** Nef and Vpu accessory proteins from HIV-1 IMCs, including those from group M transmitted/founder viruses and members of the phylogenetically distant group N, prevented exposure of Env CD4i epitopes targeted by ADCC-mediating antibodies and sera from HIV-1-infected individuals.

**Conclusions:** Our observations highlight the importance of Vpu- and Nef-mediated modulation of Env epitope exposure in preventing the elimination of HIV-1-infected cells by ADCC and help explain the functional and immunological pressure exerted on HIV-1 to downregulate CD4 and BST-2/heatin.

**MOPEA010**

Novel approach to identify new ADCC-mediating antibodies targeting the HIV-1 envelope

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**Background:** Increased evidence of Fc-mediated effector functions against HIV-1 has led to renewed interest in the role that antibody-dependent cellular cytotoxicity (ADCC) could play in controlling viral transmission and/or the rate of disease progression. Interestingly, the interaction of HIV-1 envelope (Env) glycoproteins with the CD4 receptor was recently reported to be required for efficient exposure of ADCC-mediating Env epitopes at the surface of HIV-1-infected cells. Moreover, potent CD4-induced ADCC-mediating monoclonal antibodies (mAbs) targeting the HIV-1 Env glycoprotein gp120 were isolated from vaccinees of the RV144 trial, which showed modest HIV-1 protection. The focus of this study was to establish a novel approach to allow identification of new ADCC-mediating mAbs targeting the HIV-1 gp120.

**Methods:** We developed an alternative flow-cytometry-based assay that allows specific measurement of ADCC-mediated elimination of HIV-1 gp120-coated target cells. This assay relies on staining target and effector cells with different dyes, which allows precise gating and permits the calculation of the number of surviving target cells by normalization to flow-cytometry particles. By using small concentrations of recombinant gp120, we generated suitable target cells that recapitulate the ADCC response mediated against HIV-1-infected cells.

**Results:** This method was successfully applied to screen ADCC activity in plasma from a substantial number of individuals from the Canadian Slow Progressor cohort and also from R5 SIV/SHIV-infected macaques. Furthermore, we were able to isolate new ADCC-mediating mAbs both from human and macaque samples. This was achieved by sorting individual B cells after staining with a newly-engineered Env probe, specifically sampling the CD4-bound conformation and presenting higher affinity for ADCC-mediating mAbs.

**Conclusions:** We developed a novel approach to screen for ADCC activity and isolate new ADCC-mediating mAbs targeting HIV-1 gp120. The identification as well as molecular
**MOPEA011**

**Identification of HLA-associated polymorphisms in a cohort of HIV-1 subtype A/E infection**

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**Background:** It is well known that HIV-1 specific CTLs select escape mutant viruses during acute and chronic infections. Several population-based studies have identified a significant association between viral polymorphisms and particular HLA alleles in cohorts of HIV-1 subtype B and C infections. However, these HLA-associated polymorphisms (HLA-APs) in HIV-1 subtype A/E have only partially been studied. In this study, we analyzed HLA-APs in chronically HIV-1 subtype A/E-infected Vietnamese individuals.

**Methods:** We analyzed HLA-APs in Gag, Pol, and Nef from 400 chronically HIV-1 subtype A/E-infected treatment-naive individuals. HLA-APs in the three proteins were identified using a phylogenetically corrected logistical-regression model.

**Results:** We successfully analyzed the sequence of HIV-1 Gag, Pol, and Nef in 370, 359, and 372 individuals, respectively. At a false-discovery rate q ≤ 0.2, we found 220 HLA-APs (50 in Gag, 64 in Pol, and 106 in Nef). Of these, 76% HLA-associated substitutions occurred within CTL epitopes restricted with same HLA alleles previously reported mostly in cohorts of HIV-1 subtype B and C. HLA-APs were more frequently detected in Nef (occurring at 59 of 206 codons [28.6%] compared to Gag [29 of 498 codons [5.8%]] or Pol [39 of 1003 codons [3.9%]]. The numbers of HLA-A-, HLA-B-, and HLA-C-APs were 53, 87, and 80, respectively, indicating that a higher number of amino acid mutations restricted by HLA-C alleles compared to that in cohorts of HIV-1 subtype B or C infections.

**Conclusions:** We here identified 220 HLA-APs in the Vietnamese infected with HIV-1 subtype A/E and found remarkably higher number of HLA-APs in Nef than Gag and Pol as compared to previous studies on HIV-1 subtype B or C infection. The result suggests higher immune responses to Nef in the subtype A/E infection than in the infection of other subtypes.

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**MOPEA012**

**Viral clade affects the mechanism of HLA-B27:05-mediated immune control of HIV**

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**Background:** HLA-B*27:05, expressed most commonly in B Clade infected populations, is strongly associated with viral control and slow disease progression in HIV infection. Immune control hinges largely on the CD8+ T cell response to the HLA-B*27:05-restricted p24 Gag epitope KK10. An escape mutation in this epitope, R264K, is commonly accompanied by an upstream compensatory change, S173A. We hypothesized that clade-specific differences at the 173 residue, specifically T173 in C Clade HIV, may result in differences in the fitness cost and frequency of selection of escape. Clade-specific differences may directly affect the mechanism of HLA-mediated immune control.

**Methods:** We sequenced the Gag protein in 25 C Clade infected HLA-B*27:05-positive individuals and identified polymorphisms associated with KK10 escape. We assessed the effect of KK10 escape and putative compensatory mutations on viral replicative capacity (VRC) by generating a panel of viral clones expressing escape variants and/or compensatory changes in the context of both the B and C Clade p24 gene, and measuring VRC in vitro.

**Results:** We found that all 15 subjects that had selected an escape mutation at residue R264 had no compensatory change at position 173. R264G was a more common escape variant than is seen in B Clade infection, and was less costly than R264K in VRC assays. We identified three putative compensatory mutations associated with selection of KK10 escape in C Clade infected controls; S165N, V168I, and V218M. These mutations partially compensated for the fitness cost of R264K, but less effectively than S173A compensates in B clade infection.

**Conclusions:** We conducted a whole genome transcription analysis on DC, B cells and CD4+ T cells from NP and PR to identify differential expression of genes related to cholesterol metabolism. RNA was isolated from APC derived form NP and PR (progressors) and microarray analysis of mRNA transcripts was performed on Illumina HT12.
Asymptomatic long term non-progression

**MOPEA014**

**Characterization of anti-gp41 antibodies eliciting viral neutralization and protecting against CD4 depletion in long-term non-progressors**

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**Background:** We previously showed that antibodies (Ab), which recognized a highly conserved motif of the gp41, called 3S, are protective against CD4 T cell depletion. This was analyzed after immunization in a model of SHIV162P3-infected macaques, and naturally in asymptomatic long-term non-progressor (ALT) patients. More recently, we have detected the presence of anti-3S/W614A Ab, which recognized a point-modified form of 3S, in less than 5% of HIV-1 progressor patients. These Ab remain able to protect CD4+ T cells but have also acquired the capacity to elicit viral neutralization. Here, we quantified and characterized these anti-3S/W614A Ab in non-treated patients from the French ANRS ALT cohort.

**Methods:** 64 HIV-1-unrelated ALT patients who had enrolled with ≥600 CD4+ cells/mm3 (for at least 5 years), were followed-up each year during the first 3 years to evaluate anti-3S/W614A Ab. Ab level was measured by ELISA, and its presence was correlated with different biological parameters (CD4 count, CD4/CD8 ratio, viral DNA, viral load, ...). Viral neutralization was performed against a panel of two 1 and 2 viruses, using the standard TZM-bl assay.

**Results:** 25.7% of patients had detectable anti-3S/W614A Ab at the enrollment period. The presence of these Ab is highly significantly correlated with an increased of the CD4/CD8 T cell ratio (p<0.006), and both decreased of the viral load (p< 0.0001) and viral DNA (p=0.0003). In the same subjects, measured again at 24-36 months following inclusion in the cohort, we observed that subjects with persistently specific Ab still had both significantly lower viral DNA and viral load, as compared to patients without anti-3S/W614A Ab. Importantly, we also report that the efficacy of viral neutralization mediated by anti-3S/W614A Ab is time-dependent, increasing during the follow-up in term of breadth and potency.

**Conclusions:** The presence of anti-3S/W614A Ab appears to confer crucial advantage in asymptomatic long-term non-progression HIV-1 patients. These results bring new insights for both pathophysiologic research and development of new vaccine strategy.

**Highly exposed seronegative individuals (HESN)**

**MOPEA016**

**Plasma and PBMC miRNA profile in sexually HIV-exposed seronegative individuals**

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**Background:** MicroRNAs (miRNAs) are small 20- to 24 nt non-coding RNAs involved in the post-transcriptional regulation of gene expression which play important roles in several viral infections. Global expression profiles of cellular miRNAs identified alterations of specific miRNAs post-HIV infection both in vitro and in different patient cohorts; these data suggest a potential role for miRNA in pathogenesis and disease progression. We verified if natural resistance to HIV infection in seronegative individuals repeatedly exposed to HIV (HESN) could be secondary to a peculiar miRNA signature.

**Methods:** expression levels of 84 miRNAs, selected according to their proven anti-HIV properties were analyzed by a specific miRNA array and results were confirmed by individual RT-qPCR in plasma, unstimulated PBMC and in vitro HIV infected PBMC isolated from 40 HESN, 40 HIV seropositive subjects (HIV+) and 40 healthy controls (HC).

**Results:** showed that:
1) whereas the basal PBMC miRNA profile from HESN was similar to the one observed in HC and was characterized by an increased expression of miR-138, miR-150 and miR-190, miR29a and miR223 expression was significantly upregulated in HESN alone;
2) miR-28, miR-29a, miR-150 and miR223 expression was significantly downregulated in HIV-stimulated PBMC of HESN alone;
3) miR-28, miR-29a, miR-29b, miR-29c, miR-125b, miR-146, miR-150, miR-155, miR-190 and miR-382 were increased in plasma of both HESN and HIV+ compared to HC;
4) of miR-138 and miR-223 plasmatic levels are exclusively increased in HESN compared to both HIV+1 patients and HC.

**Conclusions:** HIV exposure modifies miRNA expression even in the absence of overt infection. Because the miRNAs that are increased in HESN, i.e. miR-29a, miR-138 and miR-223 were shown to play important role in reducing HIV replication via their ability to bind the 3’ UTR of viral miRNA, the modulation of these miRNAs could represents a key protection mechanism against HIV infection.
MOPEA017

Immune activation is present in HIV-1 exposed seronegative individuals (HESN) and is independent of microbial translocation

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Background: Analyses on the presence of immune activation in HIV-exposed seronegative individuals (HESN) yielded discrepant results. To clarify this issue we performed an extensive investigation of immune parameters in HESN and, in particular, we analyzed the possible presence in these individuals of microbial translocation, the most widely accepted reason driving immune activation in HIV-infected patients (HIV+).

Methods: Twenty HESN, 20 HIV-unexposed healthy controls (HC) and 20 HIV+ individuals were enrolled: 1) T lymphocyte activation markers, maturation pathways and TLR4+CD14+ expression; 2) TLR transduction pathway in response to LPS stimulation; 3) production of proinflammatory cytokines by LPS-stimulated PBMC; and 4) LPS and sCD14 plasma levels.

Results: Results showed that in HESN and HIV+ compared to HC, 1) CD4+CD25+, CD8+CD38+, and memory T lymphocytes were increased whereas naïve T cells were reduced 2) PBMC were more responsive to LPS stimulation and were characterized by increased mRNA levels of effector mediators; and 3) IL-6, TNFα and IFNγ production was augmented. In contrast with these results, LPS and sCD14 levels were significantly reduced in HESN and HC compared to HIV+; these discrepancies were not secondary to differences in TLR4 expression.

Conclusions: Immune activation and increased responsiveness to LPS characterize the HESN phenotype; this is not driven by alterations of the gastrointestinal barrier and microbial translocation. The activation state seen in HESN may influence the induction of stronger adaptive immune responses and may represent a virus exposure-induced innate immune protective phenotype against HIV.

Correlates of immune protection

MOPEA018

Association of the presence of HIV-1 broadly neutralizing antibodies during pregnancy and prevention of mother to child transmission at delivery

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Background: Neutralizing antibody assays are now being widely employed in different laboratories in search for correlates of protective immunity. There are strong arguments in favor of a beneficial role of some broadly neutralizing antibodies in prevention of HIV infection if these antibodies exist prior to exposure. Further, correlates of broadly neutralizing antibodies may provide essential pointers to HIV vaccine development.

Methods: Archived plasma samples at the Botswana-Harvard HIV Institute, were assayed for presence of neutralizing antibodies using TZM-bl cells with a tat regulated luciferase reporter gene. A panel of well characterized HIV-1 strains was used, and results were expressed as fifty percent or ninety percent inhibitory dose (ID50/ ID90), defined as the plasma dilution causing fifty percent or ninety percent reduction in relative luminescence (RLU) compared to virus control wells after subtraction of background RLU. The plasma samples used were collected during pregnancy and at delivery.

Results: There were no statistically significant differences in the distribution of ID50 neutralizing antibody titres or neutralization breadth among transmitters and non-transmitters, observed at enrolment at ID50 and throughout. However, non-transmitters had significantly higher neutralization potency at ID90 against the HIV-1 laboratory strains. Similarly, a high neutralization for all the panel viruses was observed by the plasma samples collected at delivery by the non-transmitters.

Conclusions: HIV-1 broadly neutralizing antibodies were observed to be present in infected pregnant women with an ability to give above 50% viral neutralization at all time points. While highly potent neutralizing antibodies showing ID90 was associated with reduced mother to child transmission of HIV in utero and at delivery. However this relationship demand further investigation as giving pointers to the important components essential for vaccine development. There is need to understand further the components that exhibit HIV-1 neutralizing effects, the immunologic environments that support viral neutralization and reduced mother to child transmission, as well as their dominant effect.

MOPEA019

Neutralizing antibody response in chronically HIV-1 infected ART naïve children from India: a follow-up study

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Background: Broadly cross neutralizing antibodies develop only in a subset of individuals after primary infection. There is paucity of data on antibody response elicited by HIV-1 infected children. In this study, we assessed the neutralizing antibody specificity, over time, in HIV-1 infected children from India.

Methods: A cohort of thirty one ART naïve HIV-1 chronically infected children were enrolled. Plasma neutralization activity at two time points was assessed against a panel of six subtype B and C lentiviral strain. Max50 binding titres were determined by ELISA using consensus V1B, V1C, V2C, IDR, MPER-B and MPER-C peptides. CD4s specificity of plasma antibodies was evaluated using CD4s-selective probe R536 and its mutant R536T71FI.

Results: This is the first longitudinal study to profile neutralizing antibody activity in HIV-1 infected children from India. All HIV-1 infected children (21 male and 10 female; age range: 5-17 years) were ART naïve, asymptomatic and had mother to child transmission. Twenty (64.5%) baseline and twenty two (71%) follow up samples neutralized ≥50% of the viruses tested. Four baseline (12.5%) and seven (22.5%) follow up plasma samples neutralized all six viruses tested. A modest improvement in neutralization breadth (P=0.035) and potency (P=0.038) was observed with time. Subtype C specific neutralization predominated in baseline plasma samples (P=0.016); interestingly, follow up samples exhibited cross neutralizing activity (P=0.095). Heatmap analysis revealed that Du156.12 and Du172.17 (clade-C viruses) were most sensitive while ZMSM.BP12 (clade-C) followed by SC422661.8 (clade-B) isolates were most resistant to antibody neutralization. Epitope mapping revealed relative abundance of V3C reactive antibodies with a positive trend (P=0.043) in follow up samples. No correlation was observed between neutralization activity and Max50 binding titre of anti-V3C plasma antibodies in the baseline (P=0.468) or follow up (P=0.435) samples. None of the plasma showed MPER specific antibodies. CD4s specific antibodies were found in four plasma sample AIIMS_353, AIIMS_513, AIIMS_524 and AIIMS_525 with significantly higher Max50 binding titres (P=0.032) in respective follow up samples.

Conclusions: Improvement in plasma cross neutralizing activity with time, suggests the evolution of broadly neutralizing antibodies in the infected children. CD4s antibodies could be important neutralizing determinants and need to be characterized further.

MOPEA020

Identification of the structural determinants for the selective anti-HIV-1 activity of the all-β alternative conformer of the γ-chemokine XCL1/lymphotactin

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Background: HIV-1 replication is regulated in vivo by a complex network of cytokines and chemokines. XCL1/lymphotactin, a unique metastatic chemokine, was recently identified by our group as a broad-spectrum HIV-1 inhibitor that blocks viral entry via direct interaction with the gp120 envelope glycoprotein. Strikingly, only one of the two conformations that XCL1 can adopt is associated with antiviral activity. Indeed, HIV-1 inhibition by XCL1 requires access to the alternative all-β conformation, which interacts with glycosaminoglycans (GAG) but not with the specific XCL1 receptor, XCR1.

Methods: We investigated the structure-function correlations in XCL1 and specifically compared the determinants responsible for HIV-1 inhibition with those involved in GAG interaction. A panel of mutants of the stabilized all-β variant, XCL1 W55D, bearing individual alanine substitutions at critical residues within the C-terminal tail, was assayed for inhibition of HIV-1 infection. Virion capture assays were performed to assess the impact of alanine substitutions on the ability of XCL1 to directly bind HIV-1 virions.

Results: The results obtained by alanine scanning mutagenesis in both infection and virion-capture assays identified 5 basic residues as key determinants of the antiviral activity of XCL1.
Strikingly, four of these five residues cluster to form a large positively-charged surface in the α-β XCL1 conformation, while they are dissociated in the classic chemokine fold, which is inactive against HIV-1, thereby providing a structural basis for the selective antiviral activity of alternatively.folded, α-β XCL1 conformer of XCL1. Furthermore, we observed that changes to the N-terminal domain, which is proximal to the catalytic pocket of HIV-1 gp120-interacting residues, also affect the antiviral activity of XCL1. Interestingly, the complement of residues involved in HIV-1 blockade is partially overlapping, but distinct from those involved in the GAG-binding function of XCL1.

**Conclusions:** Here, we identify the interactive surface of XCL1 that is implicated in binding to the HIV-1 envelope and HIV-1 inhibition, providing a structural basis to explain why only the α-β XCL1 conformer is effective against HIV-1. Our findings may be useful in guiding the rational design of new inhibitors of HIV-1 entry.

### Mucosal transmission

**MOPEA021**

**Effect of rectal gonorrhea and chlamydia on cytokine expression and HIV viral load in the rectum**

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**Background:** The effect of rectal gonorrhoea (GC) and chlamydia (CT) on HIV viral load in the rectum, and its potential significance on the onward transmission of HIV is unclear. We developed a standardised method for quantifying rectal HIV viral load (VL) and investigated the effect of rectal GC and CT on rectal and plasma HIV VL and cytokine expression in HIV-1 infected MSM.

**Methods:** 42 HIV infected MSM on (n=21) and off ART (n=21) were recruited. Results of those with and without rectal gonorrhoea and chlamydia were compared. Those with rectal GC/CT were re-sampled 2-3 weeks after receiving treatment for the STI. Four rectal swabs were taken via proctoscopy and analysed for HIV VL, STI, and cytokines. Rectal HIV VL was quantified using the Roche Cobas TaqMan 48 analyzer and HIV-1 High Pure Extraction System. Total swab RNA was quantified and HIV VL expressed as copies/μg RNA. Plasma HIV VL was measured using the Roche AmplicPrep/Cobas Taqman system. Quantitative detection of 16 cytokines was carried out using cytokine array. Independent t-tests were used for comparative analysis.

**Results:** Of the 21 MSM on ART, 7 had rectal GC/CT and 14 did not. All plasma and rectal HIV viral loads were < 100 copies. There was no significant difference in rectal VL (p=0.38), IL6 (p=0.41), IFNγ (p=0.42), and TNFα (p=0.26) levels between individuals with and without GC/CT.

Of 21 ART naïve MSM, 7 had rectal GC/CT and 14 did not. There was no significant difference in rectal VL (p=0.50) or major cytokines between those with and without rectal GC/CT. Following treatment of rectal GC/CT there was a non-significant drop in rectal HIV VL (median 0.6, range 0.3-1.4; p=0.52) and no change in plasma VL (p=0.37).

**Conclusions:** A standardized method for quantifying rectal HIV VL has been established. Rectal GC/CT do not impact on rectal or plasma HIV VL in those on ART, and the impact in ART naïve individuals was not significant. This suggests minimal impact of GC/CT on onward transmission of HIV.

**MOPEA022**

**CD161-expression on CD4+ T cells is enriched in the female genital tract and identifies a subset of activated cells rather than Th17 commitment as in blood**


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**Background:** In blood the C-type lectin CD161 identifies a subset of proinflammatory activated cells rather than Th17 commitment of activated cells rather than Th17 commitment in HIV-1 infected individuals and this subset is present in the female genital tract (FGT), a portal of entry for HIV. The pattern of CD161 expression on CD4+ cells remains elusive and its relevance to identifying Th17 commitment and HIV targets cells remain unknown. In this study, we characterized CD161 expression in the FGT.

**Methods:** The study groups included female sex workers (FSW) chronically infected by HIV (n=16), HIV-negative women new to sex work (n=36), HIV-exposed seronegative (HESN) (n=33) and HIV-negative non-FSW (low-risk) (n=50) from Nairobi, Kenya. Blood and cervical cytobrushes were collected from women enrolled in the Pumwani sex worker cohort in Nairobi, Kenya. CD161+ and CD161- subsets were characterized by flow cytometry. Age, menstrual cycle phase, behavioural and clinical factors were collected for all participants.

**Results:** CD161+CD4+ T cells were enriched in the FGT of HIV-negatives and not preferentially depleted in HIV-infected FSW relative to low-risk controls. CD161+ cells harboured a more activated phenotype and expressed higher frequencies of tissue-homing markers and HIV co-receptor CCR5. PMA/ionomycin stimulation confirmed the Th17 commitment of circulating CD161+ CD4+ T cells. Stimulation of cervical cells induced only IFN-gamma in both subsets. IL-7 and IL-22 levels were high at baseline in both subsets of cervical cells and could not be induced. CD161+ cell activation phenotype was altered in FSW compared to non-FSW. FSW had higher frequency of cervical CD69+CCR5+CD161+ CD4+ T cells. The increased frequency of CD161+ HIV targets was counterbalanced in HESN by a reduction of CCR5 on CD161+ cells.

**Conclusions:** In the FGT, CD161 expression did not characterize Th17 committed cells. The unique FGT environment may promote Th17 differentiation independently of CD161 expression. However, CD161 expression in the FGT identified a subset of CD4+ cells that was highly activated and thus potential HIV targets. This subset may represent memory tissue-resident T cells that respond to exposure to sex-work derived antigens including antigens from sex, HIV or other sexually transmitted infections.

**MOPEA023**

**HIV-1 Nef controls cellular invasion through differential modulation of host proteins**

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**Background:** HIV-1 infection involves significant host-virus interaction. At mucosal membranes, HIV-1 gains access to infect activated immune cells and establishes itself. Characterization of target cells and the pathways of viral dissemination is essential to better understand HIV-1 spread. Nef is an accessory viral protein that facilitates alterations in cellular pathways via sequence specific protein-protein interactions and is known to regulate host invasion. We aimed to explore how Nef variants affect Nef mediated invasion of HIV-1 targeted immune cells.

**Methods:** Through proteomics approach, two Nef variants RP14 and RP01 sequenced from HIV-1 patients were investigated for their implications in different HIV-1 targeted cells. 2D-Gel Electrophoresis in SupT1 cells by Nef, demonstrated several differentially expressed proteins identified through LC-MS/MS and further analyzed by qPCR. Western blotting and immunofluorescence studies with Nef variants in SupT1 and THP-1 cells. Enzymatic assays, Cell migration and invasion studies were employed to determine biological function affected by Nef mediated regulation of host proteins. Based upon sequence variation a specific Nef domain was targeted for regulating the invasiveness of target cells. Site-directed mutagenesis and inhibitor confirmed the Nef mediated regulation of host invasion.

**Results:** Nef modulated host proteins were identified as Cyclophilin A, EIF5A-1 Rho GDI-1, VDAC1, OTUB1 and ENO1. Both ENO1 and VDAC1 were downmodulated by RP01 but remained unaffected by RP14. Interestingly, effects of Nef on ENO1 and VDAC1 regulation were found to be cell lineage-specific, being inhibitory in T cells, stimulatory in monocytes. ENO1 and VDAC1 being involved in cellular invasion, invasiveness was found to be enhanced in THP-1 cells but was inhibited in SupT1 cells by RP01. Both the Nef mutant and inhibitor led to reduction of enhanced expression of targeted host proteins and increased invasiveness in THP-1 cells, whereas the effect was reversed in T cells. Although Nef domain regulating spread of HIV-1 infected immune cells was thus determined.

**Conclusions:** The study suggest a possible mechanism of host invasion by HIV-1 through Nef mediated regulation of host proteins. Identification of physiologically relevant host targets involved in cellular invasion leading to viral infection at mucosal barriers would contribute for building effective therapeutic strategies.
Acute and early infection

MOPEA025

Early antiretroviral treatment (ART) fails to achieve sustained HIV viral remission but limits viral diversity

P. Zhang1, P. Palma1, H.K. Ichidji2, G. Liu2, C. Alteri2, A. Bertoli2, C.F. Penc2, P. Rossi2, S. Bernardi2

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Background: As reported by recent evidences and despite the previous excitement generated by the case of the Mississippi baby, early ART alone may not be sufficient for sustained viral remission. Major benefits of early ART include a more limited viral diversity. Few cases supported this data due to the difficulty of performing amplification and sequencing analysis during viral suppression. Here, we reported a case of limited HIV-1 viral evolution in an early treated child for which plasma samples were available at different time points.

Methods: The child was monitored for HIV-1 viral load (VL), CD4 and genotypic resistance test. The HIV-1 genetic evolution was evaluated on pol gene. A neighbor joining (NJ) tree was constructed to define the HIV-1 subtype and the sequence inter-relationships between the mother/child pair. Once the HIV-1 subtype was assigned, the statistical robustness of the monophylogenetic clad was confirmed also by the ML tree.

Results: A perinatally HIV-1 infected infant was treated within 7 weeks of age with zidovudine, lamivudine, nevirapine and tenofovir. At HAART initiation HIV-1 VL and CD4 percentage were >500,000 copies/ml and 35%, respectively. Plasma genotypic resistance test revealed a wild-type virus. The child reached VL undetectability after 33 weeks of HAART and maintained it until 177 weeks of HAART, when a low-level viremia replication was detected (VL < 40 copies/ml, ABBOTT). At this time CD4 percentage was 40%. Again the genotypic resistance test revealed a wild-type virus. The phylogenetic analysis performed on the HIV-1 pol sequences of the mother and the child revealed that sequences clustered with C subtype reference strains and formed a monophyletic cluster distinct from the other C sequences included in the analysis (bootstrap value >90%). A minimal evolutionary divergence between the two plasma sequences of the child was also detected (mean±SE:0.000090±0.000087) and it was sustained by a single nucleotide substitution at position 231 of RT (C to T [77[77]).

Conclusions: Early ART limits the viral evolution avoiding the emergence of new viral variants. This result may have important implications in host immune control and may sustain the challenge of new personalized immunotherapeutic approaches to achieve a prolonged viral remission.

T cell-based vaccines

MOPEA026

Strong functional constraint at residues in HIV-1 Gag are predicted by measures of evolutionary rather than population-level genetic conservation

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Background: Previous genetic studies have identified evolutionary conservation (EvC) in HIV-1 proteins relative to SIV orthologues. We hypothesized that such “high EvC” residues are likely to reflect inherent constraint rather than lack of immune targeting and will demonstrate high replicative cost when mutated. In contrast, residues that are conserved among HIV-1 population isolates but not conserved among phylogenetically-related lentiviruses (“low EvC/high PopC”) may represent sites of early population-level fixation of HLA- or other human-driven mutations in HIV. This latter type of site may not be substantially mutationally constrained; furthermore, population-level adaptation at these sites may render them poorly immunogenic in vivo. We would predict that HIV epitopes spanning “high EvC” sites will have greater immunogenicity than full-length autologous virus or constructs designed to capture population-level genetic conservation but poor infectivity and viral spread; suggesting a viral entry defect.

Results: Mutations at a “high EvC” site in p24 (E106L) were selected based on structure information and modeling methods and engineered into an HIV-1 NL4-3 reference strain backbone. Vesicular pseudotyped HIV-1 stocks were generated in HEK-293 cells and their p24 Gag levels assessed by ELISA. Infectivity and replication capacity of wild-type NL4-3 and mutant viruses were assessed using an established GFP-reporter T-cell assay.

Methods: The “low EvC/high PopC” mutant E106L showed similar viral particle production, infectivity and viral spread to wild-type NL4-3. In contrast, the “high EvC” mutant L188I showed no evidence of viral particle production, infectivity or viral spread, suggesting a viral egress defect. Interestingly, the “high EvC” mutant L188, where the conserved residue was replaced with a structurally similar amino acid, showed viral particle production comparable to that of NL4-3, but poor infectivity and viral spread, suggesting a viral entry defect.

Conclusions: The initial site selected support the hypothesis that EvC can be used as a probe to identify viral genotypic and/or potential host adaptation early in the pandemic. In this case, E106L falls within an area that is poorly covered by known T-cell epitopes and may represent a site of HIV adaptation to HLA at the population-level. These data may be applied in the development of HIV immunogens as well as in rational drug design.

Acute and early infection

MOPEA025

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T cell-based vaccines

MOPEA026

Strong functional constraint at residues in HIV-1 Gag are predicted by measures of evolutionary rather than population-level genetic conservation

M. John1, S. Gaudieri2, A. Chopra3, S. Leary1, J. Jorritsma3, S. Malafi4, B. Baraki5, M. Brockenb5, Z. Brumm1

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Methods: Mutations at a “high EvC” site in p24 (E106L) were selected based on structure information and modeling methods and engineered into an HIV-1 NL4-3 reference strain backbone. Vesicular pseudotyped HIV-1 stocks were generated in HEK-293 cells and their p24 Gag levels assessed by ELISA. Infectivity and replication capacity of wild-type NL4-3 and mutant viruses were assessed using an established GFP-reporter T-cell assay.

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Effect of losartan on lymphoid tissue fibrosis and inflammation in virologically suppressed HIV patients after 48 weeks


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Background: Virologically suppressed HIV patients present a higher level of residual inflammation and chronic immune activation than non-infected population. It has been related to higher rates of lymphoid tissue and end-organ diseases. HIV therapies have been developed to effectively target these inflammatory mediators. Anti-fibrotic and anti-inflammatory properties of the angiotensin receptor antagonist losartan have been described. The objective was to investigate the effect of losartan on lymphoid tissue fibrosis and inflammatory mediators in treated HIV patients.

Methods: 22 chronic HIV-patients, virologically suppressed for at least 48 weeks, in treatment with Tenofovir/Emtricitabine/Efavirenz (245/200/600 mg) were randomized either to continue with the same antiretroviral therapy (cart) (n=12) or to add losartan (n=10) for 48 weeks. Tonsil biopsy was performed at baseline and at week 48. Markers of inflammation and coagulation (hsPCR, Tumor necrosis factor (TNF) alpha, IL-6 and D-dimer), markers of CD4 and CD8 lymphocytes activation (38DR+ and 28-57+), markers of monocyte macrophage activation (CD14+, CD16+), and monocyte activation ( soluble CD163) were analyzed. The difference of these parameters between week 48 and baseline was analyzed between groups.

Results: Median age was 40 years. Median (IQR) time since HIV diagnosis was 8.5 (5.3-14.8) years and the median (IQR) time on CART before enrollment was 5.5 (3.2-13) years. All participants were with viral load < 7 copies at baseline. 11 tonsil biopsies were suitable for analysis (6 in the losartan group). All biopsies except one showed no fibrosis at baseline. At week 48 five patients had an increased proportion of fibrosis compared to baseline with no differences between groups (p=1). There were very minimum changes in hsPCR, TNF alpha, IL-6 and D-dimer between baseline and week 48 with no differences between groups. Similarly, no differences were observed during this time period between both groups in markers of CD4 and CD8 lymphocytes activation [CD4+38DR+ (p=0.19); CD8+38DR+ (p=0.67), serenescence [CD28-57+ (p=0.67); CD28-57+ (p=0.67)], monocyte differentiation CD14++16- (p=0.67); CD14+16+ (p=0.19)] neither in markers of monocyte activation [ soluble CD163 (p=0.39)].

Conclusions: Angiotensin receptor antagonist losartan did not have an impact on lymphoid tissue fibrosis or markers of inflammation, coagulation, T cell activation, senescence, monocyte differentiation and monocyte activation in HIV infected patients on cART.

Adjuvants

Modulation of binding antibody responses to trimeric gp145 and gp41 HIV-1 envelope proteins by utilizing different adjuvants and delivery platforms as a prime-boost strategy

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Background: The potential importance of binding antibodies in preventing HIV-1 acquisition and infection is evidenced by the RV144 phase III HIV-1 vaccine trial. The importance of adjuvants and delivery platforms for the generation of the desired immune response has generally been underestimated in the vaccine field. We examined if immunization with HIV-1 envelope proteins in the absence of any priming vector could induce binding and functional antibodies including V2-specific antibodies by utilizing a prime-boost strategy involving different adjuvants (monophosphoryl lipid A and E. coli heat labile enterotoxin (HL) and delivery platforms (liposomes and transcutaneous) techniques.

Methods: JR-FL HIV-1 gp145 protein trimmerized with foldon and consisting of gp120, gp41 ectodomain, and MPER, and gp41-Soc (ecto and cytoplasmic domains without the transmembrane region fused to small outer capsid protein of bacteriophage T4) were expressed individually in 203 cells and purified. New Zealand White Rabbits were immunized at weeks 0, 4, 8 and 14 with trimeric gp145 or gp41-Soc. The proteins were encapsulated in liposomes containing monocapsid lipoprotein A and injected intramuscularly for all 3 immunizations (M) or the boost at week 4 was a transcutaneous immunization (TC) administered by applying the protein mixed with HL on the surface of the skin (IM/TCIM). Serum samples were analyzed for 18 weeks post-immunization for antibodies by ELISA. Purified IgG from immune sera was assessed for neutralization of primary HIV-1 in a macrophage system before and after depletion of V2 antibodies.

Results: Rabbits immunized IM/TC/IM with trimeric gp145 or with gp41-Soc had significantly higher gp140, gp120, or gp1-specific IgG endpoint titers (4-fold, 3.2-fold, and 4.7-fold, respectively) than IM immunized rabbits. Similarly, V2-specific antibodies were approximately 16-fold higher in the IM/TC/IM group. Purified IgG from IM/TC/IM rabbits were more potent in neutralizing primary HIV-1 in the macrophage system than the IM rabbits. Depletion of V2-specific antibodies resulted in reduced neutralization; however, antibodies to other regions of the envelope protein may have also contributed to the neutralization.

Conclusions: This study highlights the importance of the adjuvants and delivery platforms and provides a novel means for inducing high tier binding and functional antibodies, which should be considered for future HIV-1 vaccines.

Novel vectors and strategies

pVLP: a new DNA vaccine strategy for HIV

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Background: We created a new DNA vaccine strategy for HIV. We developed a DNA vaccine that induces the formation of a VLP in vivo. This VLP has unique features as: the envelope is the sequence of EnvB6505, a good binder of the neutralizing antibodies PG9, PG16 and PGT145; the Gag protein is processed; the genomic RNA of Gag is encapsulated. So, this VLP was designed to elicit neutralizing antibodies, to induce better T-cell response against Gag and to activate the innate immune system through the ligation of the viral RNA to RIG-I receptors.

Methods: 5 groups of 10 mice were electroporated, on week 0 and week 3, with the following constructs: pVLP-LTR-GagPro (the full construction), pVLVPN1 (VLP without RNA), pVLP-LTR-Gag (VLP immature), pVLVPN1 and pVLP-EnvB6505 (as a regular DNA vaccine) and mock. We initially make an in vitro test to check the building of the VLP. We transfected the DNA of pVLP-LTR-GagPro to 293 T cells and treated the sup with biologically neutralized binding antibodies linked to magnetic beads. We performed intracellular staining from the mice spleen, and realized ELISA for Env antibodies and Lumines assay for inflammatory cytokines from the serum.

Results: We separated the VLP with p24 HIV ELISA kit. We showed a good binding of the VLP to the neutralizing antibodies PG9, PG16, PGT145 and VRCo4. The percentage of CD4 cells producing cytokines was 0.1% (IFNG), 0.15% (IL-2) and 0.2% (TNFa) for the construct pVLP-LTR-GagPro much higher than the others constructs. The percentage of CD8 cells producing cytokines was 0.3% (FNG), 0.2% (IL-2) and 0.25% (TNFa), also much higher than the others constructs. All pVLP constructs induced more antibodies to EnvB6505 than the Env as a regular DNA vaccine. The pVLP-LTR-GagPro to the one containing RNA, induces more IL-1B than the others constructs 24 hours post vaccination.

Conclusions: This vaccine induced both cellular and humoral responses. The pVLP-LTR-GagPro induced better T-cell responses. Env as pVLP induced greater antibodies levels than Env as a regular DNA vaccine. The pVLP-LTR-GagPro was able to trigger innate responses, as can be seen by the increased levels of secreted IL-1B.

Deletion of immunomodulatory A44L, A46R and C121 viral genes from Modified Vaccinia Ankara (MVA) genome: effect on its immunogenicity

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Background: MVA still retains genes involved in host immune response evasion. Previously, we reported the optimization of its vaccine potential after removing the C12L gene, coding an IL-18 binding-protein. Here we analyze the immunogenicity of MVA vectors harboring the simultaneous deletion of two viral genes, A44L and A46R, which inhibits transcription signals from Toll-like receptors (MVAΔA44L-A46R,MVA) or including C121 deletion also (MVAΔC121/ΔA44L-A46R,MVA).

Methods: C57Bl/6 mice were electroporated with wild-type (MVA) or deleted MVA (MVAΔC121). We evaluated the adaptive T-cell response to VACV (Vaccinia-Virus) epitopes at acute and memory phases (7 and 45 days post-immunization (dpi)) respectively in spleen.

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Methods: We are targeting CD8 T cell responses to Gag known to be associated with viral control. VLPs generated in Nod3a/benhartiana expose the membrane proximal region of gp41 important for broadly neutralizing antibodies. We tested combinations of virus and VLP producing cell systems in C57BL/6 mice to analyze CD8 T cell responses in addition to monitoring serum, vaginal, and fecal antibodies and an anti-vector response. We further characterize the interaction of VLPs with the innate immune system and cellular activation of human PBMCs and mouse splenocytes.

Results: Initial characterization shows VLPs induce cellular activation of critical cell types, such as DCs, and activation of iot-like receptor pathways. Electron microscopy shows the potential for VLP production in Vaccinia infected cells in vivo to further boost responses. Additionally, mouse experiments reveal that priming with a Vaccinia followed by boosting with both virus and VLPs induces the most robust response. The viral vector largely contributes to the CD8 T cell response while VLPs are critical for high antibody titers. Multiple boosts with vaccinia to induce anti-vector responses in serum. Mucosal IgA responses were low, but significant in fecal samples.

Conclusions: Our plant-produced VLPs appear to contain unique adjuvant-like properties, likely due to the method of production which involves Agrobacterium, thus potentially enhancing the immune response. Vaccinia showed promising T cell responses and we are attempting to increase immunogenicity by using a mouse-adapted strain. We plan to test alternate immunization routes in order to boost mucosal responses.

Therapeutic vaccines

MOPEA033

Monocyte-derived DC electroporated with mRNAs encoding both specific HIV antigens and DC adjuvants are able to improve T cell functionality

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Background: In the context of therapeutic vaccination of HIV-infected patients, we have tested in vitro a combination of mRNA sequences that fulfill two main objectives. On the one hand, a specific T cell activation immunogen mRNA that focuses the response onto the most vulnerable targets in the HIV viral proteome and on the other hand, a previously tested stimulon (TriMix: a mixture of CD70+CD40L+caTLR4 mRNA) for appropriate activation of antigen presenting cells (DCs).

Methods: DCs were generated from peripheral blood monocytes (MDDC) from chronically HIV infected patients by incubation with GM-CSF and IL-4. These cells were electroporated with TriMix (15 µg) and/or HIVACAT (20 µg) mRNA, with their respective controls. After that, DCs were cocultured with autologous PBMCs for up to 6 days. In addition, the maturation profile of MDDCs (CD80, CD83, CD86, CCR7) was analyzed by FACS 24h after electroporation. Functional analysis was performed using different techniques: 25-multiplex Lumex assay, T cell polarization by CFSE and IFN-γ ELISPOT at different time points.

Results: Increased expression of CD80, CD83 and CCR7 was observed on MDDCs upon electroporation with TriMix mRNA. Functionally, mRNA electroporated MDDCs were able to stimulate T cells from HIV-infected individuals on CART in vitro. In fact, MDDCs electroporated with both HIV antigens and TriMix, induced higher T cell activation than their respective component mRNA electroporated MDDCs. To study the innate response, Env was used to increase exposure of neutralizing epitopes. Four weeks after the second mRNA prime, Env protein with atom was injected intramuscularly as a boost. mRNA encoding adjuvants were studied for their ability to increase responsiveness. Flow cytometry, ELISAs, and neutralizing assays were used to evaluate T cell and B cell responses.

Results: Elevated levels of IFNγ, TNFα, IL-12 and CD207 in antigen-specific CD4+ and CD8+ T cells and high gp120 antibody titers could be measured following two rounds of mRNA prime - protein boost vaccination.

Conclusions: Our results demonstrate that antigen-encoding nucleoside-modified mRNA induces effective HIV-specific immune responses and has great potential for vaccination against infectious diseases.

MOPEA032

Immunological characterization of an HIV vaccine comprised of Gag and dgp41 virus-like particles produced both in plants and by live Vaccinia virus vectors

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Background: While antiretroviral therapy has greatly slowed progression to AIDS, the majority of infected people live in poor or impoverished countries without access to treatments making the lack of a preventative vaccine candidate more apparent than ever. The RV144 clinical trial produced the most promising results to date using a non-replicating canarypox viral vector and boosting with proteins, but the modest 31% efficacy left room for improvement. Our project builds upon this system via a novel combination of a replicating but highly attenuated strain of Vaccinia virus and plant-produced HIV virus-like particles (VLPs), making a cost-effective, scalable vaccine production platform.

Methods: We are targeting CD8 T cell responses to Gag known to be associated with viral control. VLPs generated in Nod3a/benhartiana expose the membrane proximal region of gp41 important for broadly neutralizing antibodies. We tested combinations of virus and VLP producing cell systems in C57BL/6 mice to analyze CD8 T cell responses in addition to monitoring serum, vaginal, and fecal antibodies and an anti-vector response. We further characterize the interaction of VLPs with the innate immune system and cellular activation of human PBMCs and mouse splenocytes.

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MOPEA033

Monocyte-derived DC electroporated with mRNAs encoding both specific HIV antigens and DC adjuvants are able to improve T cell functionality

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Background: In the context of therapeutic vaccination of HIV-infected patients, we have tested in vitro a combination of mRNA sequences that fulfill two main objectives. On the one hand, a specific T cell activation immunogen mRNA that focuses the response onto the most vulnerable targets in the HIV viral proteome and on the other hand, a previously tested stimulon (TriMix: a mixture of CD70+CD40L+caTLR4 mRNA) for appropriate activation of antigen presenting cells (DCs).

Methods: DCs were generated from peripheral blood monocytes (MDDC) from chronically HIV infected patients by incubation with GM-CSF and IL-4. These cells were electroporated with TriMix (15 µg) and/or HIVACAT (20 µg) mRNA, with their respective controls. After that, DCs were cocultured with autologous PBMCs for up to 6 days. In addition, the maturation profile of MDDCs (CD80, CD83, CD86, CCR7) was analyzed by FACS 24h after electroporation. Functional analysis was performed using different techniques: 25-multiplex Lumex assay, T cell polarization by CFSE and IFN-γ ELISPOT at different time points.

Results: Increased expression of CD80, CD83 and CCR7 was observed on MDDCs upon electroporation with TriMix mRNA. Functionally, mRNA electroporated MDDCs were able to stimulate T cells from HIV-infected individuals on CART in vitro. In fact, MDDCs electroporated with both HIV antigens and TriMix, induced higher T cell activation than their respective component mRNA electroporated MDDCs. To study the innate response, Env was used to increase exposure of neutralizing epitopes. Four weeks after the second mRNA prime, Env protein with atom was injected intramuscularly as a boost. mRNA encoding adjuvants were studied for their ability to increase responsiveness. Flow cytometry, ELISAs, and neutralizing assays were used to evaluate T cell and B cell responses.

Results: Elevated levels of IFNγ, TNFα, IL-12 and CD207 in antigen-specific CD4+ and CD8+ T cells and high gp120 antibody titers could be measured following two rounds of mRNA prime - protein boost vaccination.

Conclusions: Our results demonstrate that antigen-encoding nucleoside-modified mRNA induces effective HIV-specific immune responses and has great potential for vaccination against infectious diseases.

MOPEA032

Immunological characterization of an HIV vaccine comprised of Gag and dgp41 virus-like particles produced both in plants and by live Vaccinia virus vectors

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Background: While antiretroviral therapy has greatly slowed progression to AIDS, the majority of infected people live in poor or impoverished countries without access to treatments making the lack of a preventative vaccine candidate more apparent than ever. The RV144 clinical trial produced the most promising results to date using a non-replicating canarypox viral vector and boosting with proteins, but the modest 31% efficacy left room for improvement. Our project builds upon this system via a novel combination of a replicating but highly attenuated strain of Vaccinia virus and plant-produced HIV virus-like particles (VLPs), making a cost-effective, scalable vaccine production platform.
MOPEA034

Therapeutic conserved elements (CE) DNA vaccine increases T cell responses against highly conserved viral sequences in the setting of pre-existing immunodominant responses induced by chronic viral infection

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Background: We have previously shown that in SIV-infected rhesus macaques undergoing antiretroviral therapy (ART), therapeutic DNA immunization protected ~50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE50% of animals from viral rebound after discontinuing ART. To improve this approach, we are investigating a novel conserved elements (CE) therapeutic DNA vaccine which consists exclusively of CE sequences. We hypothesize that a CE DNA vaccine will achieve a more profound functional cure by forcing immune escape mutations in regions of the virus that would have the greatest impact on viral fitness. A question that must first be addressed is whether immunization with a vaccine expressing conserved, but generally subdominant epitopes, can induce responses against CE in the setting of an immunodominant response induced by infection. To investigate this question, we compared immunogenicity of a CE DNA vaccine to a DNA vaccine expressing whole SIV Gag in rhesus macaques chronically infected with SHIV, as well as the role of CE specific responses in long term viral control.

Methods: Two groups of rhesus macaques chronically infected with SHIV/89.6P were immunized with either a traditional DNA vaccine expressing whole SIV Gag or an SIV CE DNA vaccine. An IFN-γ ELISPOT assay was employed to map T cell responses induced in the blood and gut against the full SIV proteome and the CE sequences. Intracellular cytokine staining was also used to assess functional quality of T cell responses directed against CE.

Results: Prior to immunization, both groups had similar responses to variable and immunodominant regions of Gag with little to no detectable responses to CE. Animals immunized with whole Gag exhibited no significant increase in responses against CE. In contrast, CE vaccinated animals developed a nearly ten-fold increase in IFNγ and cytolytic T cell responses against CE.

Conclusions: These results illustrate that a CE DNA vaccine was able to overcome immunodominant responses associated with a viral infection and redirect the cellular response toward increased targeting of the subdominant conserved viral sequences when compared to a traditional full length Gag DNA vaccine. These results support the feasibility of developing a therapeutic CE DNA vaccine to induce a functional cure against AIDS.

MOPEA035

Immune response to sequences surrounding the 12 protease cleavage sites generated during ARV treatment improved CD4 counts of SIVmac251 infected rhesus monkeys

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Background: Effective therapeutic vaccines used in combination of ART to treat HIV infected patients can reduce drug induced toxicity, help to re-establish immune system and achieve a functional cure. We conducted a pilot study to test the therapeutic effect of a novel HIV vaccine targeting the 12 protease cleavage sites in combination of ART.

Methods: SIVmac251 infected rhesus monkeys were treated with a combination of FTC, PMPA and raltegravir for 49 days. Seven days after ART initiation the monkeys in the treatment group received ΔSL3 (i.m.). Three additional therapeutic treatment with ΔSL3 (i.m./NANOPoci[n], NANOPsci[n], and NANOpcc[n]) were carried out with 2-week intervals. ART treatment was stopped after 49 days and viral load, CD4/CD8 counts, antibody and T cell response to PCS peptides and pooled Gag and Env peptide were analyzed.

Results: ART treatment suppressed viral load of all macaques, but only the viral load of 6 out of 11 macaques was suppressed to non-detectable level during the treatment/ARV period. However, even with the short duration of ART treatment and incomplete viral load suppression, the immune responses to PCS peptides were generated after 4 therapeutic treatments. The CD4 counts of PCS vaccine treated macaques were significantly improved after 35 days and 49 days of ART treatment(p=0.027 and 0.044), whereas there is no significant improvement in CD4 counts of monkeys only received ART treatment despite the viral load suppression.

Conclusions: Our study showed that new immune response to PCS peptides can be generated even with incomplete viral load suppression after a short period ART treatment. The combination of PCS vaccine treatment and ARV generated new immune response to PCS peptides, improved CD4 counts of SIVmac251 infected monkeys and can be used to improve patient care to achieve a functional cure.

MOPEA036

Safety and immunogenicity of ChAd.HIVconsv and MVA.HIVconsv therapeutic vaccines in a cohort of early treated HIV-1 infected individuals

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Background: T-cell vaccines targeting the most conserved regions of the HIV-1 proteome may be required for the elimination of the latent viral reservoir. HIVconsv vaccines were designed by chimpanzee adenovirus (ChAdV63) and modified vaccinia virus Ankara (MVA) have shown to induce high levels of effectors T cells in healthy individuals (HIVCORE02 trial). BCN01 (NCT01712425) is a phase I study to evaluate the safety and immunogenicity of ChAdV63 and MVA-HIVconsv vaccines in early-treated HIV-1 infected individuals.

Methods: 24 individuals identified with recent HIV infection (< 6m from acquisition) who were given an oncofibre/Embitricibine/Raltegravir within 1 week after diagnosis, received an intra-muscular ChAdV63/HIVconsv (5x10^14vp) vaccination after 6 months under ART. Participants were given an MVA.HIVconsv booster immunization (2x10^9pfu) 24 or 8 weeks afterwards and were followed for 6 months. Local and systemic events were recorded for a minimum of 7 days following each immunization. Immunoactivity to the vaccine insert and the rest of the HIV-1 proteome was assessed by IFNg ELISPOT.

Results: Local and systemic events after vaccination occurred in 22/24 individuals, mostly severity grade 1-2 and transitory (48 hours). Local pain was more often reported with MVA than ChAdV63 vaccination. Responses to conserved regions before cART initiation were only observed in 4 individuals and diminished significantly after achieving viral suppression. All participants significantly increased T-cell responses that targeted the vaccine insert, with a peak 1-4 weeks after MVA-vaccination (median of 0.155SCF/10^6 PBMC, range 140-6,805, p<0.0003, Wilcoxon t-test compared to baseline). Over vaccination period, no unspecific expansion of T cells targeting ChAdV63 regions outside HIVconsv insert or CE was noted, allowing for an optimal focusing of T-cell responses on conserved regions (48% of total HIV immune response being directed against CE specific regions for 4 weeks after MVA vaccination). Among vaccinees, no significant differences in peak immunogenicity was observed between short and long prime/boost regimens.

Conclusions: ChAd.HIVconsv and MVA.HIVconsv was a safe strategy to shift pre-existing immune response towards conserved, vaccine-encoded regions of HIV in a cohort of early-treated individuals and may be of use for successful subsequent of cure strategies.

MOPEA037

Development of a latency reversing activator vaccine (ACT-VEC) platform for HIV-1 cure therapy

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Background: HIV-1 persists within cellular reservoirs as a transcriptionally silent provirus, creating a significant roadblock to cure research. Numerous promising therapeutic and pharmacological interventions are currently being evaluated; however to date none have resulted in reservoir eradication. We have designed an activator vaccine (ACT-VEC), using autologous derived VLPs, which target the resting CD4 T cell reservoir, inducing latency reversal.

We describe the safeguards incorporated into our VLPs as well as preliminary data from our in vitro latency reversal studies.

Methods: Plasmids used in these studies were derived from the laboratory strain NL4-3, env.C0106 and patient derived HIV-1 inserted into the pREC2agag-UC VLP-vector. ACT-VEC were generated with deleted (Δ) SLTR, AAV1HRKX integrase mutation and deletions within the RNA packaging element (ΔSL3). VLPs were then created by HEK293T transfection. Resulting VLPs were assessed by RT-PCR for RNA content and for the presence of viral proteins by western blot. VLPs were co-cultured with autologous patient derived DCs and then used to ac-
C. Katlama1, J.K. Rockstroh1, J.M. Gatell2,3, R. Ho Tsong Fang4, P.M. Girard5, L. Slama6,7, C. Stagmar3, M. Murphey-Corb4

Background: VAC-3S is a novel vaccine directed to the highly conserved gp41, 3S motif of HIV-1. Anti-3S antibodies (Abs) block 3S binding to gp120, prevent CD4 surface expression of NKG44L, the natural ligand of NKG44 expressed on activated Natural Killer cells. Anti-3S Abs have anti-C244 acytotic effects, in vitro. High 3S Abs are associated with low inflammation biomarkers in SHIV-infected macaques. Anti-3S Abs have been shown to be negatively correlated with HIV DNA. We hypothesize that VAC-3S enables re-establishment of CD4CD8 homeostasis hence can comprise the immunological component of an HIV functional cure approach.

Methods: Prospective, randomized, placebo-controlled, double-blind, 3-step study in Europe, assessing immunotherapeutic properties of VAC-3S at 16, 32, 64 mg with 3 IM immunizations at 4 wk intervals and 3 maintenance boosters in the 16, 32 mg arms. Ninety vaccinations. Pts are 62% Caucasian, 30% African heritage. Median age 46 years (23-59); BMI 23 kg/m

Results: In these first two steps, 56 pts (47 male / 9 female), randomized, and completed vaccinations. Pts are 62% Caucasian, 30% African heritage. Median age 46 years (23-59); BMI 23 kg/m (16-33); HIV duration 60 months (1-348); baseline CD4 count 386 cells/mm (205-505); nadir CD4 167 cells/mm (31-410). One serious Adverse Event (AE) prior to vaccination in one viral rebound post-ART non-adherence. One hundred twenty Abs were detected most frequently in the

Conclusions: VAC-3S is a novel mechanism immunotherapeutic HIV vaccine. Phase II preliminary results, confirms phase I safety, as well as, immunogenicity for all new dose levels assessed. Scheduled long term evaluation includes CD4CD8 homeostasis, HIV DNA and biomarkers of chronic inflammation.

**MOPEA039**

**VAC-3S immunotherapeutic HIV vaccine combined with ART is immunogenic and safe.**

Phased II initial analysis of the IMPROTECT1 multicenter European study

C. Katlama1, J.K. Rockstroh1, J.M. Gatell2,3, R. Ho Tsong Fang4, P.M. Girard5, L. Slama6,7, C. Stagmar3, M. Murphey-Corb4

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**MOPEA040**

**Prevalence and clinical impacts of HIV-1 intersubtype recombinants in Uganda**

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Background: Few epidemiological and clinical outcome data exist for HIV-1 intersubtype recombinants in rural African communities. The objective of this study is to estimate prevalence, examine time trends, and test for clinical correlates and outcomes associated with HIV-1 intersubtype recombination in Mbarara, Uganda, where HIV-1 subtypes A1 and D co-circulate.

Methods: Near-full-genome HIV-1 RNA population sequence data was collected using nested PCR targeting gag to nef as five amplicons followed by Sanger sequencing from n=504 treatment-naive individuals enrolled between 2005-2010 in the Mbarara-based UARTO cohort, who then received PI or NNRTI-containing regimens and were monitored until 2013. HIV-1 subtypes were inferred by Leo Alamo RIP 3.0 (window size 400). Statistical significance was defined as p<0.003 after Bonferroni correction.

Results: When each genomic region was individually examined, intersubtype recombinants were detected most frequently in the vif-vpr region (24%), followed by G4F1 (11%), gag

**HIV-1 super-infection/intra/subtype co-infection**

**MOPEA038**

**VAC-3S immunotherapeutic HIV vaccine combined with ART is immunogenic and safe.**

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**MOPEA039**

**Broadly specific, cytolytic T cell responses and lower inflammatory responses correlate with durable viral remission following therapeutic DNA vaccination in SIV-infected macaques**

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Background: We previously reported (DOI: 10.1371/journal.pone.0033715) that an adjuvanted DNA vaccine that stimulated mucosal CD8+ T cell responses in the gut of SIV-infected macaques at 4 wk intervals produced significant delay in viral rebound after stopping ART were compared to macaques that exhibited immediate viral rebound within 6 months after stopping ART.

Results: The 4 macaques with no detectable virus in the blood had detectable viral RNA and/or DNA in at least one lymph node or in gut tissues demonstrating the vaccines substantially reduced residual virus but did not clear the virus. Animals that exhibited delayed viral rebound or no viral rebound had a higher frequency of CD8+ T cells with cytolytic effector function, higher CD4+ T cell proliferation, and broadly specific mucosal SIV-specific CD8+ T cell response targeting more conserved viral sequences in Gag when compared to animals that rebounded within 6 months after stopping ART.

In addition, lymphocytes isolated from macaques that exhibited delayed or no viral rebound post-ART expressed lower levels of the inflammatory cytokines (TNF-c, IL-6) prior to stopping ART when compared to macaques that exhibited immediate viral rebound within 6 months post-ART.

Conclusions: These results show that immunotherapeutics that can broaden virus-specific T cell responses against more conserved viral sequences and at the same time, reduce inflammation during HAART may be an effective approach to achieve durable viral remission.
HIV-1 and HCV concurrently would be a tremendous advantage for dually infected individuals. Here, we report the discovery of a novel class of naturally occurring antiviral peptides against both HIV-1 and HCV infection.

**Methods:** In this study, the antiviral activities of our peptides were tested in physiologically relevant cell-based systems of viral infection against both HCV [JFH-1 strain; human hepatoma cells (Huh7.5.1 cells)] and HIV-1 [NL4-3 strain; human T-cells (GXR cells of CEM origins)]. We identified the critical amino acid residues necessary for the broad-spectrum antiviral activities using alanine scanning and positional scanning. Using circular dichroism spectroscopy and nuclear magnetic resonance spectroscopy, we demonstrated a structure-activities relationship between membrane-induced peptide folding and antiviral activity. Furthermore, by applying peptide bioinformatics to peptide folding assays coupled with high throughput mass spectrometry (MS), we identified the molecular targets of our antiviral peptides.

**Results:** Our peptide-based therapeutics with submicromolar antiviral activity acted extracellularly, reducing challenges associated with intracellular delivery of drug candidates. Pre-treatment of the host cells with our peptide antivirals is not required to block HIV-1 and HCV viral infection. Using MS, we identified host-cell tetraspanin-enriched microdomains (TEMs) - ubiquitous specialized membrane platforms - as the main targets of our antiviral peptides. Taken together, the results of our virological, chemical, and biological studies reveal a novel class of indirect-acting antivirals (IAAs) that specifically interact with the host’s TEMs and interfering with the virus lifecycle.

**Conclusions:** Given the limited number of anti-HIV/HCV drugs in clinical trials, our discovery of a novel class of IAAs against HIV-1 and HCV infection is timely and important. With the increasing number of human viruses hijacking the TEM platforms, our novel class of TEM-directed antivirals represent powerful molecular tools for dissecting the emerging role of TEMs in viral infections and their therapeutic potential.

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**MOPEA044**

**Stability of the NS3 Q80K polymorphism over time within HCV genotype 1a infected patients**

J. Joy, W. Dong, C. Chui, C. Brumme, A. Poon, P.R. Harrigan

**Background:** HCV genotype 1a (GT1a) infections harboring a baseline Q80K polymorphism in the NS3 gene display reduced virologic response to IFN-based HCV treatments containing siteselective integrase inhibitors. In the context of individual infections, the stability of this clinically important polymorphism over time is unknown.

**Methods:** Using plasma samples serially collected over a 10-year period (mean 4.5 years between samples) from 121 HCV treatment naive GT1a infected injection drug users, we sought to investigate gain or loss of the Q80K polymorphism over time. RNA was extracted using the NucliSens easyMag. HCV NS3 was amplified by nested RT-PCR and a 1200- or 564-bp fragment was sequenced by Sanger methods. Sanger chromatograms were interpreted automatically using in-house software (RECall). Each sample was HLA typed to confirm database annotations on source individuals. HCV sequences were multiply aligned using MAFFT v7.154b. Phylogenetic trees were inferred using an approximate maximum likelihood method (FastTree2) and rooted under a molecular clock model using Path-O-Gen.

**Results:** In no case did patients whose first and last samples formed a monophyletic group alter their Q80K status. Nine patients changed genotypes (6 GT3a to GT1a, 2 GT1a to GT3a, and 1 GT1b to GT1a). Furthermore, in 10 patients, GT1a infections did not form a monophyletic group. Both between genotype and within genotype changes in viral lineage between collection dates suggest either (1) clearance followed by reinfection with a new variant or (2) a mixed infection.

In sum, we observed 9 changes in Q80K in 121 patients, but in every case this resulted from patients switching HCV lineages rather than a mutation in their original HCV lineage.

**Conclusions:** These results suggest that, in the absence of therapy, Q80K is highly stable within HCV lineages and does not evolve in response to immune or other host specific effects. Future work will employ deep sequencing to evaluate the importance of mixed infections relating to clearance and reinfection by a different HCV lineage. The observed changes in infection status amongst these patients supports genotypic and resistance testing of patients prior to starting therapy, particularly amongst those at high risk of exposure to new variants of HCV such as intravenous drug users.

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**MOPEA042**

**Discovery of a novel class of naturally occurring indirect-acting antiviral agents against both HIV-1 and hepatitis C virus infection**


**Background:** Due to similar routes of infection for HIV-1 and hepatitis C virus (HCV), it is estimated that up to one-third of people with HIV-1 are co-infected with HCV. Concurrent treatment of HIV-1 and HCV is feasible but may be complicated by pill burden, drug-drug interactions, and toxicities. In this context, access to new broad-spectrum antivirals that can treat both...
**MOPEA044**

**External quality assurance improves both domestic and international laboratory performance for peripheral blood mononuclear cell cryopreservation**

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**Background:** The research quality of HIV-1-infected peripheral blood mononuclear cell (PBMC) specimens collected for storage depends on the processing steps before specimens arrive at a biorepository. Our objective was to evaluate whether an ongoing external quality assurance (EQA) program improved PBMC cryopreservation.

**Methods:** Four PBMC proficiency-testing panels per year were evaluated from the first quarter (Q1) of 2010 to Q2 of 2014. Fresh PBMC were collected from two donors at each participating site, processed and counted, viability determined and aliquots containing 5-million cells each were prepared and stored at -80°C Celsius before shipping on dry-ice to the Immunology Quality Assurance Program (IGA) program for temporary storage in liquid nitrogen. These PBMC were assessed for percent viability and viable recovery. Mixed-effects or linear regression model trajectories were used to determine trends in laboratory performance over the study period.

Among the participating 82-96 domestic (DPL) and 28-36 international processing laboratories (IPLs), a subset of 22-35 AIDS Clinical Trial Group laboratories (ACTG2) contributed additional data for analysis.

**Results:** The overall median (IQR) range PBMC viability and viable recovery for 1,602 PBMC proficiency-testing specimens from DPLs was 98% (97-99; 72-100) and 91% (78-104; 1.5-220); for the 583 PBMC specimens from IPLs, the median was 98% (96-99; 40-100) and 90% (74-105; 1.3-197). The trend in DPL mean PBMC viability increased from 97% to 98% in 2010 to 98% in 2012; the IPL viability response was biphasic and increased rapidly from 94% in 2010 to 98% in 2014.

**Conclusions:** Participation in a PBMC cryopreservation EQA program was associated with significant trends toward improved PBMC viability and viable recovery.

**Novel assays for assessment of ARV resistance/tropism**

**MOPEA045**

**Applying TRIP technology to visualise latent HIV-1 integrations on chromosome landscapes**

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**Background:** HIV-1 latency is currently the main challenge for antiretroviral therapy. As of today, there has been no systematic study of latent HIV integrations for lack of high throughput technologies to discover them. In this study, we used TRIP (Thousands of Reporters Integrated in Parallel) to map HIV-1 provirus integration and measure their individual transcription. Brieﬂy, the principle of TRIP is to tag proviruses with random barcodes in order to quantify their individual expression.

**Methods:** Transgenic barcoded viruses infected Jurkat T cells with M.O.I. 0.5. Infected cells were separated into two populations (high- and low-expression) based on expression of transducing GFP on the HIV-based vector. DNA of each cell population was digested by the restriction enzyme. Fragments containing provirus insertion points were self-ligated and amplified by nested PCR. Paired-end high throughput sequencing allows us to map the insertion point, determine where proviruses integrate. Meanwhile, RT-PCR was applied on mRNA extracted from the same cell population to quantify barcode expression.

**Results:** We divided infected Jurkat T cells in high and low HIV expression and mapped 102 and 159 unique integrations containing detectable provirus expression, respectively, 72.5% (respectively 70.5%) of the integration sites were located inside genes. The majority of the integrations were found in introns and gene-rich chromosomes. We used PHA and vorinostat to reactivate latent HIV infections. Surprisingly, integrations had different tropism towards antiretroviral drugs, meaning that PHA and vorinostat had very different action on the latency landscape of HIV. Interestingly, many integrations were reactivated by none of the drugs.

**Conclusions:** Latency is the main roadblock to the development of a cure for HIV-1. In this study, we illustrate the use of dual maps to visualise HIV-1 provirus integrations and expression. Our results implied that certain new antiretroviral drugs, like vorinostat can not globally reactivate latent HIV. In the future, such dual maps will be applied as novel diagnostic guidelines on validating the spectrum of antiretroviral drugs towards latent proviruses.

**MOPEA046**

**Determination of integrase inhibitor resistance using a novel HIV phenotype assay**

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**Background:** Although the integrase inhibitor dolutegravir (DTG) can overcome prior raltegravir (RAL) and elvitegravir (EVG) resistance, resistance to DTG sometimes emerges, leading to treatment failure. We developed a HIV integrase inhibitor phenotype assay to test patient resistant viruses for resistance with the objective of producing a more predictive resistance report for physicians. Here we report integrase inhibitor phenotype results for viruses from two patients on DTG with previous RAL failure.

**Methods:** Genotypic (Sanger) and phenotypic integrase inhibitor (RAL, EVG and DTG) analyses were done on longitudinal samples prior to RAL treatment, at the time of RAL failure, at initiation of DTG treatment and at DTG failure, if applicable. Recombinant viruses were produced by co-transfection of polymerase chain reaction (PCR) amplicons with linearized pNL4-3 integrase-deleted plasmid into a reporter T-cell line (CEM-GXR) that produces green fluorescent protein (GFP) when infected with HIV. Matching genotypes were generated for PCR amplicons. To phenotype patient viruses, 1 percent of virus-infected (GFP positive) cells were plated with 11-fold dilutions of RAL, EVG or DTG drugs and inhibitory concentration 50 percent (IC50) and fold change (FC) were determined on days 3 to 6. Predicted integrase inhibitor resistance was generated using the Stanford database (HIVdb).

The mean viable recovery steadily converged upon 100% from an absolute distance of 19% to a distance of 15% for domestic laboratories and from 33% to 15% for international laboratories. All lines represent individual laboratories and the linear trends were in direction of improvement, p<0.01; the bold line represents a ‘typical’ lab and is the centroid of the distribution about which the individual laboratory trajectories vary. The improvement in PBMC viable recovery was most pronounced for the international laboratories.

**Figure 1. Trends in PBMC viable recovery**

The trend in viable recovery steadily approached 100% for both groups; all linear trends were in direction of improvement (p<0.01), which likely reflected improved PBMC processing practices. For the ACTG, 127.878 protocol-related HIV-1-infected PBMC specimens were shipped to the BRI specimen biorepository. The median (IQR) processing time remained unchanged at 120 minutes (150-95) but the median freeze time declined from 250 minutes (335-180) to 220 minutes (300-170) and compliance with prompt shipping criteria increased from a mean of 89% (Q1 2010) to 97% (Q2 2014) of laboratories (both comparisons p<0.01).
Animal models of transmission, disease resistance and progression

MOPEA047

**SIVagm from vervet African green monkeys can utilize non-CCR5 entry pathways *in vitro* and *ex vivo***

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**Background:** CCR5 has been described as a coreceptor for SIV. A recent study identified SIV-infected sooty mangabeys that were genetically CCR5-deficient. This finding suggests that the use of non-CCR5 entry pathways in vivo may be a feature of SIV strains found in natural hosts. We sought to further examine the role of CCR5 as an entry coreceptor for SIV derived from another natural host species, the vervet African green monkey. We also examined the ability of AGM-derived alternative coreceptors to serve as potential entry coreceptors for SIvagm.

**Methods:** PHA-stimulated AGM PBMC were infected with SIVagm in the absence or presence of CCR5 antagonist, maraviroc. Viral replication kinetics were determined by measuring reverse transcriptase activity in culture supernatant. In vivo infections with pseudotype reporter viruses were conducted in target cells expressing CD4 and various coreceptors. AGM PBMC were sorted into multiple subsets using a FACSAria cell sorter. cDNA synthesized from ex-vivo viruses were conducted in target cells expressing CD4 and various coreceptors. AGM PBMC were sorted into multiple subsets using a FACSAria cell sorter. cDNA synthesized from ex-vivo viruses were conducted in target cells expressing CD4 and various coreceptors.

**Results:** SiVagm/VRo50 efficiently replicated in AGM PBMC in the absence and presence of maraviroc, which suggests the use of non-CCR5 entry pathways. In vivo infections revealed that reporter viruses carrying various SIvagm envelopes, including transmitted/founder (TF) envelopes, utilized AGM-derived GPR15 and CXCR6, in addition to CCR5, for entry into target cells. AGM PBMC were sorted into various cell subsets to determine if GPR15 and CXCR6 are expressed on CD4 lymphocytes. CCR5, GPR15 and CXCR6 mRNA were detected in the CD4 memory subset, while CXCR6 mRNA was also detected in the CD4 naïve subset. Messenger RNA from all three coreceptors was also detected in the CD8 cell subsets.

**Conclusions:** These results indicate that SIvagm viruses can utilize non-CCR5 entry pathways *ex vivo*, and various SIvagm envelopes, including TF envelopes, utilized GPR15 and CXCR6 for entry into target cells. Detection of GPR15 and CXCR6 mRNA in AGM CD4 lymphocytes supports the notion that these alternative coreceptors may serve as potential SIV entry coreceptors. These data suggest that the use of non-CCR5 entry pathways may be a common feature to SIV derived from natural hosts, and may contribute to the non-pathogenicity seen in these animals.

**MOPEA048**

**Probing and characterizing resistance to integrate inhibitors using simian immunodeficiency virus 239**

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**Background:** We previously showed that SIVmac239 is susceptible to raltegravir (RAL), elvucitabine (EVL) and dolutegravir (DTG) with IC50s in the nanomolar range, and integrase (IN) mutant SIV displayed similar resistance profiles to HIV. A long-acting form of a new IN strand transfer inhibitor (INSTI) termed S/GSK-1265747, a DTG analogue, was shown to protect macaques against repeated vaginal and rectal exposures of SHIV. These data show that nonhuman primates can be utilized to investigate the potential role of INSTIs in HIV therapy, pathogenesis and transmission. Our objectives were to observe whether HIV and SIV share similar resistance pathways under INSTI pressure in selection and cell-free assays and to test the effects of HIV-1 IN resistance mutations on SIV IN activity.

**Methods:** Tissue culture selections were performed in rhesus macaque peripheral blood mononuclear cells infected with SHIVmac239 in the presence of INSTIs. The SHIVmac239 IN gene was cloned into a pET15b vector. Purified recombinant SHIVmac239 WT, E92Q, T97A, G118R, Y143R, Q148R, N155H, R263K, E92Q/T97A, E92Q/Y143R, R263K/H51Y and G140S/G148R in vitro enzymes were generated and strand transfer activities and INHIBITORY CONs were assessed using cell-free assays.

**Results:** Genotypic analysis of the IN coding region of SHIVmac239 in tissue culture selections under EVG pressure revealed the E92Q mutation after 30 weeks, and a mixture including the 263R/K mutation after 22 weeks of DTG pressure. The G118R and G140S/G148R substitutions diminished target DNA affinity (>5.5 and 2-fold) and enzyme efficiency by 80% and 60%, respectively. G140S/G148R negatively impacted strand transfer activity (70% of WT levels). RAL and EVG showed reduced activity against the Q148R, E92Q/Y143R and G140S/G148R variant enzymes. The Q148R and G140S/Q148R enzymes showed moderate resistance to DTG.

**Conclusions:** SIVmac239 viruses treated with DTG led to the emergence of a R263K/R mixture, and the detection of the E92Q mutation in SIVmac239 viruses treated with EVG. This study further confirms that the same mutations associated with drug resistance in HIV display similar profiles in SIV. This study provides support for a DTG monotherapy study that should be conducted in SIV-infected rhesus macaques and for studies aimed at SIV eradication in the macaque model.

**Novel animal/virus models for vaccine, cure research, and inhibitor development**

**MOPEA048**
Impact of co-factors / viral clade / tropism / genetic factors / age on disease progression

**MOPEB148**

Antiretroviral resistance following first-line antiretroviral therapy failure across diverse middle-income settings in the SECOND-LINE study

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**Background:** Antiretroviral therapy (ART) resistance data is predominantly derived from understanding of HIV subtype B. This study describes mutations and correlates after first-line ART virologic failure in participants in the SECOND-LINE study with diverse HIV subtypes. We expect to find the rates, types and predictions of mutations will be similar between B and non-B subtype viruses.

**Methods:** Parent study participants were assessed at baseline for demographics, HIV history, ART exposure, viral load (VL), CD4 count (CD4+) and genotypic ART resistance testing (GART). We used backwards stepwise multivariate regression (MVA) to assess the association of baseline variables with presence of ≥3 nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) mutations, ≥1 non-nucleoside/nucleotide reverse transcriptase inhibitor (NNRTI) mutation, ≥3 thymidine-analogue NRTI (≥3NRTI) mutations (TAMs), the K65K70 mutation, and etravirine/rilpivirine activity (ETR/RPV) at entry to study (first line failure of a NNRTI+2NtRTIs regimen).

**Results:** Of 541 modified intention-to-treat SECOND-LINE participants, 491 (91%) had a successfully characterised baseline viral isolate. Subtype distribution: B (n=123, 25%), C (n=202,41%), AE (n=109,22%), G (n=25,55%) and AG (n=27,5%). In multiple MVA's, higher CD4+ and lower VL at baseline were associated with fewer mutations. Higher VL was significantly associated with ≥3 NRTI mutations (OR=1.39, 95%CI 1.07-1.81; p=0.003) and ≥3 TAMs (OR=1.62, 95%CI 1.15-2.29; p=0.006). CD4+ 200-399 cells/mm3 was significantly associated with <3 NRTI mutations (OR=0.47, 95%CI 0.29-0.77; p=0.003), not having K65K70 mutations (OR=0.43, 95%CI 0.26-0.73; p=0.002) and higher ETR sensitivity (OR=0.52, 95%CI 0.35-0.78; p=0.002). Recent TDF-use was associated with K65K70 mutations (OR=8.91, 95%CI 5.00-15.85; p<0.001) and also showed novel mutation predictors by clade: subtype CRF01_AE was significantly associated with ≥3 NRTI mutations (OR=2.34, 95%CI 1.31-4.17; p=0.004) and higher RPV resistance (OR=2.13, 95%CI 1.03-4.40; p=0.033), subtype C with <3 TAMs (OR=0.52, 95%CI 0.19-0.99; p=0.015). Subtypes CRF01_AE (OR=2.46, 95%CI 1.26-4.78; p=0.008) and G (OR=2.77, 95%CI 1.44-5.76; p=0.01) were both associated with K65K70 mutations.

**Conclusions:** The associations of first-line resistance across HIV subtypes in this study are consistent with knowledge derived from subtype B. With some exceptions. Our results support WHO recommendations of earlier ART initiation and ≥3NRTI use after first-line TDF-containing ART. They also stress the importance of VL testing and its priority over genotypic resistance testing in low/middle-income countries.

**MOPEB149**

Factors associated with incomplete immunologic recovery in HIV-infected patients with clinical and virologic success after 10 years of antiretroviral therapy: a prospective cohort study

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**Background:** HIV infected patients with virologic suppression and absence of recent clinical events after 10 years of antiretroviral therapy might have incomplete immune recovery.

**Methods:** Prospective APROCO-COPOLITE cohort of patients started on protease inhibitor (PI)-containing regimen in 1997-1999. Evaluation of patients with 10 year follow-up and clinic- and virologic-success. Impact of antiretroviral treatment history on the immunologic response measured at 10 years was assessed by multivariate logistic regression models. Outcome variables were CD4 response (CD4 cell counts > 500/µl) and complete immunologic response (CD4 cell counts > 500 µl and CD4:CD8 ratio > 1).

**Results:** Among the 610 patients (median follow-up on antiretroviral therapy: 120.3 months (95%CI 95.1-152.5), 399 had no clinical progression and sustained virologic suppression during the last year. Median baseline values were: age 38.5 years, CD4 254± µl, HIV RNA 4.6 log10 c/ml. Initial PI was boosted indinavir or nelfinavir (77%). Of the 399 patients, 67% had CD4 response and 20% complete immunologic response. In multivariate analyses, factors associated with incomplete CD4 response were older age at baseline (OR 2.62, 95% CI 1.56-4.40), absence of CD4 recovery > 500µl at month (M1) (OR 2.39, 95% CI 1.15-5.12) or M12 (OR 4.57, 95% CI 2.23-9.36), not being antiretroviral-naive at time of PI-containing HAART initiation (OR 1.89, 95% CI 1.12-3.22) and a higher number of treatment sequences (OR 2.16, 95% CI 1.27-3.67). Factors associated with incomplete immunologic response were non-African origin (OR 0.26, 95% CI 0.11-0.70), low CD4:CD8 ratio at M4 (OR 3.97, 95% CI 1.55-9.86) or M12 (OR 1.72, 95% CI 1.03-12.8), and longer duration of antiretroviral treatment interruption (OR 1.75, 95% CI 1.84-32.7), while baseline CD4 and CD4:CD8 ratio were not predictors of 10 year immunologic outcomes.

**Conclusions:** In this population having started antiretroviral therapy with first generation PI, long-term immunologic recovery was rarely complete after 10 years of antiretroviral therapy despite clinical and virological success. Failure to achieve long-term immunologic response was not associated with baseline immunological parameters but with immunologic response during the first year of treatment, as well as with less complex therapeutic history and shorter duration of treatment interruptions.

**MOPEB150**

Rate of CD4 decline and factors associated with rapid CD4 decline in asymptomatic HIV-infected patients

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**Background:** CD4 cell count decline to <200 cells/mm3 prompts HIV-infected patients to have risk of opportunistic infections. Currently, data of CD4 decline and factors associated with rapid CD4 decline among asymptomatic HIV-infected patients in resource-limited settings is still limited and the threshold to initiate antiretroviral therapy (ART) varies among different developing countries.

**Methods:** A retrospective cohort study was carried out in asymptomatic HIV-infected patients who were antiretroviral-naive, having CD4>200 cell/mm3, and following up for at least a year in a medical-school hospital in Bangkok. Time to CD4<200 cells/mm3 was estimated using Kaplan-Meier analysis. Factors associated with rapid CD4 decline were determined using Cox proportional hazard model.

**Results:** Eighty patients were included. Median(SD) age was 36(4.9) years and 58.8% were females. Twenty-one(26.2%) patients had comorbid diseases. Median(SD) baseline CD4 was 423(119) cells/mm3. During a median(QQR) follow-up time of 29.0(14-49.6) months, 21(26.3%) patients had CD4 decline to <200 cells/mm3. From Kaplan-Meier analysis, median time to CD4<200 cell/mm3 was 36.0 months. Probabilities of CD4 decline to <200 cells/mm3 at 1, 2, 3, 4, and 5 years were 8.1%, 14.5%, 20.1%, 29.8% and 38.8% respectively. Estimated time to 25% of patients having CD4 decline to <200 cells/mm3 was 48.4± 14.0 months (log-rank test, p=0.008). From univariate analysis, baseline CD4 <350 cells/mm3 was significantly associated with rapid CD4 decline (hazard ratio(HR) 3.291, 95% confidence interval(CI) 1.268-8.290, p=0.012) and age<30 years.

[NRTI mutation frequency by subtype]

**Conclusions:** The associations of first-line resistance across HIV subtypes in this study are consistent with knowledge derived from subtype B. With some exceptions. Our results support WHO recommendations of earlier ART initiation and ≥3NRTI use after first-line TDF-containing ART. They also stress the importance of VL testing and its priority over genotypic resistance testing in low/middle-income countries.
achieve medical control (MC) with ART. We evaluated rates and reasons for hospitalization among HIC and MC participants in the US Military HIV Natural History Study.

Methods: The HIC group (n=221) was composed of elite (n=33) and viemic (n=188) controllers defined by VL control below the limit of detection or ≤200 copies/mL, respectively, for ≥12 months without ART. HIC were censored upon ART initiation. MC participants (n=870) were defined by VL < 400 copies/mL for ≥12 months on continuous ART. Person-time was accumulated only during periods of VL control. Hospitalizations were tallied annually from 2000-2013 and assigned a diagnostic category. Negative binomial regression with GEE was used to calculate incidence rate ratios (IRRs) for factors associated with hospitalization.

Results: The median age at the start of VL control for the HIC and MC groups was 32.2 and 33.8 years, respectively (p=0.025). Compared with the MC group, a higher proportion of HIC were female (11% vs. 5%; p<0.003) and African American (54% vs. 40%; p<0.001). There were 483 hospitalizations during 5,096 person-years (PY).

Mean hospitalization rates were 9.4110 PY among HIC and 8.8100 PY among MC participants. Non-AIDS-defining infections were the most common reason for hospitalization (31% of admissions in each group).

In multivariable analysis, independent risk factors for hospitalization included age ≥60 years (IRR 2.16 [1.01-4.63], as compared with <30 years) and CD4 ≥200 cells/µL (IRR 2.59 [1.46-4.57], as compared with ≥750 cells/µL). There was no significant difference in hospitalization rate for HIC compared with MC (IRR 1.15 [0.80-1.65]) after adjusting for age, race, sex, CD4, and year, and duration of HIV infection.

Conclusions: Hospitalization rates were similarly low for both HIC and MC participants, with infectious causes being the most common reason for admission. Differences in rates and reasons for hospitalization may have been difficult to detect due to the young age of our cohort and continued long-term follow-up is warranted.

Disease burden: morbidity / mortality / life expectancy

MOPEB153
Advancing in age: what effect on mortality and loss to follow-up in the course of ART? The IeDEA West Africa cohort collaboration

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Background: A growing number of people aged 50 years and older are living with HIV in low- and middle-income countries. With the increase of antiretroviral therapy (ART) use in these countries, HIV-related mortality is decreasing in the WHO African region. Studying the effect of age on mortality and loss to follow-up (LTFU) is essential as older HIV positive patients are at greater risk of all-cause mortality outcomes.

Methods: We analyzed data collected within the International epidemiological Databases to Evaluate AIDS (IeDEA) West Africa collaboration. Eligible patients were ART-naïve HIV-1 infected adults aged 16 years or older who initiated ART, and attended ≥2 clinic visits during their first 24 months of follow-up. Age was divided in 4 age groups: 16-29, 30-39, 40-49, ≥50 years. LTFU was defined as no contact within 6 months before the cohort closure date. Kaplan-Meier curves and multivariable Cox proportional hazard regression analyses were performed to study the effect of age on mortality and LTFU.

Results: Among the 50,459 eligible patients, 65.6% were women, with a median age of 36.3 years (IQR: 30.5-43.2) at ART initiation: 5,325 (10.6%) were aged ≥50 years, and 1,033 (2%) aged ≥60 years. The median follow-up time was 31.1 months [IQR: 11.4-57.4]. At month 24, 5,855 (3.7%) of the patients had died, and 11,178 (22.2%) were LTFU. In multivariable Cox analyses, those aged ≥50 had an increased risk of death (hazard ratio [HR]=1.54; 95% CI: 1.31-1.82, ref. 16-29 age group). Male gender, a WHO clinical stage III or IV, an initial CD4 count <350 cells/µL, an initial hemoglobin <12 g/dL, or a BMI < 18 were also all associated with an increased risk of death (all p < 0.001). Those in the older group were less likely to be LTFU after ART initiation than those in the 16-29 age group (HR=0.86; 95% CI: 0.80-0.93).

Conclusions: Being older at ART initiation was associated with an increased risk of mortality and a lower risk of being LTFU. Tailored programs focused on improving the outcomes of older HIV patients in sub-Saharan Africa are needed.
MOPEB154
Cause of death comparison in a US HIV-infected patient cohort and the National Death Index

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Background: Complete cause of death (COD) information for HIV-infected persons is important epidemiologically but difficult to obtain. Whether National Death Index (NDI) supplements and corroborates COD provided by medical records and research-collected data is unclear.

Methods: Records for HIV Outpatient Study (HOPS) decedents at 8 U.S. HIV clinics who died during 2001-2010 were matched to the NDI database. We assessed primary and contributing COD terms and corroborates COD provided by medical records and research-collected data is unclear.

Results: Of 969 deaths, HOPS and NDI COD data were fully concordant for 62 (11%) and partially concordant for 138 (24%) decedents. HOPS lacked COD data for 279 (49%) decedents and NDI for 77 (14%). p=0.01; no COD was available for 45 (8%) in either database.

Conclusions: Matching with NDI data enhanced COD ascertainment for HIV-infected persons, particularly persons who died >6 months after last HOPS contact. Our findings support use of NDI to improve the quality of COD capture among contemporary HIV-infected persons.
Conclusions: Our findings show that hospitalization rates decrease during time in ICONA patients, and is approaching the rate of the Italian general population. This decrease is striking during the period 2000-2005 and for ARV and non-AIDS infections, which however are responsible for more than 50% of hospitalization even in the more recent time period.

MOPEB156
Reductions in mortality rates among HIV-positive people who inject drugs in Vancouver, Canada, during a treatment-as-prevention-based HAART scale up initiative: a gender-based analysis

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Background: HIV/AIDS remains a major cause of death among people who inject drugs (PWID). However, little is known about the impact of recent efforts to expand access to antiretroviral therapy (ART) on mortality in this population, including how such impacts might vary by gender. We conducted a gender-based analysis to identify rates and predictors of death among HIV-positive PWID in Vancouver, Canada.

Methods: Longitudinal cohort data on HIV-positive PWID were linked to a provincial vital statistics database to ascertain rates and causes of death between May 1996 and May 2013. Age-adjusted Poisson regression was used to examine changes in HIV-related mortality rates before and after the implementation of a Treatment-as-Prevention initiative in 2010. Multivariable Cox proportional hazards regression was used to identify predictors of all-cause mortality. Analyses were stratified by gender.

Results: Among 961 participants, including 353 (36.7%) women, there were 264 deaths during the study period, resulting in a mortality rate among men of 4.64 (95% confidence interval: 3.89 - 5.40) and 4.41 (95% CI: 3.65 - 5.32) deaths per 100 person-years among women. In both genders, HIV-related mortality rates have declined since 2010 (p < 0.01). In multivariable survival analyses, those who initiated ART at a CD4 cell count ≥200 cells/mm³ and had ≥95% adherence to ART in the first year of treatment had a significantly lower hazard ratio of 2.8 (95% CI: 1.4 - 5.7). The 3 patients who had ≥95% adherence to ART in the first year of treatment had a significantly lower hazard ratio of 2.06 (95% CI: 1.35 - 3.14).

Conclusions: Patients with new HIV infection present with multiple comorbidities including renal and CV prior to ART initiation and the trend in these comorbidities has risen since 2003. Understanding these risk factors will help optimize HIV treatment.

Opportunistic infections (excluding TB)

MOPEB157
Comorbidities of patients with newly diagnosed human immunodeficiency virus (HIV) in the USA: a longitudinal analysis of incident HIV patients

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Background: Patients with HIV infection can present with multiple comorbidities prior to starting antiretroviral therapy (ART). Some of these comorbidities are potential risk factors for future diseases such as cardiovascular (CV) and renal impairment. Furthermore, choice of ART may hadden the process of future disease development. The prevalence of these comorbidities has not been well-defined over the course of the HAART era. This study examined comorbidities that may impact risk of developing CV and renal conditions in incident HIV populations and compared the prevalence of these comorbidities between 2003 and 2013.

Methods: Patients newly diagnosed with HIV (ICD-9 diagnosis code: 042.xx, 795.71, V98) were selected from MarketScan Commercial and Medicare Databases (2002-2014) and Medicare database (2002-2013). MarketScan databases are longitudinal and patients’ risk factors and treatment patterns can be observed over multiple years. In this analysis, index date was the first HIV diagnosis date. All patients had 6 months of data prior to index date and were followed until end of data. Patients with baseline evidence of HIV or ART were excluded. Baseline comorbid conditions, including diabetes, hypertension, CV conditions, and renal impairment were examined using ICD-9 diagnosis codes.

Results: A total of 35,997 newly diagnosed HIV patients (mean age: 39.2, male: 74.0%) were selected from the Commercial database, 2,279 (mean age: 73.0, male: 56.5%) from Medicare, and 19,699 (mean age: 36.0, male: 45.1%) from Medicaid. Among all Commercial patients in 2003-2013, mean Charlson comorbidity index (CCI) was 0.2; 5.2% patients had diabetes, 12.0% hypertension, 6.6% dyslipidemia, 1.7% CVD, and 2.4% renal impairment. Medicare patients had a mean CCI of 0.7; 30.4% patients had diabetes, 48.0% hypertension, 24.4% dyslipidemia, 15.9% CVD, and 17.62% renal impairment. Medicaid patients had a mean CCI of 0.2; 8.4% patients had diabetes, 15.9% hypertension, 5.1% dyslipidemia, 2.3% CVD, and 3.2% renal impairment. Patients diagnosed with HIV in 2013 had higher prevalence of comorbidities than those newly diagnosed in 2003 (Table 1).

Table 1

<table>
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<td>38.5(12.9)</td>
<td>72.2(8.5)</td>
<td>72.7(7.2)</td>
<td>34.2(15.3)</td>
<td>39.2(14.1)</td>
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<td>CCI (mean,SD)</td>
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<tr>
<td>Myocardial Infarction</td>
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<tr>
<td>Peripheral Vascular Diseases</td>
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<td>10.7%</td>
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Conclusions: Patients with new HIV infection present with multiple comorbidities including renal and CV prior to ART initiation and the trend in these comorbidities has risen since 2003. Understanding these risk factors will help optimize HIV treatment.

MOPEB158
Clinical presentation and management of parvovirus B19 associated red cell aplasia: experience at the tertiary care institute in Durban, South Africa

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Background: In HIV infected individuals persistent anaemia and immune reconstitution anaemia are manifestations of parvovirus B19 (PB19) disease. Up to 25% of severe chronic anaemia in AIDS has been ascribed to PB19. Diagnosis in HIV/AIDS is made on serum DNA PCR and treatment includes immunoglobulins, HAART and supportive blood transfusion. However, relapse is common.

We describe the presentation, management and response to treatment of HIV related severe PB19 associated anaemia at a resource limited public hospital.

Methods: A retrospective audit of cases managed by our infectious diseases unit. Clinical and laboratory data were anonymously collected using a standard data collection worksheet and entered on IBM Statistical Package for the Social Sciences (SPSS) version 22. Adults with anaemia were eligible if they were PB19 positive on serum PCR and HIV co-infected.

Results: Eleven patients, representing 18 admission episodes were identified from 2011 to 2014. The majority were female (7) with a mean age of 30yrs. The median CD4 count was 100 cells/mm³ and had ≥95% adherence to ART in the first year of treatment had a significantly lower hazard ratio of death compared to those who never accessed ART among both men (adjusted hazard ratio [AHR]: 0.17; 95% CI: 0.09 - 0.33) and women (AHR: 0.35; 95% CI: 0.17 - 0.72). Daily illicit prescription opioid use was independently and positively associated with mortality among men only (AHR: 2.26; 95% CI: 1.35 - 3.14).

Conclusions: Patients with HIV infection present with multiple comorbidities including renal and CV prior to ART initiation and the trend in these comorbidities has risen since 2003. Understanding these risk factors will help optimize HIV treatment.

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Conclusions: PBV19 is an uncommon opportunistic infection but resource intensive. Se- nology is misleading as 40% had positive IgM whilst two had confirmed PBV19 in the presence of IgG.

Current treatment was suboptimal as six patients on HAART and IVIG relapsed.

Tuberculosis and other mycobacteria

MOPEB159

CYP2B6 genotype based efavirenz dose recommendations during rifampicin based anti-tuberculosis co-treatment for a sub-Saharan Africa population

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Background: Pharmacogenetics is a major determinant of the efavirenz-rifampicin inter- action during HIV-TB co-treatment, leading to variations in both efavirenz plasma exposure and dose requirements. The purpose of this study was to assess the effect of genetic factors on Efav pharmacokinetics, and provide genotype based Efav doses recommendations for adult TB-HIV co-infected Ugandans receiving rifampicin based anti-tuberculosis co-treatment.

Methods: Steady state plasma EFV concentrations (n=1216) from 158 HIV-TB co-infected patients (76 females) treated with efavirenz/lamivudine/zidovudine and rifampicin based anti-TB treatment were analyzed. Patient genotypes for CYP2B6∗6/1∗1, CYP3A5∗3/*3 and ABCB1 c.4046A>G, baseline biochemistries and CD4 and viral load change from baseline were determined. A one-compartment population PK model with first-order absorption (NONMEM®) was used to estimate genotype effects on EFV pharmacokinetics. PK simulations were per- formed based upon population genotype frequencies. Predicted AUCs and trough concentra- tions were compared between the product label / known reference values and simulations for the different doses (200mg, 250mg, 300mg, 450mg, 600mg).

Results: EFV post-induction CL/F was 2.5 and 1.7 fold higher in CYP2B6*6/6 and CYP2B6*1/*1 compared to CYP2B6*1/*1, while a 23% increase in F1 was observed for the variant ABCB1:c.4046A>G. EFV mean AUC was significantly higher in CYP2B6*6/6 genotypes com- pared to CYP2B6*1/*1 (p = 0.0001). Simulation based AUCs for a 600 mg EFV dose were 1.25 and 2.10 times greater than the product label mean AUC for the Ugandan population in general and CYP2B6*6/6 genotypes respectively. Simulated exposures for EFV daily doses of 450mg and 250mg for the general population and CYP2B6*6/6 genotypes respectively were compa- rable to the product label. Viral load fell precipitously on treatment with only fourteen (8.9%) patients having HIV RNA > 40 copies/mL after 48 days of treatment. No trend with exposure was noted for these fourteen patients.

Conclusions: During rifampicin co-treatment, daily doses of 450mg and 250mg might meet the EFV dosing needs of HIV-TB infected Ugandans in general and individuals homozy- gous for CYP2B6*6 variant allele, respectively.

MOPEB160

Prevalence of tuberculosis in post-mortem studies of HIV-infected adults and children in resource-limited settings: a systematic review

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Background: Tuberculosis (TB) is a major cause of HIV-related deaths worldwide. How- ever, since TB frequently remains unascertained in HIV-infected people, data from autopsy studies are needed to assess the true burden of TB at death.

Methods: We systematically searched Medline and Embase databases and conference abstracts for literature reporting on autopsy studies of HIV-infected adults and children in low- or middle-income countries. We summarized the prevalence of TB found at autopsy and explored how this varied with age and geographic region, using forest plots, and with national TB prevalence, using linear regression. Statistical heterogeneity was assessed using the I-squared statistic.

Results: A total of 38 studies (reporting on 3,237 autopsies) were included, of which 20 studies were from sub-Saharan Africa. The overall median TB prevalence at autopsy was 27.5% but was extremely heterogeneous (range, 0-64.4%). Prevalence was markedly higher in adults (median, 40.4%; range, 12.5%-64.4%) than in children (median, 3.2%; range, 0-17.8%). Post-mortem TB prevalence varied by world region: the median prevalence in adults was 61.4% (range, 58.3%-64.4%) in South Asia (n=2 studies), 40.6% (range, 33.6%-64.1%) in sub- Saharan Africa (n=9 studies); and 27.2% (range, 12.5%-62.5%) in the Americas (n=5 studies).

![Figure 1: Forest plots showing post-mortem prevalence of tuberculosis (TB) stratified by world region in studies that included adults only (n=17). Data presented represents a total of 1,562 autopsies. CI = confidence interval. ‘Studies that presented % of subjects with TB at autopsy as cause of death only’ Autopt prevalence correlated with national TB prevalence (R²=0.24; P=0.045). The vast ma- jority of TB cases (median, 95%) had disseminated, multi-organ disease. The organs most fre- quently involved were the lungs (median, 79%), spleen (median, 82%), liver (median, 79%) and lymph nodes (median, 59%). A median of 44% (range, 14%-67%) of TB cases remained undiagnosed before death. In studies done in Africa in adults over a 20-year period (1992-2012), there was no reduction in post-mortem TB prevalence over time. TB was the primary cause of death in a median of 95.1% (range, 50-100%) of those with prevalent TB found at autopsy.

Conclusions: TB accounts for approximately 40% of HIV/AIDS-related deaths in adults in resource-limited settings. The vast majority of this TB disease is widely disseminated, but half of the disease burden remains undiagnosed at the time of death. This highlights the critical need to improve the prevention, diagnosis and treatment of HIV-associated TB globally.

MOPEB162

Population-based, active TB case finding during large-scale, mobile HIV testing campaigns in rural Uganda

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Background: Shifting TB screening out of health facilities and into communities may reduce delays in TB diagnosis and undiagnosed disease. Population-based surveys from sub- Saharan Africa have found a large range (29-5000) in the number needed to screen to identify one new case of TB; data from rural settings are lacking. We sought to determine the yield of TB screening during population-based, mobile HIV testing campaigns in rural Uganda.

Methods: We performed 2-week mobile, multi-disease community health campaigns (CHC) in seven communities of 10,000 persons each in eastern Uganda, within an ongoing community cluster randomized trial of universal HIV testing and treatment in Uganda and Kenya (SEARCH, NCT01864603). At each CHC, staff attempted to obtain two spot sputum samples from adults (≥15 years) reporting prolonged cough (>2 weeks). We performed same-day fluo- rescence microscopy (FM) on sputum, and referred participants with acid-fast bacilli (AFB)- positive spuut for TB treatment at local clinics. We determined the number of persons needed to screen to identify one TB case, and the number of cases identified that linked to clinic and initiated TB treatment.
Results: Of 36,691 census-enumerated adults in seven communities, 27,113 (74%) attended CHCs: 5,765 (21%) adults reported cough, and 2,860 (11%) reported cough >2 weeks. Staff obtained sputum in 2,112,880 (74%) participants with prolonged cough, and identified 7 adults with smear-positive sputum: 6 new diagnoses, and one known case already on treatment. The yield of symptom and sputum screening was 7,727.11 (0.02%) among all adults, and 7,280 (0.24%) among adults with prolonged cough. All six newly diagnosed AFB+ participants linked to TB care within 2 weeks; five patients initiated TB treatment. BCH-based HIV testing was >99%, with 878 (3.2%) HIV-infected adults identified; all seven TB cases were HIV-uninfected.

Conclusions: In a rural Ugandan setting, the number of adults needed to screen to detect one new TB case was 477 among adults with cough >2 weeks. TB screening as an adjunct to large-scale, mobile HIV testing campaigns provides an opportunity to increase TB case detection.

MOPEB163
Is prophylaxis against tuberculosis required for HIV-infected individuals in low incidence settings?
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Background: HIV infected patients are at high risk of reactivation of latent TB. Current data suggest combined antiretroviral therapy (cART) can reduce the rate of incident TB. The UK guidelines recommend screening of HIV infected patients for latent TB and offer of prophylaxis to those with positive interferon gamma reactive assays (IGRA).

The recommendation is mainly based on data from settings with high incidence of TB that may not apply to settings with low incidence of the infection. We investigated the effectiveness of TB prophylaxis in a HIV cohort in the UK.

Methods: This was an observational study on a cohort of HIV infected patients followed between 1st April 2011 and the 31st October 2013. Patients’ countries of origin were classified in high and low risk groups. Patients from sub-Saharan African countries, Indian subcontinent, Eastern European countries (Russia, Latvia, and Ukraine) not on cART or on cART for less than two years were considered as high risk. Patients with culture proven TB after HIV diagnosis were classified as having “active TB”. A Kaplan-Meier plot was produced to show the survival time of patients to “active TB”. The estimated “active TB” rates were then used to calculate the Number Needed to Treat (NNT) with TB prophylaxis to prevent one case of TB.

Results: 1,330 HIV infected patients were followed up for a median of 27 (quantiles: 14, 29) months; giving 2,385 patient-years (PY) of follow up. There were 16 cases of active TB in the period; an incidence of 6.7/1000 PY.

There were 301 patients who met the UK guidelines’ criteria for being at risk of latent TB infection. The patients classified as high risk were significantly more likely to develop active TB than those who were low risk (Hazard Ratio=4.46, 95% CI=1.64-12.1; p=0.003). Prophylaxis TB treatment of every high risk patient at HIV diagnosis would prevent one case of TB for every 62 patients treated, within one year.

Conclusions: Patients meeting the criteria set by UK guidelines should be offered to start cART prophylaxis for asymptomatic at-risk patients in cohorts with low incidence of active TB may not be necessary.

MOPEB164
The role of new molecular TB tests in South Africa’s Xpert MTB/RIF algorithm: evaluation of Abbott RealTime MTB assay
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1National Health Laboratory Services, Johannesburg, South Africa, 2University of the Witwatersrand, WITS Reproductive Health and HIV Institute, Johannesburg, South Africa, 3University of the Witwatersrand, Department of Molecular Medicine and Haematology, Johannesburg, South Africa

Presenting author author: anura.david@uhnhs.ac.za

Background: The WHO endorsed Xpert MTB/RIF (Sunvalye, CA) test was implemented in South Africa in 2011. To date, >3 million tests have been performed as the initial diagnostic test for Pulmonary TB and this has dramatically increased the detection of TB. Challenges still remain with the diagnosis of Paucibacillary patients whose bacterial burden is ≤10^3 cfu/mL. Most new molecular tests are therefore needed to improve TB case identification. A potential assay is the Abbott RealTime MTB assay (Des Plaines, IL) which utilizes the high-throughput m200 platform.

Methods: Presumptive TB patients attending the Hillbrow Community Health Centre in Johannesburg were consented and enrolled in the study. Participants were requested to provide 2 sputa at 2 visits (7 days apart) in order to perform Abbott RealTime MTB testing. Xpert MTB/RIF, culture (specifics confirmation by GenoType MTBDRPlus v2 (Mila N钱财, Germany)), and DST, smear and GenoType MTBDRPlus v2 (direct pellet). The Abbott RealTime MTB assay was tested on raw sputa and NALC-NaOH pellets.

Results: Preliminary culture results on 62 (out of 79 enrolled to date) patients yielded 44 (69%) MTB positives. The sensitivity and specificity using culture as the gold-standard were: smear 59% (95% CI: 37-77%) and 97% (95% CI: 84-99.9%), MTBDRPlus v2 (direct pellet) 77% (95% CI: 56-91%) and 39% (95% CI: 56-91%); Abbott RealTime MTB 92% (95% CI: 75- 99%) and 79% (95% CI: 61-91%); Xpert MTB/RIF 92% (95% CI: 75-99%) and 94% (95% CI: 80-99%). On raw sputa, the sensitivity and specificity were: Abbott 92% (95% CI: 75-99%) and 85% (88-85%); GeneXpert 77% (95% CI: 56-91%) and 97% (84-99%).

Conclusions: The Abbott RealTime MTB assay evaluated on this preliminary small sample size has comparable performance with Xpert MTB/RIF on decontaminated sputa for identification of MTBC. This assay identified 4 additional patients’ directly off raw sputa and therefore has the potential to support an existing Xpert MTB/RIF screening program. The reduced specificity and reflex testing for DST needs to be addressed.

MOPEB165
Optimal timing of initiation of antiretroviral therapy in HIV-infected adults with newly diagnosed pulmonary tuberculosis: a systematic review and meta-analysis of randomised controlled trials
O. Ulthman1, C. Okwurudie2, K. Gbenga1, J. Volmink4, D. Dowdy1, A. Zumla1, J. Nachega3
1Warwick Centre for Applied Health Research and Delivery (WCAHRD), Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry, United Kingdom, 2Centre for Evidence-Based Health Care, Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa, 3Julius Centre for Health Sciences and Primary Care, University Medical Centre Utrecht, Utrecht, Netherlands, 4South African Cochrane Centre, South African Medical Research Council and Stellenbosch University Centre for Evidence-Based Health Care, Cape Town, South Africa, 5Johns Hopkins Bloomberg School of Public Health, Epidemiology, Baltimore, United States

Presenting author email: jbn16@pitt.edu

Background: Concomitant tuberculosis (TB) and HIV treatments remains challenging due to non-adherence, drug-drug interactions, overlapping side effects and tuberculosis immune response inflammatory syndrome (TB-IRIS). We aimed to assess the evidence from randomised controlled trials (RCTs) for the optimal timing of initiation of ART in HIV-infected adults with newly diagnosed pulmonary TB.

Methods: We conducted a systematic review with meta-analysis and trial sequential analysis (TSA) including a comprehensive literature search from October 1, 1980 to September 30, 2014, including PUBMED, EMBASE, Cochrane CENTRAL, Conference Abstracts and Clinical trials.gov. Eight RCTs (N = 4,563) met our study eligibility criteria, evaluating early ART initiation (2 to 4 weeks after starting TB treatment), versus delayed ART initiation (8 to 12 weeks after starting TB treatment), or deferred ART initiation (end of 6 months of TB treatment).

Results: Overall, early ART reduced all-cause mortality compared to delayed ART initiation (6 trials: RR = 0.82, 95% CI 0.67 to 1.01, p = 0.16, I² = 17%). TSA showed insufficient evidence to confirm or refute a 25% or greater relative risk reduction for all-cause mortality. In pre-specified subgroup analysis, early ART reduced all-cause mortality compared with delayed ART among patients with baseline CD4+ T-cell count <50 cells/μL (3 trials: RR = 0.66, 95% CI 0.49 to 0.89, p=0.007, I²=0%). However, patients with CD4+ T-cell counts >50 cells/μL, a mortality benefit among those taking early ART could not be demonstrated (3 trials: RR = 0.89, 95% CI 0.54 to 1.46, p=0.64, I²=62%). Early initiation of ART was associated with a higher incidence of TB-IRIS than delayed ART (5 trials: RR = 2.19, 95% CI 1.77 to 2.70, p<0.00001, I²=0%). All-cause mortality, ART adherence, TB cure rate, and grade 3 or 4 adverse events did not differ between patients with ‘early’ or ‘delayed’ ART initiation.

Conclusions: In this TB-HIV co-infected population, early ART initiation improves survival in those with CD4+ T-cell counts <50/mm³, although this is associated with a two-fold higher frequency of TB-IRIS. In patients with higher CD4+ T-cell counts >50/mm³, current evidence is insufficient to support or refute a survival benefit conferred by ‘early’ versus ‘delayed’ ART initiation.
**MOPEB166**

**Prognostic indicators for severely ill HIV-infected patients with suspected tuberculosis**

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2University of Cape Town, Infectious Diseases and HIV Medicine, Cape Town, South Africa
3University of Cape Town, Microbiology, Cape Town, South Africa

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**Background:** The World Health Organization (WHO) recommends an algorithm for the diagnosis of smear negative tuberculosis in HIV-infected patients with cough and danger signs (respiratory rate >30/min; Heart rate >120/min; temperature >39°C; unable to walk unaided). The danger signs were defined by expert opinion and not proven to be associated with poor prognosis. We aim to determine the prognostic significance of danger signs and clinical covariates in this group, using death at 56 days as the primary outcome.

**Methods:** We enrolled 500 HIV-infected patients presenting with cough and danger signs. Using an outcome of death at 56 days after discharge we compared a multivariate regression model containing the WHO danger signs only (WHO-model), to a multivariate regression model containing the WHO danger signs and additional baseline characteristics: age, sex, CD4 count, whether the patient was on antiretroviral therapy (ART), and whether the patient was confined on admission (Augmented-model).

**Results:** Twenty-three patients died during admission and 39 died after discharge (total 62/500, 12%). The median age was 36 years (IQR 30-42). Sixty-five percent of patients were female. The median CD4 count was 941/mm3 (IQR 35-316) and 35% were on ART at the time of admission. Sixty-three percent (315/500) had a respiratory rate >30, 77% (383/500) had a heart rate >120, 51% (243/500) were unable to walk unaided, 16% (81/500) had temp>39°C, and 18% (90/500) were confined on admission.

In the WHO-model, death was associated solely with being unable to walk unaided (adjusted odds ratio [aOR] 3.56 [95% CI 1.92-6.60]). In the Augmented-model, death was associated with age (aOR for 1 year increase 1.4 [95% CI 1.05-1.87]); CD4 count (aOR for 100 cells/mm3 increase 0.66 [95% CI 0.49-0.88]); and being unable to walk unaided (aOR 2.9 [95% CI 1.52-5.52]).

The Augmented-model with AUC (area under ROC curve) of 0.75 (95% CI 0.69-0.81) performed better than the WHO-model (AUC 0.67, 95% CI 0.60-0.74) in predicting death at 56 days (likelihood ratio test p = 0.001).

**Conclusions:** In severely ill HIV-infected tuberculosis suspects, an augmented model including covariates, age and CD4 count, is a better predictor of 56 day mortality than the current WHO model.

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**MOPEB167**

**Performance of latent TB infection diagnostics in HIV-infected pregnant women in western Kenya**

S. LaCourse1, L. Cramer1, D. Matemo1, J. Knuthia1, D. Home2,3, G. John-Stewart1,4

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**Background:** Maternal HIV/TB co-infection is associated with poor maternal and infant outcomes. Pregnancy provides a unique opportunity for TB screening and prevention efforts including isoniazid preventive therapy (IPT). Both HIV and pregnancy may affect latent TB infection (LTI) testing performance of tuberculin skin tests (TST) and interferon gamma release assays (IGRA). There are no published studies addressing the performance of LTBI diagnostics in HIV-infected pregnant women in sub-Saharan Africa.

**Methods:** Cross-sectional LTBI screening were performed on HIV-infected pregnant women in two antenatal clinics in Nyanza Province, western Kenya. Women underwent TST placement and IGRA testing were performed in the KEMRI/CDC lab using QuantiFERON® TB Gold In-tube (QFT). Agreement was measured using kappa statistic. Indeterminate QFT results were excluded from kappa analysis.

**Results:** Between August 2014-January 2015, 100 women were enrolled with median age of 27 years (IQR 22-32), median CD4 of 566 cells/µL (IQR 340-740), and median gestational age of 28 weeks (IQR 20-32). The majority (84%) were on combination ART (aART). Eighty-nine had their TSTs read within 96 hours, of which 14% were positive. Of the 94 available QFT results, 38.1% (33) were positive, 45.9% (46) were negative, and 16.0% (15) were indeterminate. Among the 83 women with both available TST and QFT results, 10.8% (9) were concordant positive (QFT=TST+), 44.3% (37) were concordant negative (QFT=TST-). Twelve (14.5%) women had indeterminate QFT results (11 TST-, 1 TST+). A higher proportion of women had a positive QFT compared to TST (32/83 [38.5%] vs. 12/83 [14.5%], p = 0.004). Excluding indeterminate QFT results, agreement between IGRA and TST was 64.8% (κ = 0.24, 95% CI 0.06-0.43). Discordant QFT-TST- results were associated with reported household TB contact (OR 4.5, 95% CI 1.1-17.4, p = 0.03), and older median age (32 vs. 25 years, p<0.001).

**Conclusions:** The performance of LTBI testing between QFT and TST differed significantly among HIV-infected pregnant women in western Kenya, with more QFT positive women compared to TST. A reliance on TST would miss >60% of women who could potentially benefit from IPT. Further research is required regarding impact of pregnancy stage and HIV status on LTBI diagnostics and cost-effectiveness of different LTBI screening strategies.

**MOPEB168**

**Augment of CD4+ T cells count and decrease of cellular activation are observed in HIV-co-infected patients with first episode of visceral leishmaniasis but not in those with previous VL relapses**

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**Background:** High incidence of visceral leishmaniasis (VL) occurs in HIV-1 co-infected patients. Both diseases cause lymphocytes depletion and augmented cellular activation, enabling the maintenance of Leishmania infection in a continuous vicious circle, causing frequent relapses. Previously, we pointed leishmaniasis as a cofactor to the heightened activation status in VL/HIV-1 patients despite anti-Leishmania and antiretroviral (ART) therapies. Thus, we now evaluated whether VL/HIV-1 presenting the first VL episode have quantitative and qualitative differences on T-cell effector response in comparison to those that suffered previous relapses.

**Methods:** VL/HIV-1 patients under ART and treated with amphotericin B were grouped: 1st-first episode of VL (n=6) and 2-previous episodes of VL (n=7). Both groups were followed from

**Other bacterial infections and parasitic infections (including malaria)**
the active phase of VL up to 12 months post-treatment (mpt) and maintained amphotericin B as secondary prophylaxis. VL only (n=6), HIV-1 only (n=17) and healthy subjects (n=12) were included as controls. CD4+ T-cell counts, cellular activation degree (CD38)/HLA-DR+ or senescence (CD57)/HLA-DR+, effector memory (CD45RO)/CD27+ and plasmatic sCD14 were performed.

Results: During active VL, both groups presented similar levels in all the parameters evaluated. However, at 12 mpt group 2 remained with lower CD4+ T cells, while group 1 showed a significant increase of these cells (p<0.05). At this time, group 2 patients presented higher median levels of CD38+HLA-DR+ on CD4+ and CD8+ T cells (p<0.05) and elevated levels of sCD14, suggesting a persistent degree of immune activation. During this evaluation relapses were more frequent in group 2 than in group 1. The viral load remained low or undetectable without correlation with CD38+HLA-DR+ levels. Both VLVH groups showed similar percentages of senescent and effector memory (T EM) CD4+ T and CD8+ T cells, that were higher in relation to the controls (p<0.05).

Conclusions: Secondary prophylaxis may help modify the natural history of VL in co-infection for individuals that are experiencing the first episode. The worse capability of group 2 to downmodulate the activation levels in comparison with group 1, could be related to any functional impairment of effector response that was shaped at each previous relapses. Ongoing studies regarding the specific immune response may help clarify the different reactivation rate of VL in co-infected patients.

MOPEB169 Causes of hospitalization among people living with HIV/AIDS: a global review

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During active VL, both groups presented similar levels in all the parameters evaluated. However, at 12 mpt group 2 remained with lower CD4+ T cells, while group 1 showed a significant increase of these cells (p<0.05). At this time, group 2 patients presented higher median levels of CD38+HLA-DR+ on CD4+ and CD8+ T cells (p<0.05) and elevated levels of sCD14, suggesting a persistent degree of immune activation. During this evaluation relapses were more frequent in group 2 than in group 1. The viral load remained low or undetectable without correlation with CD38+HLA-DR+ levels. Both VLVH groups showed similar percentages of senescent and effector memory (T EM) CD4+ T and CD8+ T cells, that were higher in relation to the controls (p<0.05).

Conclusions: Secondary prophylaxis may help modify the natural history of VL in co-infection for individuals that are experiencing the first episode. The worse capability of group 2 to downmodulate the activation levels in comparison with group 1, could be related to any functional impairment of effector response that was shaped at each previous relapses. Ongoing studies regarding the specific immune response may help clarify the different reactivation rate of VL in co-infected patients.

MOPEB170 Incidence of malaria by cotrimoxazole use in HIV-infected Ugandan patients on antiretroviral therapy: a randomized placebo controlled study

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Conclusions: At global level, infectious diseases, including TB and other bacterial infections, remain a leading cause of hospitalization among adults and children living with HIV. In high and middle-income settings, cardiovascular and liver disease accounts for an important proportion of cases.

Syphilis

MOPEB171 Repeat syphilis among HIV-infected patients: a nationwide population-based cohort study in Taiwan

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Background: Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention. Identifying risk factors for and delineating the trends in repeat syphilis are essential for STD prevention.

Methods: A population-based cohort design was used, in which the Taiwan National Health Insurance Research Database from 2000 to 2010 was applied to identify 13,239 patients with HIV infection and 4,907 (36.1%) with regular syphilis screen tests. The syphilitic cases were defined by the International Classification of Disease, Ninth Revision, Clinical Modification, in combination with the prescription of antimicrobial therapy for syphilis. The Poisson regression test was used to identify risk factors for repeat syphilis.
MOPEB173
What men don’t know can hurt them.
Prospective survey on syphilis knowledge and behaviours in the ANRS CO3 Aquitaine cohort of HIV-infected men, 2014
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Background: The incidence of syphilis among HIV-infected men who have sex with men (MSM) has risen substantially in the last 15 years in France, including in the Aquitaine (South-western) region. We investigated sexual behaviour and knowledge about syphilis in persons living with HIV (PLHIV) in care in the ANRS CO3 Aquitaine Cohort to better understand this trend and inform future interventions.
Methods: An anonymous self-administered questionnaire was proposed to all male PL-HIV attending seven Aquitaine Cohort clinics between September 22nd and October 24th, 2014. Knowledge, attitudes and behaviours towards syphilis were explored.
Results: Among 302 patients surveyed, all were under ART 34% of respondents (n=288) reported having syphilis at least once and were more often aware that a “skin rash” (RR=1.67 [1.23-2.27]) and “store on skin” (RR=1.83 [1.35-2.47]) were syphilis symptoms than those who never had syphilis. Sixty-nine patients (23.5%) reported using recreational drugs for intercourse and had more often a history of syphilis (RR=1.62 [1.19-2.22]) than non-users. Less than half (43.5%, n=292) were aware that syphilis increases HIV transmission, 20.7% (n=300) thought that syphilis could not be contracted more than once and 31.1% (n=299) were unaware that syphilis could be transmitted by oral sex. About half of all respondents (51.5; n=272) estimated that their risk of getting syphilis was very low or non-existent. A majority (56.4%; n=156) did not know that syphilis was increasing in MSM in South-western France. Among patients reporting having sex with men in the last 12 months (n=160), 73.6% reported rarely or never using condoms for oral intercourse whereas 71.9% reported using often or always condoms for anal intercourse; 58.8% were ready to change their sexual behaviour if they were informed that syphilis was more diagnosed among MSM.
Conclusions: These preliminary findings reveal misinformation about syphilis among PL-HIV in care in Aquitaine and potential receivability to behavioural change if informed.

MOPEB172
The rapid syphilis test: is it useful for syphilis diagnosis among HIV-vulnerable groups? The Argentinean experience
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Background: In Argentina, syphilis, caused by infection with Treponema pallidum, has been reported in high prevalence in HIV-vulnerable groups. A new syphilis-rapid test (syphilis-RT) was implemented in our country for the initial diagnosis of syphilis. Two studies have shown that the rapid syphilis test is as useful as the syphilis treponemal test (TP) for syphilis diagnosis in patients under ART. We evaluated the diagnostic value of this test in HIV-vulnerable groups.
Methods: A cross-sectional study and HIV prevalence study was conducted at different settings (non-governmental organizations, hospitals and field visits) (September 2013-May 2014). Men who have sex with men (MSM), female transgenders/travesties, drug users (DU) and female sex workers (FSW) were included. Syphilis diagnosis was done using: Ailer Determine Syphilis TP, VDRL, TPPA and FTA. HIV diagnosis was also done (Ailer Determine HIV-1/2, Genscreen Ultra HIV AgAb, IDEIA Versant HIV RNA).
Results: 1517 individuals were tested. Comparison of syphilis-RT with standard laboratory diagnosis showed that 53 samples non-reactive for syphilis-RT were positive for syphilis according to other laboratory tests. Among these, 16 had reactive TPPA, 5 had reactive VDRL/FTA and 31 had both. Seventeen samples that were reactive for syphilis-RT were confirmed as negative by standard laboratory. Sensitivity and specificity for syphilis RT was 81.3% and 98.8% respectively (PPV 93.1%, NPV 96.4%). Prevalence of syphilis was 17.7% (179/1014, 95% CI 15.2-20.0) for MSM, 47.3% (78/165, 95% CI 39.3-55.2) for transgender/travesties, 7.7% (20/259, 95% CI 4.3-11.2) for DU and 14.1% (117/830, 95% CI 7.2-22.5) for FSW. Co-infection with HIV was detected among 17,0% transgender/travesties, 4.2% MSM and 0.8% DU. In few patients clinical data were obtained: 78.2% (43/55) with reactive RT and 90% (10/11) with no reactive RT (but reactive by laboratory assays) presented clinical manifestations that justified penicillin treatment.
Conclusions: Early detection and treatment of syphilis is critical in preventing severe long-term complications, co-infection with agents like HIV and transmission to sexual partners. Syphilis-RT implementation could aid early diagnosis. Since treponemal RT cannot distinguish between active and past infection, treatment of all RT-positive individuals will result in over-treatment. However, with the high prevalence of infection in vulnerable groups and the serious consequences of missed treatment, the benefits of syphilis-RT implementation should be considered in some settings.

Abstract Book I www.ias2015.org

MOPEB174
Vaginal cytomegalovirus shedding before and after initiation of antiretroviral therapy in Rakai, Uganda
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Background: Asymptomatic genital cytomegalovirus (CMV) replication in HIV-infected men is associated with increased systemic inflammation, HIV disease progression, end-organ disease and transmission of both viruses. Fewer data are available about the frequency of CMV shedding in the genital tract of HIV-infected women, or about factors affecting vaginal CMV shedding.
Methods: Vaginal shedding of CMV was measured among 96 women co-infected with HIV, herpes simplex type-2 (HSV-2) and CMV who began anti-retroviral therapy (ART) during a placebo-controlled trial of HSV-2 suppression with acyclovir in Rakai, Uganda. Monthly vaginal
Prophylaxis for HIV-associated infections

MOPEB175
Safety and immunogenicity of yellow fever vaccine in HIV+ patients: ANRS EP46 NOVAA

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Background: Yellow fever vaccine (YFV) uses a live attenuated viral strain and is contra-indicated in HIV-infected patients with <200 CD4 cells/mm3. Whether YFV is safe and efficacious in patients with higher CD4 count remains to be clarified. We performed a prospective, comparative, non-randomized study to assess safety and immunogenicity of YFV in uninfected (HIV−) and HIV-infected (HIV+) adults with CD4 count >350/mm3.

Methods: 40 YFV-naïve HIV+ adults under antiretroviral therapy (ART) with CD4 >350/mm3 and plasma HIV RNA < 50 c/ml for at least 6 months, and 31 HIV− healthy adults received primary vaccination with YFV 17D strain. Follow-up was performed at day 7, 14, 28, 91, 365. Safety was assessed by grading clinical and biological adverse events (AEs), detection of YFV viremia using RTPCR, CD4 count and plasma HIV RNA levels. Serologic response was assessed by neutralizing antibody titers using a reference plaque reduction neutralization test (PRINT) and a new pseudotype based neutralization assay, with protection associated titers >10 (PRRT) and a new pseudotype based neutralization assay, with protection associated titers >10.

Results: Shedding of CMV was detected in at least one monthly visit among 75 of the 96 women (78.0%) and 379 of the 1080 individual visits (35.1%). In univariate analysis, ART status (PRRT: 1.34 [95% confidence interval (CI): 1.13-1.59], p=0.001), younger age (PRRT: 0.05 [95%CI: 0.01-0.18], p< 0.001), higher baseline plasma HIV RNA viral load (PRRT: 2.06 [95%CI: 1.19-3.38], p=0.028), and presence of vaginal HSV-2 DNA the month preceding CMV shedding (PRRT: 1.20 [95%CI: 1.00-1.44], p=0.05), were associated with detectable CMV DNA in vaginal swabs. CD4 count prior to ART initiation, study arm (acyclovir versus placebo), and HIV-2 shedding during the same month were not associated with increased CMV shedding. In a multivariate analysis, ART status (PRRT: 1.34 [95%CI: 1.13-1.59], p=0.001), higher HIV viral load (PRRT: 1.84 [95%CI: 1.09-3.11], p=0.02) and younger age (PRRT: 0.05 [95%CI: 0.01-0.18], p< 0.001), remained significantly associated with higher frequency of CMV shedding. HSV-2 shedding the month prior was not significantly associated with CMV shedding after adjustment. Compared to pre-ART levels, CMV shedding peaked from month two to four after ART initiation (p< 0.001).

Conclusions: CMV DNA shedding significantly increased after ART initiation and may be associated with subclinical immune reconstitution inflammatory syndrome (IRIS). Further studies are needed to determine the clinical significance and long-term effects of asymptomatic CMV reactivation in ART-treated HIV-infected individuals.

Immune reconstitution disorders / immune reconstitution inflammatory syndrome (IRIS)

MOPEB176
High CRP and low hemoglobin predict IRIS in a prospective multicenter international study

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Background: Initiation of ART in severely lymphopenic HIV+ patients may be complicated by a dysregulated inflammatory response to a pre-existing (paradoxical) or subclinical (umnaking) infection known as immune reconstitution inflammatory syndrome (IRIS). The pathogenesis of IRIS is unclear and there are no available clinical prediction criteria.

Methods: IRIS was a prospective, multi-center, international study conducted in the US, Thailand (THAI) and Kenya (KEN) which enrolled HIV-infected individuals naïve to HIV therapy with CD4+100 cells/µl, between 2006 and 2014 (NCT00288677). The primary endpoints were incidence and predictors of IRIS in the 24 weeks following ART initiation. IRIS events were adjudicated by an independent end point committee using the ACG criteria. Wilcoxon rank-sum, Fisher’s Exact tests, and logistic regression were used for analysis.

Results: 506 individuals were enrolled; 206 in US, 100 in THAI and 200 in KEN with characteristics as shown in the table. There were 109 IRIS events, occurring in 97 (19.2%) individuals (23.8% US, 16.5% KEN, 15.0% THAI) at a median of 27 (QGR 14-54) days after ART initiation. Of these, 31.2% were TB IRIS, 16.5%, MAC IRIS, 33.0% viral IRIS, and 16.5% fungal IRIS. 47 participants (9.3% total, 9% US, 14.5% KEN, 10% THAI) died: 14.4% with IRIS vs 8.1% without IRIS (p=0.077). At baseline, those who would develop IRIS had lower Hgb (10.0 vs 11.2 g/dL, p<0.001), CD4 count (22 vs 33 c/mm3, p<0.025) and CD4 count (357 vs 478 c/mm3, p<0.029) and higher plasma HIV RNA (5.37 vs 5.28 log10 c/ml, p<0.039), D-dimer (1.54 vs 0.99 μg/ml, p<0.001) and CRP levels (9.6 vs 4.11 mg/L, p<0.001). Having TB was also associated with IRIS (41.0% vs 15.2%, p<0.001). Low Hgb (<10 g/dL) combined with CRP levels >5 mg/L remained an independent predictor of IRIS (39% vs 16%, p<0.001) after adjusting for TB, age and site.

Conclusions: IRIS is common, and is frequently associated with TB. Anemia with high CRP levels may help identify at risk patients who may benefit from closer follow up or preventive interventions.
**MOPEB177**

Cryptococcal immune reconstitution inflammatory syndrome in HIV-infected Ugandans is associated with memory T cell phenotype and increased GXM capsul-specific cytokine responses


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**Background:** Immune Reconstitution Inflammatory Syndrome (IRIS) occurs in up to 30% of HIV-infected patients with cryptococcal meningitis (CM), and is proposed to result from exaggerated immune responses upon initiation of antiretroviral therapy (ART). T cell responses in the immunopathogenesis of cryptococcal IRIS (CM-IRIS) are not well understood.

**Methods:** We assessed in vitro cytokine responses to cryptococcal Glucuronoxylomannan (GXM) capsular antigen in circulating T cells from 17 subjects with CM in Kampala, Uganda at CM diagnosis and a time of CM-IRIS (n=11) or CM controls without IRIS (Controls) (n=6). We quantified T cell memory and activation phenotypes and measured intra-cellular interleukin (IL)-2, IL-17 and interferon-γ (IFN-γ) cytokine expression by flow cytometry.

**Results:** At CM diagnosis, central memory CD4+ T cells (CD27-CD45RO) and naive CD8+ T cells (CD30-CD45RO) were the predominant T cell phenotypes among CM-IRIS patients and Controls. GXM-induced CD4+ and CD8+ T cells were more frequent among the CM-IRIS group vs Controls (median 3% vs 2%, respectively; p = 0.028). CD4+ and CD8+ T cell activation (HLA-DR expression) was similar at baseline between CM-IRIS and Controls. At the time of CM-IRIS and the matched time point, CD4+ central memory and CD8+ effector memory (CD27-CD45RO) T cells predominated among both groups. Subjects with CM-IRIS had a lower frequency of CD4+ T cells vs CM Controls (median 6% vs 14%; p = 0.038) and a higher frequency of total CD8+ T cells (median 95% vs 85% p = 0.018). Upon stimulation with GXM, subjects with CM-IRIS more frequently expressed poly-functional IL-2/17-CD4+ T cells vs Controls (0.24% vs 0.02%, p = 0.04). IL-2/17-CD8+ T cell responses were also more robust among CD8+ central and effector memory T cells at CM-IRIS compared with paired patient-matched CM diagnosis cells and with time-matched CM-Control samples.

**Conclusions:** CD4+ T cells from patients who later developed CM-IRIS appeared primed for response at baseline with increased GXM-induced IFN-γ. Indeed, polyfunctional T cells were also induced with GXM stimulation at the time of IRIS. Thus, distinct functional T cell cytokine responses to GXM may both predict and characterize CM-IRIS.

**Therapeutic vaccine trials**

**MOPEB178**

HIV-1 reservoir dynamics after vaccination and antiretroviral therapy interruption are driven by dendritic cell-vaccine induced T cell responses


DC2V/MAN097-0RVA/CS Study Group

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**Background:** We recently reported a peak decrease of viral set-point of 1.2 log10 associated with an increase in HIV-specific T cell responses in HIV-infected individuals receiving autologous myeloid derived dendritic cells (MDDC) pulsed with autologous heat-inactivated whole HIV. Here we assessed if the HIV specific immune responses induced by the vaccine might have cleared some of the reservoir and drove the dynamics of replenishment of viral reservoir during the antiretroviral therapy (cART) interruption.

**Methods:** We measured total and integrated HIV-1 DNA in isolated CD4 T cells in 36 patients on cART randomized to receive 3 immunizations with MDCC pulsed with autologous HIV-1 (n=24) (DC-IRIS) or with non-pulsed MDDCs (n=12) (DC-control) at 6 time-points: before any cART, before STOP1 (a final cART interruption 56 weeks before the first immunization to isolate virus for pulsing MDDCs), before and after vaccinations (VAC1 and VAC2) and at weeks 12 and 48 after second interruption of cART.

**Results:** Vaccinations did not influence HIV-1 DNA levels in vaccinated subjects. After cART interruption post-vaccination (week 12), while total HIV-1 DNA significantly increased in both vaccinated (n=24) and controls (n=12), integrated HIV-1 DNA did not change in vaccines (1.8 to 1.9, p=0.22) and increased in controls (1.8 to 2.1, p=0.05) (p=0.03 for the difference between groups). HIV-1 specific T cell responses at VAC2 time-point were strongly and inversely correlated with total and integrated HIV-1 DNA after vaccination (r = -0.48, p=0.04 and r = -0.79, p<0.001, respectively) and after cART interruption in vaccines (r = -0.82, p=0.0001, respectively), while a direct correlation was observed in DC-controls (r = 0.72, p=0.03 and r = 0.67, p=0.05 total and integrated HIV-1 DNA after vaccination, respectively) and no correlations were found after cART interruption. These associations were mainly observed with HIV-1 specific T cell responses targeting gag p24 and p17 and nef antigens.

**Conclusions:** HIV-1 specific T cell immune responses elicited by therapeutic DC vaccines could drive changes in viral reservoir after vaccination and the replenishment of reservoir after cART interruption in chronic HIV-1 infected patients treated at early stages.

**Nourishment and HIV**

**MOPEB179**

Randomized control trial on the effect of nutritional supplementation and nutritional counseling on HIV-positive adults initiating antiretroviral therapy at Calcutta School of Tropical Medicine, India

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**Background:** Nutrition plays an important role in the treatment of HIV patients on antiretroviral therapy (ART). The basic ART package of Nation AIDS Control Organization of India includes free antiretroviral to all eligible clients and counseling services by trained counselors for psycho-social, adherence, nutrition and prevention counseling. The role of elaborate nutritional counseling and nutritional supplementation on such patients remains unclear. Hence, this study was designed to observe the effect of the above interventions on PLHIV.

**Methods:** Three hundred ART naïve patients were randomly assigned to one of the four arms while starting ART: Arm-1 providing basic ART package as control arm, Arm-2 provided additional nutritional counseling, Arm-3 provided protein supplementation and Arm-4 provided both additional nutritional counseling and protein supplementation. The supplementation comprised of 16 gm of protein/ day and additional nutritional counseling was done by a clinical nutritionist by administration of 6 specifically developed modules for the study period over a 6 months.

The patients were observed for 6 months. BMI, Triceps skin fold (TSF), mid upper arm circumference(MUAC), grip strength(GS), CD4, serum albumin, total protein, hemoglobin and food frequency data was collected at baseline and at the end of six months. SPSS 16.0 was used to do test, ANOVA and LSD.

**Results:** All study parameters of Arm- 2, 3 & 4 were compared with those of the control arm (Arm-1) at 6 months(Table-1)

<table>
<thead>
<tr>
<th>PARAMETERS</th>
<th>COUNSELLING ARM</th>
<th>SUPPLEMENT ARM</th>
<th>SUPPLEMENT &amp; COUNSELLING ARM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical stage</td>
<td>0.02**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Body mass index</td>
<td>0.08**</td>
<td>0.06**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Grip strength</td>
<td>0.00**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Mid arm circumference</td>
<td>0.00**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
<tr>
<td>CD4 count</td>
<td>0.00**</td>
<td>0.04**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Troops skin fold</td>
<td>0.00**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Albumin</td>
<td>0.00**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>0.00**</td>
<td>0.00**</td>
<td>0.00**</td>
</tr>
</tbody>
</table>

[ t test between control arm and intervention arms]
MOPEB180

Efficacy and acceptability of outpatient nutritional rehabilitation among HIV-infected Senegalese children and adolescents under active follow-up in pediatric care: a pilot study within the MAGGSEN ANRS12279 cohort study

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Background: Severe (SAM) and moderate (MAM) acute malnutrition is highly prevalent in HIV-infected children, even when antiretroviral treatment (ART) is initiated. Since 2007, the United Nations recommends ready-to-use therapeutic foods (RUTF) for the outpatient rehabilitation of children <5 years with MAS. However, nutritional interventions take a long time to be assessed in HIV-infected children and adolescents with the aim of their integration in the ‘global care’ of HIV-infected children. The objective was to describe the efficacy and acceptability of outpatient rehabilitation with RUTF (Plumpy Nut® and Plumpy Sup®), in compliance with international recommendations, among HIV-infected children attending 2 hospital facilities in Dakar. Methods: Children aged 6 months to 18 years with MAS, defined as Body Mass Index (BMI) ≤ -3z-scores, were prescribed Plumpy Nut® (200kcal/kg/bd of body weight/day) and those with MAM, BMI < -2z-scores were prescribed Plumpy Sup® (75kcal/kg/day), until they reached their target weight defined as BMI ≥ -1.5z-score. Results: From April to October 2014, 44 (n=22 girls) children were included in the pilot study and 27 had successful outpatient rehabilitation.

Table: Characteristics of HIV-infected children en

<table>
<thead>
<tr>
<th>Children with SAM (n=22)</th>
<th>Children with MAM (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, year</td>
<td>14.3</td>
</tr>
<tr>
<td>In school, n</td>
<td>11</td>
</tr>
<tr>
<td>ART at enrollment, n</td>
<td>14</td>
</tr>
<tr>
<td>Discharged at target weight, n</td>
<td>8</td>
</tr>
<tr>
<td>Median duration to target weight, week</td>
<td>17.5</td>
</tr>
<tr>
<td>Mean weight gain, g/kg/week</td>
<td>9.5</td>
</tr>
<tr>
<td>Exited for ART initiation, n</td>
<td>6</td>
</tr>
<tr>
<td>Discontinued, n</td>
<td>3</td>
</tr>
<tr>
<td>Died, n</td>
<td>1</td>
</tr>
</tbody>
</table>

Among these, organoleptic acceptability of and adherence to RUTF were satisfactory but decreased, notably in children with MAS, as rehabilitation duration increased. Eight children who were eligible to gain weight during the intervention were provisionally excluded and referred to hospital care and ART or second line treatment initiation. The main reasons for intervention discontinuation were school resumption and living too far from the hospital. Overall, stigmatization and family leakage associated with RUTF provision were low in this study. Results: This pilot study provides the first data on outpatient nutritional rehabilitation of HIV-infected children >5 years and adolescents in sub-Saharan Africa. The results are encouraging and address the main issues and challenges of such intervention in this particular and vulnerable population. The next step is scaling-up of the research in Senegal within the SNAC’s study, to start in 2015.

MOPEB181

Risk factors for mortality among malnourished HIV-infected adults eligible for antiretroviral therapy

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Background: While many studies have reported risk factors for early mortality in patients starting ART, to our knowledge none have studied a large cohort of malnourished patients and included the high-risk period, usually 2-3 weeks in Africa, between referral for antiretroviral therapy (ART) and actually starting ART. We used the extensive data collected during the Nutritional Support for Africans Starting Antiretroviral Therapy (NUSTART) trial to assess understanding of this vulnerable population in the pre-ART and early ART period.

Methods: We analysed potential baseline risk factors from a randomised, double blind, controlled phase-III clinical trial in Lusaka, Zambia and Mwanza, Tanzania. Malnourished patients (BMI < -18.5 kg/m²) were recruited at referral to ART into two-stage nutritional rehabilitation programme, randomised to receive a lipid-based nutrient supplement with or without added micronutrients. Demographics, measures of body composition, blood electrolytes and clinical conditions were investigated as potential risk factors for mortality using Cox regression models.

Results: The mortality rate from recruitment until 12 weeks after starting ART was 33.1 deaths/100 person-years (95% CI 75.0 to 92.1) and in the pre-ART period was particularly high at 11.9 (95% CI 94.5 to 130). In adjusted analyses low CD4 count, anaemia, high C-reactive protein and presence of oedema were risk factors for mortality throughout follow-up. Male sex and abnormal serum phosphate level carried a risk in the pre-ART period, while low BMI or mid-arm circumference had a stronger effect after starting ART. Being on TB treatment at recruitment was strongly protective (HR 0.46, 95% CI 0.32 to 0.66). Increased grip strength, a simple marker of functional lean mass, improved the chance of survival independent of BMI (HR 0.95 for every 1kg increase in strength, 95% CI 0.93 to 0.97) and mainly in the pre-ART period.

Conclusions: Mortality among this population of malnourished patients eligible for ART was extremely high, especially in the pre-ART period, pointing again to the need for earlier initiation of treatment. The positive effect of TB treatment suggests under-diagnosis of both TB and bacterial infections in this group. Grip strength measurement could be a useful tool in assessing risk among malnourished HIV patients.

MOPEB182

Malnutrition and pediatric HIV: prevalence and characteristics at inclusion from HIV-infected children enrolled in a nutritional protocol in Bamako, Mali

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Background: Malnutrition is highly prevalent among HIV-infected children in sub-Saharan Africa and nutritional care needs to be improved. The purpose of this study is to assess the prevalence of malnutrition in a pediatric HIV care programme in Mali where a nutritional intervention is ongoing.

Methods: Between July and December 2014, HIV-infected children aged less than 15 years diagnosed with malnutrition during their routine follow-up in the University Hospital of Bamako, Mali, were included in a protocol to receive nutritional supplementation based on Ready-to-Use Therapeutic Food, and followed monthly until that they catch-up their growth. Malnutrition was determined using anthropometric indicators, expressed in Z-scores, according to the WHO child growth standards. Height and weight Z-score (WHZ) for children <5 years, and BMI for age Z-score (BAZ) for children ≥5 years, defined acute malnutrition, whereas Height for age Z-score defined chronic malnutrition. All inclusion, socio-demographic, immunological, viral, biological and treatment data were collected. Comparisons between children according to their nutritional status were made using Chi-square and Kruskal-Wallis tests.

Results: During the study period, 350 HIV-infected children were screened, of whom 200 (57%) were malnourished. Among them, 164 (82%) were enrolled in the nutritional protocol, 36 refused or lived outside of Bamako; 13% of included children were followed for severe acute malnutrition, 45% for moderate acute malnutrition, 26% for moderate chronic malnutrition and 15% for severe chronic malnutrition. Median age was 9 years (IQR: 6-12), 63% were boys, 40% were orphans, 96% were on antiretroviral therapy, with 42% of them on a protease-inhibitor based regimen; 99% were on cotrimoxazole. Twenty percent were severely immunodeficient,
**MOPEB183**

**Plasma proteins binding of atazanavir and ritonavir with boceprevir**

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**Presenting author email:** tungadex@gmail.com

**Backgrounds:** HIV-1 protease inhibitors that are highly-bound to plasma proteins with high affinity to α1-acid glycoproteins (AGP) may be influenced by fluctuations in AGP due to HIV/HCV co-infection which may influence antiviral pharmacokinetics. Rapid equilibrium dialysis (RED) measures the free fraction of drugs using smaller sample volumes, increased sample throughput and is less labor-intensive in comparison to traditional equilibrium dialysis procedures. RED procedures are more reproducible and less likely to be affected by non-specific binding issues compared to ultrafiltration procedures. The objective was to validate an assay to measure the free % ATV in spiked human plasma. The effect of different concentrations of human albumin and AGP associated with different inflammatory and nutritional status and addition of boceprevir (BOC) and ritonavir (RTV) were also evaluated.

**Methods:** A novel approach to assimilate different inflammatory and nutritional status (normal, mild and severe hypoaalbuminemia) was used. RED was performed for 22 hours at 37°C under rotation on samples that were pre-diluted with phosphate buffered saline (PBS). Both the plasma and buffered dialysates were measured for ATV using an ultra-performance liquid chromatography method. The percentage free was calculated as the ratio of the buffer to the plasma dialyseate concentrations. After the RED method was optimized for human plasma, the effects of albumin and AGP concentration were investigated by adding ATV to different concentrations of proteins. Also tested was addition of RTV and BOC with ATV in human plasma of different albumin and AGP concentrations. As part of validation freeze/thaw cycles of plasma samples prior equilibrium dialysis were assessed.

**Results:** This method was accurate and precise within a concentration range of 1000 to 2000 ng/mL for ATV. Free % ATV was related to the change in albumin and AGP concentration as opposed to addition of BOC and RTV.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Mean % Free</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATV</td>
<td>21.6</td>
</tr>
<tr>
<td>ATV/RTV</td>
<td>22.0</td>
</tr>
<tr>
<td>ATV/RTV/BOC</td>
<td>24.4</td>
</tr>
<tr>
<td>Mean</td>
<td>22.7</td>
</tr>
<tr>
<td>STD</td>
<td>1.50</td>
</tr>
<tr>
<td>%CV</td>
<td>6.60</td>
</tr>
</tbody>
</table>

**Conclusions:** The described validated RED method is accurate and precise in measuring ATV protein binding in human plasma. Care in processing and storing plasma samples must be considered due to lack of stability when samples are taken through freeze/thaw cycles. Our methodology facilitates analysis of samples from patients with different disease states and protein status.

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**MOPEB184**

**Serum zinc concentration and C-reactive protein in persons with human immunodeficiency virus infection in the Positive Living with HIV (POLH) study**

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**Background:** Human Immunodeficiency Virus (HIV) infection has been frequently associated with zinc deficiency and chronic inflammation. Zinc deficiency can cause significant impairment in both adaptive and innate immune responses, and promotes systemic inflammation however no studies have investigated the association between serum zinc concentration and inflammation among HIV-positive people. To assess the association between serum zinc and C-reactive protein (CRP) concentration in a cohort of HIV-positive people.

**Methods:** A cross-sectional survey was conducted among 311 HIV-positive people (177 men and 134 women) aged 18-60 years residing in Kathmandu, Nepal. Serum CRP and zinc concentrations were measured by the latex agglutination turbidimetric method and the atomic absorption method, respectively. Relationships were assessed using multiple linear regression analysis.

**Results:** The geometric mean of serum zinc concentration in men and women were 73.83 μg/dL and 71.93 μg/dL, respectively, and of serum CRP concentrations were 1.63 mg/L and 0.96 mg/L, respectively. In multiple regression analysis, we found a significant inverse relationship between log zinc and log CRP concentrations (beta for 1 unit change in log zinc; β = -1.95, p = 0.001). In sex-specific analysis, an inverse association between zinc and CRP concentrations was slightly stronger in women (β = -2.64, p = 0.008) than in men (β = -1.27, p = 0.03).

**Conclusions:** Serum zinc concentration is inversely associated with serum CRP concentrations in HIV-positive people. Further prospective study to confirm the role of zinc in inflammation among HIV-positive people is warranted.

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**Pharmacokinetics and outcomes of ARV in women during and after pregnancy**

**MOPEB185**

**Maternal tenofovir disoproxil fumarate (TDF) use in pregnancy not associated with adverse growth outcomes at 6 weeks and 9 months among Kenyan HIV-exposed uninfected infants**

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**Presenting author email:** jplintye@gmail.com

**Background:** Tenofovir disoproxil fumarate (TDF) is commonly used in antiretroviral treatment (ART) and in pre-exposure prophylaxis (PrEP) regimens. Acruting TDF safety data among infants exposed to TDF in pregnancy is important, especially in sub-Saharan African settings.

**Methods:** Data from a cross-sectional survey of mother-infant pairs conducted July-December 2013 in 140 maternal-child health clinics throughout Kenya were analyzed to evaluate the relationship of maternal TDF use in pregnancy and growth outcomes among infants with PCR-confirmed HIV-negative status. Maternal ART regimen during pregnancy and birth information was determined by self-report and confirmed with clinic records. Anthropometric measurements from infants attending 6-week or 9-month immunization visits were assessed by mobile evaluation teams. Age & sex-adjusted z-scores for weight (WAZ), weight-for-length (WZL), length (LAZ), and head circumference (HCZ) were calculated using WHO Child Growth Standards and analyzed as continuous variables. Comparisons of HIV-exposed uninfected (HEU)
infants with and without TDF exposure were assessed using t-tests and multivariate linear regression models adjusted for maternal and infant demographic and medical characteristics accounting for clinic-level clustering.

Results: Overall, 277 HEU infants had mothers who used three-drug combination ART during pregnancy, of whom 63% initiated ART before pregnancy and 32% (32% of HEU) used TDF-containing regimens. Prenatal TDF use was associated with concurrent use of protease inhibitors (28% vs 7%, p<0.001) and with WHO clinical stage III (14% vs 6%, p=0.030). No differences in birth weight (3.0 kg vs 3.1 kg, p=0.205) or gestational age at birth (38 weeks vs 38 weeks, p=0.160) were detected between TDF-exposed and unexposed infants. Mean WAZ at 6 weeks was lower among TDF-exposed infants in unadjusted comparison (0.8 vs 0.4, p=0.033); the association was less significant in adjusted analyses, (p=0.07). There were no associations between maternal prenatal TDF use and WLZ (p=0.519), LAZ (p=0.989) and HCAZ (p=0.964) among infants in the 6-week postpartum cohort. Among infants attending 6-month visits, no association was detected between maternal prenatal TDF use and WAZ (p=0.439), WLZ (p=0.855), LAZ (p=0.514) and HCAZ (p=0.888) after adjustment.

Conclusions: Our results add to previous data suggesting that maternal TDF use during pregnancy is not associated with adverse infant growth outcomes compared to non-TDF ART use.

MOPEB186
Virolological response among HIV-infected pregnant and lactating women initiated on Option B+ attending the PMTCT program at Mulago National Hospital, Kampala, Uganda
R.A. Ayangaa1, Z. Namukwaya2, E. Namara Lutobogo1, J. Nabwetere Mugwera1, S. Akasiima Afrika1, A. Kakande1, S. Kamya1, J. Byamugisha2, P. Musoke1,3, M. Nolan1
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Background: HIV-1 Viral load (VL) is a direct quantification of HIV replication and a marker of HIV disease progression. VL monitoring is recommended by WHO for clients on ART to detect early treatment failure resulting from poor adherence or drug resistance and allows intervention to reduce morbidity and preserve treatment options. Current WHO policy is ART for life for PMTCT clients with a treatment as prevention approach.

Methods: In Uganda, virological treatment failure is defined as detectable circulating viral load above a set threshold of 1000 copies/ml using plasma. The PMTCT program at Mulago National Referral Hospital has been offering ART according to adult treatment guidelines until October 2012 and ART for life (Option B+) to all HIV-infected pregnant and lactating women since October 2012. The Central Public Health Laboratory (CPhL) established VL testing in Kampala, Uganda and offered routine VL testing on plasma samples to all PMTCT clients from October 2012. Plasma samples were collected and transported to the CPhL and results received in a week. A retrospective analysis of VL data for PMTCT clients who had initiated ART for six months or more was done around 6, 12 and 24 months.

Results: Between 1st Nov, 2014 and 31st Jan, 2015, a total of 1,158 viral load tests were done. Of these, 75 (75.1%) were for clients on ART/Option B+ and 251 (24.9%) on ART/Option B+. Among clients on option B+ 70(9.3%) had been on option B+ for 6 months, 187(24.7%) for 12 months, 500(66.1%) for more than 24 months. 6770(95.7%) women on option B+ had VL<1000 copies/ml at 6 months, 147(18.3%) had VL<1000 copies/ml at 12 months, 497(65.6%) had VL<1000 copies/ml at 24 months.

Conclusions: At Uganda’s national referral hospital, the majority (>93%) of the clients initiated on option B+ and in follow-up had virological suppression between 6 and 24 months after ART initiation. However, intensive adherence counseling and close monitoring is still needed to achieve close to 100% viral suppression for women on option B+. Long term follow-up and effective linkage to ongoing care will be critical for individual and public health effectiveness of the Option B+ strategy.

Other issues related to pregnancy
MOPEB187
Socio-demographic and clinical predictors of preterm birth, low infant birth weight, and pregnancy complications among women living with HIV (WLWH) in Ontario, Canada
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Background: Pregnancies amongst WLWH are increasing as a result of advances in combination antiretroviral therapy and the increasing proportion of WLWH of childbearing age. These women are also at increased risk of adverse obstetric outcomes. This study examined socio-demographic and clinical characteristics as correlates of premature birth (PB), low birth weight (LBW), and pregnancy complications (PC).

Methods: The HIV Mothering Study is an observational mixed methods study exploring psychosocial experiences and needs of mothers living with HIV in Ontario. Data during the 3rd trimester of pregnancy and at 3 months postpartum was obtained through surveys and medical records. The UCLA Loneliness, HIV Stigma, Everyday Discrimination-Racism, and Medical Outcomes Study-Social Support Survey scales were used for psychosocial assessments. We employed the penalized-maximum likelihood logistic regression to eliminate small-sample bias and deep learning techniques to create final multivariate models. For each of the outcomes, covariates with p-values ≤ 0.20 were included, followed by backward elimination of covariates until best-fit models were reached.

Results: Of the seventy-six women in this analysis, eight deliveries were PB, eleven were LBW, and fourteen PCs were encountered (E.g. pre-eclampsia, gestational diabetes, antepartum hemorrhage; feet/hand swelling, prolonged vomiting). Having a CD4 count higher than 200cells/mm3 correlated with a reduced chance of PB (OR=0.01; p=0.002), while history of cardiovascular disease increased the risk (OR=3.25; p=0.014). Interestingly, higher risk for LBW was found to be associated with prepartum depression (OR=24.81; p=0.014), divorce/separation (OR=32.50; p=0.024), and reduced social support (OR=9.22; p=0.018). The strongest correlates of both delivery outcomes, PB and LBW, was having CD4 count lower than 200cells/mm3 (OR=10.57; p=0.049) and depression (OR=0.21; p=0.016). As for maternal PCs, the significant correlates were low CD4 count (OR=0.004; p=0.004), use of protease inhibitors (OR=0.13; p=0.025), and experience of racism (OR=1.18; p=0.036).

Conclusions: Low CD4 count, history of cardiovascular disease, depression, marital status, use of protease inhibitors, social support, and racism can elevate the risk of adverse obstetric outcomes and pregnancy complications for pregnant WLWH. Specific strategies addressing these clinical and socio-demographic risk factors should be adopted prior to delivery in order to improve health trajectories for both mother and child.
MOPEB188

From option A to B+: exploring challenges of navigating evolving PMTCT strategies among postpartum women living with HIV in rural Uganda

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Backgrounds: In late 2012, Uganda adopted the WHO Option B+ strategy for preventing mother to child transmission (PMTCT) of HIV whereby pregnant HIV-positive women initiate antiretroviral therapy (ART) for life. National guidelines recommend breastfeeding for up to 6 months with maternal ART and Nevirapine prophylaxis for infants. How women understand and navigate evolving PMTCT guidelines remains unclear.

Methods: We conducted 31 in-depth interviews with HIV-positive women with pregnancy in the past 2 years, sampled from an on-going HIV cohort study in Mbarara, Uganda (February-August 2014). Interview guide explored women’s conception, pregnancy, and postpartum experiences with a specific emphasis on how their HIV status affected their experiences. Content analysis of transcribed and translated interviews was conducted using NVIVO software.

Results: Twenty-three women were interviewed: median age 33 (IQR: 28, 39), 67 CD4 count, 66.7% of women were virally suppressed (<400 copies/mL). Most women had more than one pregnancy since being diagnosed with HIV. An emergent theme was that women struggled to understand and adhere to evolving PMTCT practices. Personal and community experiences of having infected or uninfected children while following certain recommendations was sometimes more compelling than advice from healthcare professionals. For example, women who had, or knew of, a child infected during breastfeeding were afraid to breastfeed, even while on ART. Many women described negative provider experiences such as being scolded for being HIV-infected and pregnant, prizing them to distract novel information delivered by providers. Women reported increasing pressure from providers to comply with Option B+ requirements, such as increased frequency of infant testing. Difficulties complying with additional maternal and child clinic visits that are part of Option B+ was described, due to structural barriers including transportation costs, absent partner support, and the stigma of accessing PMTCT services.

Conclusions: HIV-positive women express confusion and concern about changing recommendations to reduce perinatal transmission. Effectively communicating the rationale for evolving strategies, reducing structural barriers to care, and working with providers to reduce stigma for women accessing PMTCT care is critical to maximizing uptake of recommendations, reducing perinatal transmission of HIV, and maximizing maternal-child health.

MOPEB189

Integration of TB screening in Kenyan PMTCT programs

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Background: Integration of tuberculosis (TB) screening into prevention of mother-to-child transmission (PMTCT) programs provides an opportunity for improved TB detection and provision of isoniazid preventive therapy (IPT). We assessed the prevalence and correlates of maternal TB symptoms and TB exposure in a national survey of the Kenyan PMTCT program.

Methods: A cross-sectional survey of mother-infant pairs attending 6-week and 9-month immunization visits at 140 maternal and child health (MCH) clinics in Kenya was conducted between July and December 2013. Maternal sociodemographic information, clinical history of TB, TB exposure, World Health Organization (WHO) TB symptom screen (any fever, cough, right neck swells or weight loss) and infant clinical data were collected by questionnaires and verified by MCH booklets. Among HIV-infected mothers, prevalence of maternal WHO TB symptoms and TB exposure was determined and maternal and infant correlates were assessed using t-tests or chi-squared tests and logistic regression.

Results: Among 498 HIV-infected mothers, median age was 28 years (IQR 22-32) and 11% reported a history of TB. Overall, 33% of mothers had a positive WHO TB symptom screen (31% in 6-week cohort and 35% in 9-month cohort). The most prevalent WHO TB symptom was cough, followed by fever, right swells and, least commonly, weight loss. Maternal positive WHO TB screen was associated with household crowding (p<0.05) and lower CD4 count (p<0.06), but not with other HIV status or TB exposure. Compared to women without a positive WHO TB screen, women with a positive WHO TB screen were more likely to have an infant with TB symptoms, including cough (44% vs. 26%, p<0.002), fever (30% vs. 19%, p<0.05), and difficulty breathing (16% vs. 6.9%, p<0.01), and infant HIV (7.6% vs. 2.8%, p=0.02). TB exposure was reported by 11% of women, but only 15% of TB-exposed women received IPT.

Conclusions: HIV-infected mothers frequently had TB exposure and positive WHO TB symptom screen in this national PMTCT program. Maternal TB symptoms were associated with infant symptoms, suggesting potentially undiagnosed TB. Few mothers with TB exposure received IPT. Integration of maternal TB screening and prevention into PMTCT programs may improve maternal and infant outcomes.

MOPEB190

Reproductive choices of women with HIV-1 infection: the ELLA study

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Methods: ELLA enrolled HIV-positive women ≥18 years in 4 global geographic regions (China, Central/Eastern Europe (CEE), Latin America (LA), and Western Europe/CANADA). Women completed the Reproductive Choices questionnaire; responses were catego rized by patient age group. The chi-square test was used to examine the association between age group and method of birth used in discordant couples.

Background: The cross-sectional, noninterventional ELLA epidemiologic study examined barriers to carrying women with HIV infection. The reproductive choices of these patients, including parity, willingness to have children, and birth control methods used, were examined. Methods: ELLA enrolled HIV-positive women ≥18 years in 4 global geographic regions (China, Central/Eastern Europe (CEE), Latin America (LA), and Western Europe/CANADA). Women completed the Reproductive Choices questionnaire; responses were categorized by patient age group. The chi-square test was used to examine the association between age group and method of birth used in discordant couples.
Results: A total of 1931 women (mean age, 40.1 years) completed the questionnaire (Table). In the total population, 70% had ≥ 1 live births, 61% were unwilling to have more children, and 48% lived with a discordant partner. The most common method to prevent pregnancy in all regions was the male condom (47%-52%). Between 20% (LA) and 27% (CEE) used no birth control. Abstinence (all time or at the time of ovulation) rates varied by region from 20% (LA) to 7% (China). Eighteen percent of women had a surgical sterilization procedure and 11% used an intrauterine device (IUD). Use of other forms of birth control (oral contraception, female condoms, withdrawal/pullout, and emergency contraception) was lower (1%-10%, by region). With increasing age, use of male condom, oral contraception, and withdrawal/pullout or any birth control method declined. Abstinence, IUD use, or surgery for women increased with increasing age group. There were no associations between methods used to prevent pregnancy for discordant (vs concordant) couples, except for a greater likelihood of IUD use in women aged 35-49 with a discordant partner (P=0.013).

Conclusions: Despite the considerable variability of reproductive choices across geographic regions and age groups, 25% of women overall in this study practiced no form of birth control, and approximately half reported use of barrier protection (male or female condoms). Renewed efforts to educate women living with HIV regarding use of barrier methods to prevent HIV transmission should be considered.

**Other sex- or gender-specific issues**

**MOPEB191**

Safety, tolerability and efficacy of dual therapy in women in the GARDEL study

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**Background:** The objective was to investigate the safety and efficacy of dual LPV-based therapy in women in the GARDEL study.

**Methods:** The GARDEL STUDY compared the efficacy and safety of a dual therapy (DT) combination of LPV/r +3TC to a triple therapy (TT) with LPV/r + 3TC or FTC and a third investigator-selected NRTI. We analyzed data regarding efficacy, tolerability and safety of this dual therapy in women. Results: Among 416 dosed participants, 69 were women (16%), 35 were assigned to DT (51%) and 34 to TT (65%) (Baseline characteristics were comparable in both arms). At 48 weeks, 85.8% of women in DT and 67.6% in TT achieved a HIV RNA <50 copies/mL in ITT, NC = F analysis (p=0.070, difference 21.3%, [CI -10.9% to +42.6%]). CD4 increases (mean) showed no significant differences between gender or treatment arms. Safety and tolerability were generally similar between groups. A total of 33 Grade 2-3 clinical AE were reported in women, 48.5% (DT) and 51.5% (TT) (p=0.56) while 120 AEs were reported in men: DT, 40.8% and 59.5% TT (p=0.556) Numerically more discontinuations were reported in men: DT, 5.6% (n 10) and 11.4% (n 4) (p=0.238). Median viral load at failure was 813 copies/ mL for women and 440 copies/ mL for men. Virologic failure was observed in 6 women (1 DT, 5 TT; p= 0.238) and in 16 men (9 DT, 7 TT; p=0.238). Median viral load at failure was 813 copies/mL for women and 440 copies/mL for men. CCA increases (mean) showed no significant differences between gender or treatment arms. Safety and tolerability were generally similar between groups. A total of 33 Grade 2-3 clinical AE were reported in women, 48.5% (DT) and 51.5% (TT) (p=0.56) while 120 AEs were reported in men: DT, 40.8% and 59.5% TT (p=0.56) Numerically more discontinuations were reported in women 21 % vs 10.9% in men. Tolerance/tolerability-related discontinuations were more frequent in the TT arm for both gender see tables 1 and 2

**Table 1. Proportion of patient of plasma HIV-1 RNA less than 50 copies/mL by gender**

<table>
<thead>
<tr>
<th>HIV VL at Week 48</th>
<th>DT</th>
<th>TT</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VL &lt; 50 (n=192)</td>
<td>88.5%</td>
<td>97.7%</td>
<td>0.070 (difference 21.2% [CI -9.9% to +42.8%])</td>
</tr>
<tr>
<td>VL ≥ 50 (n=134)</td>
<td>80.3% (n=104)</td>
<td>80.9% (n=114)</td>
<td>0.204 (difference 0.4% [CI -6.2% to +6.5%])</td>
</tr>
<tr>
<td>VL ≥ 100,000 (n=238)</td>
<td>88.6% (n=187)</td>
<td>82.2% (n=190)</td>
<td>0.035 (difference 6.5% [CI -9.9% to +11.9%])</td>
</tr>
</tbody>
</table>

**Conclusions:** Although this study is not powered to support statistically significant results we observed that DT with LPV/r+3TC in women was non-inferior to triple therapy after 48 weeks of treatment, with a larger point estimate for the difference between arms in women in the lower baseline viral load strata. The DT regimen tended to have better safety and tolerability in both genders. Women discontinued more frequently due to tolerability/toxicity reasons.

**MOPEB192**

Intimate partner violence among HIV-infected pregnant women initiating antiretroviral therapy in South Africa

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**Background:** Intimate partner violence (IPV) during pregnancy may be common in many settings where HIV is prevalent but there are few data on IPV in populations of HIV-infected pregnant women. We examined the prevalence and predictors of IPV among pregnant women initiating lifelong antiretroviral therapy (ART) in a large primary care clinic in South Africa.

**Methods:** Consecutive pregnant women seeking antenatal care in Gugulethu, Cape Town were recruited into the M-ART study examining service models for postpartum ART care. IPV, depression, alcohol and drug use, and psychological distress were assessed using the 13-item WHO Violence Against Women questionnaire, the Edinburgh Postnatal Depression Scale (EPDS), alcohol and drug use disorders identification test (AUDIT/DUDIT) and the Kessler-10 (K-10) scale, respectively. Questionnaires were administered privately by trained interviewers. Women identified with specific IPV or mental health concerns were referred to appropriate services. Logistic regression was used to examine factors independently associated with experiences of IPV after adjusting for age and socioeconomic status.

**Results:** From April 2013-May 2014, 623 women were enrolled (median age, 28 years); 97% reported being in a relationship, 31% were married and/or cohabiting and 70% reported not having discussed or agreed on pregnancy intentions prior to conception. Overall, 21%(n=132) reported experiencing ≥1 act of IPV in the past 12 months, including emotional violence(15%), physical violence(15%) and sexual violence(2%). Of those reporting any IPV, 48% reported experiencing multiple types (Figure 1). Emotional and physical violence were most prevalent among women 16-24 years old, while sexual violence was most commonly reported among women 25-26 years old. Women who reported not discussing or disagreeing on pregnancy intentions with their partners prior to conception were significantly more likely to experience IPV(0.030), and women who experienced IPV reported higher levels of substance abuse, depression and psychological distress(< 0.001 for all associations).

**Conclusions:** These data demonstrate high levels of IPV in this population. While the potential impact of HIV-infected pregnancy and pregnancy intention on the risk of IPV and related factors require further research, IPV-related screening and support services should be considered as part of the package of care for ART in pregnancy.

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**Figure 1:** Venn diagram of types of intimate partner violence experienced in past 12 months
**MOPEB193**

Antiretroviral drug use in a cohort of women in the United States


**Background:** Antiretroviral (ARV) drugs are used by HIV-uninfected individuals for pre- and post-exposure prophylaxis and to treat hepatitis B virus infection. Recent reports indicate that some ARV drugs are also used for recreational purposes. ARV drug resistance can emerge if individuals become HIV infected while using ARV drugs. We evaluated ARV drug use among HIV-uninfected women in the HIVTPN 064 study. The study enrolled 2,096 women at increased risk for HIV acquisition living in ten urban and periurban areas of the United States with high poverty rates and high HIV prevalence.

**Methods:** Plasma samples collected from 1,808 women who were HIV uninfected at the last study visit were analyzed. Enrollment samples from a randomly-selected subset of 384 HIV-uninfected women were also analyzed. Samples were screened for 16 ARV drugs from three ARV drug classes using a high-throughput, qualitative assay based on high-resolution mass spectrometry. Chi-square and Fisher’s exact tests were performed to examine the association of ARV drug detection with participant and partner characteristics.

**Results:** ARV drug classes detected in 38 (2.2%) of the 1,808 women at the last study visit: 27/181 (14.9%) in Baltimore, MD and 12/179 (6.7%) in Bronx, NY. ARV drugs were not detected in samples from the other eight study sites. In Baltimore, efavirenz and protease inhibitors (nelfinaivir, saquinavir, tipranavir, and indinavir) were detected; 22 women had one drug detected, and five had more than one drug detected. In Bronx, only efavirenz and indinavir were detected, and three had both drugs detected. ARV drugs were not detected in the random subset of enrollment samples.

**Conclusions:** Regionally-distinct patterns of ARV drug use were observed in HIV-uninfected women in the HIVTPN 064 study using a high-throughput ARV drug assay. Some of the drugs detected are often used in HIV care or prevention. Further research is needed to explore the prevalence of ARV drug use among HIV-uninfected individuals in different populations, the mechanisms by which those drugs are acquired, and the reasons for their use.

**MOPEB194**

Coercive sex as a mode of HIV acquisition among a cohort of women with HIV in Canada: an under-recognized public health concern

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**Background:** Women experience coercive sex at alarming high rates, worldwide, due to entrenched gender and social inequities. We assessed the prevalence of and factors associated with HIV acquisition via coercive sex among women with HIV enrolled in the Canadian HIV Cohort Study (CHIWOS).

**Methods:** Baseline survey data were analyzed for women with HIV (≥16 years), enrolled in a longitudinal, community-based cohort study in British Columbia (BC), Ontario (ON), and Quebec (QC). Coercive sex was assessed through self-report of non-consensual sex as a mode of HIV acquisition or sexual violence as a child or adult resulting in HIV. Univariate logistic regression analyses examined the relationship between self-reported coercive vs. consensual sex as the mode of HIV acquisition.

**Results:** Of 1,070 participants, 25% were from BC, 33% ON, and 22% QC, median age was 42 (IQR=35-50), 28 % identified as African/Caribbean/Black, 39% as Caucasian, and 27% as Aboriginal. Coercive sex was the second most dominant mode of HIV transmission at 17% (N=185) (vs. 57%-consensual sex, 15%-sharing needles, 4%-blood transfusion, 4%-perinatal, 4%-other). Amongst the women who acquired HIV from coercive sex, 38% (N=70) reported the assault occurring during war. In univariate analyses, covariates significantly associated with acquiring HIV from coercive vs. consensual sex included: province, ethnicity, birth country, year of arrival and legal status in Canada, sex at birth (p<0.001), sexual orientation (p=0.058), education (p=0.048), different regional residence in ON (p=0.055), living in an urban area, ever being in foster care or a group-home, ever being under Child Protection Services care (p=0.006), being incarcerated ever (p=0.038) and in the past year (p=0.022), recreational drug (p=0.010), illicit drugs (p=0.029) and injection drug (p=0.021) use, hepatitis C (p=0.034) and ever taking antiretrovirals (p=0.010) (p-values ≤0.01 were not stated).

**Conclusions:** Coercive sex is a significant under-considered HIV risk factor among women. Given the high rates of self-reported coercive sex as a mode of HIV acquisition, it should be considered a distinct HIV risk factor, and reported separately from heterosexual transmission. The intersecting social determinants associated with coercive sex as an HIV risk factor warrant particular attention by policy makers and care providers.

**Pharmacokinetics / pharmacodynamics / pharmacogenomics in children and adolescents**

**MOPEB195**

A pharmacokinetics-based adherence measure for antiretroviral therapy in HIV-infected Kenyan children


**Background:** Traditional medication adherence measures do not accommodate the pharmacokinetic (PK) properties of the drugs and thus do not reflect patients’ true therapeutic exposure. Medication Event Monitoring Systems (MEMS®) dose timers coupled with established PK parameters offer an opportunity to quantify the proximity of patient’s actual drug exposure to its intended level. We tested the concept by constructing a PK-based measure for nevirapine (NVP) adherence in HIV-infected Kenyan children.

**Methods:** We used 1-compartiment model with previously established PK parameters and actual MEMS®-recorded dosing times to estimate the mean plasma concentration of NVP (CP) in individual patients after 1 month of follow-up. Intended NVP plasma concentration was calculated given a perfectly followed dosing regimen and frequency (CP). The difference between the 2 (Δ (CP-CP)) quantified the extent to which the patient’s NVP actual exposure deviated from its intended level. We validated Δ by evaluating its associations with MEMS®-defined adherence, CD4%, and spot-check NVP plasma concentrations assessed after 1 month.

**Results:** We analyzed data from 152 children (54 female). Mean age was 7.9 years (range 5.1-14.9). Subjects were on NVP for an average of 2.2 years. Children had moderate to severe clinical disease (61.7% were at WHO Stages 3 or 4) with mean CD4% of 27.7%. Mean MEMS® adherence was 78.6%. Figure 1 shows examples of fitted CP “observed” and CP “optimal” curves of 4 patients; a larger Δ value suggests greater deviation of the observed plasma concentration from the intended one.

The mean Δ value was -0.04 ng/ml (SD 0.16 ng/ml). Δ was negatively associated with MEMS® adherence; patients with MEMS® adherence ≥90% had mean Δ value of -0.10 ng/ml versus mean Δ of 0.35 ng/ml in those with MEMS® adherence <90% (p<0.001), confirming a larger Δ was associated with non-adherence and thus a greater deviation from the intended level. A larger Δ was also associated with lower CD4% (p=0.0238) and spot-check plasma concentration (p=0.0008).
MOPEB196
Raltegravir (RAL) pharmacokinetics (PK) and safety in HIV-1 exposed neonates at high-risk of infection (IMPAACT P1110)

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Background: RAL is primarily metabolized by UGT1A1, whose activity is low at birth and increases exponentially over the first weeks of life. IMPAACT P1109 demonstrated that RAL crossed the placental wall and elimination of transplacentally acquired RAL in infants whose mothers received RAL during pregnancy was highly variable and prolonged. The objectives of IMPAACT P1110 are to evaluate the pharmacokinetics and safety of RAL and to determine an appropriate neonatal dose during the first 6 weeks of life using a two cohort adaptive design, where PK data from Cohort 1 are included in PK modeling to guide daily dosing in Cohort 2.

Methods: IMPAACT P1110 is a Phase I multicenter PK study of RAL in full-term HIV-1 exposed neonates at high risk of acquiring HIV-infection. Cohort 1 infants received RAL administered as a single oral 3 mg/kg dose within 48 hours of birth in addition to standard of care ARVs for PMTCT prophylaxis, and a second dose administered at 7-10 days of life. Pharmacokinetic sampling was done around the first dose (pre-dose and 1-2 hours, 4-8 hours, 12 hours, 24 hours post-dose, random sample on day 3-4 of life) and second dose (pre-dose and 1-2 hours, 24 hours post-dose). PK samples were analyzed for RAL concentrations on a validated HPLC-MS-MS method. Protocol exposure limits for each subject are Cmax ≤ 19.6 μM and AUC12 ≤ 63 μMhr.

Results: 6 mother-infant pairs enrolled in Cohort 1 (all RAL-unexposed in utero). Complete PK parameters following the first single dose are available for 5 of the 6 neonates (see Table). Although the Cmax upper limit was not exceeded by any subject, two patients exceeded the AUC12 upper limit. All infants tolerated the two single oral doses well.

Conclusion: Given that 40% (2/5) infants exceeded the AUC12 target, these data suggest that daily neonatal dosing with RAL 3 mg/kg in RAL unexposed infants may be excessive. Dosing with 2 mg/kg for first dose is now under study. Neonates exposed to RAL in utero may require a different dosing strategy and are also being studied in P1110.

Plasma concentration using the PK-based measure in 4 infant PK Parameters Following First Dose

<table>
<thead>
<tr>
<th>Parameter</th>
<th>GM</th>
<th>%CV</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cmax (μM)</td>
<td>6.9</td>
<td>27.6</td>
<td>4.5-9.6</td>
</tr>
<tr>
<td>AUC12 (μMhr)</td>
<td>60.6</td>
<td>31.5</td>
<td>42.5-89.9</td>
</tr>
<tr>
<td>T 1/2 (hours)</td>
<td>12.8</td>
<td>19.6</td>
<td>9.9-15.7</td>
</tr>
<tr>
<td>T max (hours)</td>
<td>6.4</td>
<td>101.2</td>
<td>4-21</td>
</tr>
<tr>
<td>C24h (μM)</td>
<td>3.2</td>
<td>69.2</td>
<td>1.5-8.2</td>
</tr>
<tr>
<td>Vz/F (L/kg)</td>
<td>1.9</td>
<td>32.8</td>
<td>1.4-3.0</td>
</tr>
<tr>
<td>CL/F (L/hr)</td>
<td>0.03</td>
<td>31.5</td>
<td>0.02-0.05</td>
</tr>
</tbody>
</table>

[Infant PK Parameters Following First Dose]
Therapeutic drug monitoring in children and adolescents

MOPEB198

Very high levels of drug resistance in HIV-infected children failing first line ART in Bobo-Dioulasso, Burkina-Faso

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1IRD, UMR 233, Montpellier, France, 2Centre Hospitalier de Bobo Dioulasso, Département de Pédiatrie, Bobo-Dioulasso, Burkina Faso, 3Centre Hospitalier de Bobo Dioulasso, Laboratoire, Bobo Dioulasso, Burkina Faso

Background: Access to ART for HIV-infected children is expanding in Africa, emergence of HIV drug resistance is inevitable, especially where biological monitoring is limited. The objective of this study was to describe drug resistance mutations in HIV-infected children that were clinically suspected to be failing first line treatment in the outpatient clinic of paediatric department in Bobo-Dioulasso, Burkina Faso.

Methods: In October 2014, all children on first line ART (3TC+ATV+EFV+NNRTI-DDI/3TC/EFV) for more than 6 months and who were suspected failing ART (based on clinical and immunological) were invited in the outpatient clinic for a dried blood spot sample (DBS). Genotypic drug resistance testing in protease and reverse transcriptase was performed on DBS according to ANRS protocol. HIVDR was determined using the ANRS (v24.2014) HIVDR algorithm.

Results: Among 61 HIV infected children on first line ART, 72 (11.8%) were in clinical or immunological failure (53 male, 37 female) with a median age of 12 years (IQR 8-14). The median duration on ART was 45 months (IQR 30-74). For 63 children, CD4 counts were performed between January and October 2014: the median was 455 cells/mm3 (IQR 179-681). Genotyping was successful for 64/67 (96%) children: 61/64 (95%) were resistant to at least one drug, 59/64 (91%) to NRTIs and NNRTIs, 26/3 (4%) to NRTIs and 18/4 (2%) to NRTIs. Overall, 43/64 (67%) were resistant to all drugs from their actual first line ART and 15/64 (23%) were on mono-therapy. Moreover, they accumulated high numbers of mutations inducing cross-resistance to potential second line RTIs, i.e. ABC (30/64 (47%)), TDF (23/64 (36%)) or ETR (25/64 (39%). This study shows the importance of early detection of treatment failure. The extensive accumulation of HIVDR and cross-resistance may compromise second-line regimens. These data stress the need of biological monitoring and advocate for more robust first-line regimens and surveillance of HIV drug resistance in HIV infected children.

Drug formulations in children and adolescents

MOPEB199

Two open label, randomized, cross-over, single-dose, bioavailability evaluations of abacavir sulfate/lamivudine dispersible tablets 60/30mg resp. 120 mg/60mg compared with that of ePZIcoM® 600/300 mg tablets

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Presenting author email: emmanuel.patras@mylan.in

Background: A dispersible tablet formulation of DTG has been developed as an alternative to the granule formulation for administration to paediatric populations. The oral bioavailability of DTG is affected by metal cation-containing supplements. This study was conducted to evaluate the relative bioavailability of the dispersible tablet compared to the granule formulation and to compare DTG pharmacokinetics (PK) when tablets are dispersed in either low or high mineral content water.

Methods: This was a randomized, open-label, 5-way, single-dose crossover study in healthy adults. Treatments consisted of 20 mg DTG administered as: (A) DTG granules in purified water and consumed immediately, (B) dispersible tablets (4 x 5mg) dispersed in low mineral content (LMC) water, consumed immediately, (C) dispersible tablets in high mineral content (HMC) water, consumed immediately, (D) dispersible tablets in LMC water, consumed after standing for 30 minutes, (E) dispersible tablets in HMC water, consumed after standing for 30 minutes. Safety evaluations and serial PK samples were collected during each treatment period. DTG PK parameters were determined by nonparametrical methods and compared between treatments by analysis of variance (ANOVA). A palatability questionnaire was administered after the first period.

Results: Fifteen subjects were enrolled into the study and completed all treatment periods. Summary ANOVA results from treatment comparisons are presented in the following table.

<table>
<thead>
<tr>
<th>PK Parameter</th>
<th>Geometric Least Square Mean Ratio (90% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC(0-&gt;∞)</td>
<td>Trt B / Trt A</td>
</tr>
<tr>
<td>AUC(0-&gt;∞)</td>
<td>1.00 (1.02, 1.11)</td>
</tr>
<tr>
<td>Cmax</td>
<td>1.94 (0.97, 1.99)</td>
</tr>
<tr>
<td>C24</td>
<td>1.03 (0.97, 1.09)</td>
</tr>
</tbody>
</table>

**Table 1**

AUC(0->∞) = area under the curve extrapolated to infinity; C24 = concentration 24 hours post-dose; Cmax = peak concentration.
The DTG dispersible tablet was bioequivalent to the granule formulation. Neither water mineral content within the range evaluated nor 30 minute delay in dispersed tablet consumption affected DTG PK. Study treatments were well tolerated. All adverse events (AEs) reported were mild, and no subjects were withdrawn due to AEs. Based on the limited palatability assessment data, the granule formulation seemed to be more acceptable than the dispersible tablets.

**Conclusions:** The dispersible tablet is suitable for further development and the formulation is being improved to adjust taste.

### Adherence in children and adolescents

#### MOPEB201 Virological suppression among adolescents and young adults living with HIV in Canada


**Background:** Compared with adults, adolescents and young adults (AYA) living with HIV have poorer treatment and clinical outcomes. AYA are important treatment population, yet the reasons for poorer outcomes are poorly understood. The aims of this study are to assess time to virological suppression in the first year of cART among AYA and to explore factors associated with suppression.

**Methods:** Participants are HIV-positive individuals from a multi-site Canadian cohort of antiretroviral-naïve patients initiating cART on/after 1 January 2000. A Ti was defined as a gap in treatment >90 consecutive days during the follow-up time. Univariate and multivariable analyses were conducted to explore factors associated with treatment interruptions (TIs) among AYA.

**Results:** 562 people living with HIV were included in this analysis, with 1304 (14%) aged 18-29 (AYA). Approximately 30% of AYA were female, 5.1% identify as Indigenous, 37% identify as MSM, and 19.2% report a history of injection drug use (IDU). AYA were more likely to experience treatment interruptions (26.2% vs. 19.9%, p<0.001). In the adjusted analysis, factors associated with TIs among AYA were female gender (adjusted hazard ratio [AHR]: 1.86, 95% confidence interval [CI]: 1.46-2.36, p<0.001), self-identifying as Indigenous (AOR: 1.86; 95% CI:1.11—1.66, p< 0.001), having a history of IDU (AHR: 2.25, 95% CI: 1.71-2.96, p< 0.001), having a baseline CD4 count >350 cells/µl (AHR: 1.71; 95% CI: 1.30-2.26, p<0.001) and starting cART in earlier years (2000-2003) (AHR: 1.77; 95% CI: 1.19-2.54, p=0.017) relative to 2007-2012.

**Conclusions:** AYA disproportionally experienced treatment interruptions than non-AYAs over the study period. Despite the universal health care setting and cART availability, a quarter of AYA are not remaining on treatment. Tailored health care strategies are needed to support AYA to remain in care and to receive the full benefits of cART.

### MOPEB202 Treatment interruptions common among adolescents and young adults living with HIV in Canada


**Background:** Adolescents and young adults (AYA) comprise nearly one-quarter of all Canadian HIV-positive tests. Despite available treatment, AYA face on-going challenges with adherence to cART. Incomplete adherence and treatment interruptions (TIs) result in viral re-bound and are associated with treatment failure, HIV resistance, suboptimal clinical outcomes and increased potential for HIV transmission. This study will examine correlates of treatment interruptions.

**Methods:** Participants are HIV-positive individuals from a multi-site Canadian cohort of antiretroviral-naïve patients initiating cART on/after 1 January 2000. A Ti was defined as a gap in treatment >90 consecutive days during the follow-up time. Univariate and multivariable analyses were conducted to explore factors associated with treatment interruptions (TIs) among AYA.

**Results:** 562 people living with HIV were included in this analysis, with 1304 (14%) aged 18-29 (AYA). Approximately 30% of AYA were female, 5.1% identify as Indigenous, 37% identify as MSM, and 19.2% report a history of injection drug use (IDU). AYA were more likely to experience treatment interruptions (26.2% vs. 19.9%, p<0.001). In the adjusted analysis, factors associated with TIs among AYA were female gender (adjusted hazard ratio [AHR]: 1.86; 95% confidence interval [CI]: 1.46-2.36, p<0.001), self-identifying as Indigenous (AOR: 1.86; 95% CI:1.11—1.66, p< 0.001), having a history of IDU (AHR: 2.25, 95% CI: 1.71-2.96, p< 0.001), having a baseline CD4 count >350 cells/µl (AHR: 1.71; 95% CI: 1.30-2.26, p<0.001) and starting cART in earlier years (2000-2003) (AHR: 1.77; 95% CI: 1.19-2.54, p=0.017) relative to 2007-2012.

**Conclusions:** AYA disproportionally experienced treatment interruptions than non-AYAs over the study period. Despite the universal health care setting and cART availability, a quarter of AYA are not remaining on treatment. Tailored health care strategies are needed to support AYA to remain in care and to receive the full benefits of cART.
HIV-exposed uninfected children (including effects of ART exposure during pregnancy)

MOPEB205

The effects of maternal HIV infection on infectious morbidity of HIV exposed uninfected (HEU) infants in South Africa

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Background: HEU South African infants, comprising 30% of the infant population, may be at risk for substantial infectious morbidity, potentially explained by advanced maternal HIV disease. To understand the relationship between maternal CD4 count, viral load, antiretroviral therapy and infant infectious morbidity we compared these parameters in HEU infants with and without infectious cause hospitalizations.

Methods: The Mother-Infant Health prospective cohort study conducted from 2012-2014 identified HIV-infected and HIV-uninfected mothers at delivery from a single community midwife unit. Infants were enrolled at 2 weeks and followed to 6 months. Maternal antenatal CD4 counts were retrieved from the public health laboratory database and delivery CD4 counts and HIV viral loads were performed by the study. The primary outcome, infectious cause hospitalization before 6 months, was determined through active surveillance using the province-wide electronic hospital administration system allowing complete outcome determination on all infants. We present a descriptive analysis of the HIV-infected mothers and their HEU infants.

Results: 94 HIV-infected mothers and their HEU infants were enrolled. 48 mothers (51.1%) had HIV diagnosed pre-pregnancy and 47 (50.5%) received combination antiretroviral therapy (cART) during pregnancy. Seventeen (18.1%) HEU infants experienced an infectious-cause hospitalization. There were no differences between hospitalized and not hospitalized infants in timing of maternal HIV diagnosis, cART or zidovudine prophylaxis, maternal CD4 count or HIV viral load at delivery (Table 1). Neither were there differences in infant gestational age, birth weight, exclusive breastfeeding at 2 weeks or complete immunizations by 6 months. Infants of mothers on zidovudine prophylaxis were more often anaemic at 2 months than infants of mothers on cART (26/36(55.6%) vs. 14/42(33.3%), p = 0.03). Nineteen (40.4%) mothers on zidovudine prophylaxis had CD4 counts < 350 cells/mm3 at delivery and 43 (46%) HEU infants were not receiving trimethoprim-sulfamethoxazole prophylaxis at 8 weeks.

<table>
<thead>
<tr>
<th>Timing of maternal HIV diagnosis</th>
<th>Total N=94</th>
<th>Infants hospitalized N=17</th>
<th>Infants not hospitalized N=77</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-pregnancy</td>
<td>48(51.1%)</td>
<td>10(58.8%)</td>
<td>38(49.4%)</td>
<td></td>
</tr>
<tr>
<td>During pregnancy or peripartum</td>
<td>46(49.4%)</td>
<td>7(41.2%)</td>
<td>39(50.7%)</td>
<td></td>
</tr>
<tr>
<td>Maternal antiretroviral type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination antiretroviral therapy</td>
<td>47(50.5%)</td>
<td>8(47.1%)</td>
<td>39(50.7%)</td>
<td></td>
</tr>
<tr>
<td>Zidovudine prophylaxis</td>
<td>44(46.8%)</td>
<td>7(41.2%)</td>
<td>37(48.1%)</td>
<td></td>
</tr>
<tr>
<td>Antenatal CD4 count - median (IQR)</td>
<td>420(284,539)</td>
<td>408(384,640)</td>
<td>410(284,515)</td>
<td>0.19</td>
</tr>
<tr>
<td>Delivery CD4 count - median (IQR)</td>
<td>343(238,501)</td>
<td>308(202,694)</td>
<td>346(246,486)</td>
<td>0.87</td>
</tr>
<tr>
<td>Log10 HIV viral load - median (IQR)</td>
<td>2.05(1.59,3.22)</td>
<td>1.87(1.59,2.85)</td>
<td>2.11(1.59,3.31)</td>
<td>0.42</td>
</tr>
</tbody>
</table>

| Table 1: Maternal HIV factors |

Conclusions: Maternal CD4 count, HIV viral load and receipt of either cART or zidovudine prophylaxis were not associated with infant infectious morbidity. Of concern is the proportion of mothers with delivery CD4 counts below the threshold for cART and the low proportion of infants receiving trimethoprim-sulfamethoxazole.
MOPEB206

Perturbations in gut microbiome in infants born to HIV-infected mothers are related to maternal microbiome and human milk oligosaccharides

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Background: Programs to prevent mother-to-child HIV transmission have been highly successful in reducing the risk of HIV transmission to the infant. However, these infants do not escape unscathed. HIV-exposed infants experience higher rates of morbidity and mortality than unexposed infants, even HIV-exposed uninfected (HEU) infants. Here we investigate a potential mechanism to explain the higher rates of mortality and morbidity in this vulnerable group.

Methods: Infants born to 25 HIV-infected and 25 uninfected mothers were recruited at a nutrition clinic in Port au Prince, Haiti. All infants were breastfed and the mean age was two months (range one to three months). Mucosal samples were collected from each mother-infant pair at six months of age (mother - breast milk, areola, vagina; and infant - oral, and skin). For each sample we performed 16S bacterial metagenomic sequencing and analyzed the data using QIIME 1.8.0. Human milk oligosaccharides were characterized using high-performance liquid chromatography.

Results: Alpha diversity was significantly reduced in the gut microbiome of infants born to HIV-infected mothers. Taxonomic composition in the infant stool sample differed by maternal HIV status. Infants born to HIV-infected mothers had more Proteobacteria and Actinobacteria and less Bacteroidetes and Fusobacteria than unexposed infants. Classes within these phyla were also significantly different. The Bacteroidetes to Firmicutes ratio has been used as a marker of diversity. This link to bacterial diversity was lost in infants born to HIV-infected mothers. Individual mother-infant pairs were significantly similar to each other with the strongest association being between maternal breast milk and infant stool microbiomes. The increases in Proteobacteria and Actinobacteria in HIV-exposed infants were explained by increases in the concentration of 3’-sialyllactose (3SL) in breast milk from HIV-infected mothers.

Conclusions: Both oligosaccharide composition of breast milk and infant stool microbiome were influenced by maternal HIV status. Maternal HIV infection may disrupt the bacteria growth in developing infants. Perturbations caused by HIV in the oligosaccharide composition of breast milk or in the maternal microbiome may lead to these perturbations in infants. Close linkage between maternal and infant microbiomes may help explain some of the increased vulnerabilities of HEU infants

MOPEB207

Health outcomes among HIV-exposed uninfected infants in Quebec, Canada

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Background: HIV-exposed uninfected (HEU) infants are at increased risk of adverse health outcomes when compared to unexposed infants, though the precise cause is yet unknown. Our objective was to study the association between maternal health status at the time of delivery and infant health outcomes.

Methods: HEU infants followed in the CMIS (Canadian Multicentre Infant Study) cohort of HIV+ and HIV- pregnant women and HIV-exposed uninfected (HEU) and HIV-unexposed uninfected (HUU) infants were included. Maternal health status at delivery included maternal smoking in pregnancy, maternal antiretroviral therapy (cART) in pregnancy, and maternal CD4 count and viral load (VL) at time of delivery.

Results: There were no significant differences in gestational age, birth weight, APGAR scores, sex, race/ethnicity, or birth weight, length and head circumference at 6 and 12 month of age, or rate of hospitalization in the first two years of age, among infants born to mothers with delivery CD4 count < 350 cells/mm³ and detectable viral load (VL) at time of delivery (n=67) vs. >350 cells/mm³ and undetectable VL (n=133). Data on hospitalization was extracted by chart review, and compared among infant groups defined by maternal health status.

Conclusions: Maternal CD4 count and VL at delivery may have an impact on health outcomes among HEU infants, with increased rate of infection seen among infants born to mothers with CD4 count < 350 cells/mm³ and higher rate of hospitalization seen among infants born to mothers with detectable VL at the time of delivery. Further work needs to be directed at understanding the contributing factors.

MOPEB208

Leukocyte telomere length (LTL) dynamics in a cohort of HIV-exposed uninfected (HEU) infants exposed to combination antiretroviral therapy (cART) in utero

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Background: Maternal cART in pregnancy could have long-term consequences for HEU children. Some antiretrovirals and HIV proteins inhibit telomerase, a potential mechanism of injury as LTL reflects cellular aging and is linked to age-related morbidities. We evaluated the impact of HIV and cART exposure on LTL by comparing a cohort of HEU and HIV-uninfected (HUU) control infants at birth, over the first 3-6 weeks postpartum period, and over the first three years of age.

Methods: Relative LTL was measured in 324 HEU (0-3y, n=215 had ≥2 blood samples collected) and 308 HUU children (0-3y, single blood sample each) via qPCR. Factors associated with LTL were investigated using linear regression modeling. Longitudinal LTL in HEU was analyzed via a generalized linear model with random intercept and time as factors.

Results: In a cross-sectional analysis of LTL at birth (0-3d) in 115 HEU (56% male and 91 HUU (54% male) children, maternal cART (duration or type) was unrelated to HEU LTL. Male sex was associated with shorter LTL (p<0.02). Maternal smoking in pregnancy (56% HEU, 43% HUU mothers smoked) was associated with significantly shorter LTL in HEU and longer LTL in HUU, indicating a significant smoking*HEU/HUU interaction (p=0.001). Percent change in LTL over the first 3-6 weeks was associated with birth LTL (p<0.001) whereby infants with longer LTL at birth showed greater LTL shortening. Overall, LTL slopes for the first six weeks were positive in both groups. In HEU, this was followed by rapid decline in LTL to one year of age, then leveling off. Although a similar model could not be built for HUU, LTL attrition rates were similar in both groups among a subset of age and sex-matched children (n=214, p=0.69).

Conclusions: This first detailed investigation of human LTL dynamics early in life suggests an apparent gain in LTL during the first 6 weeks of life followed by a rapid decline that levels off up to age three. These results further support that exposure to maternal HIV/cART in utero does not affect infant LTL, a reassuring finding. Rather, smoking acts as a major modulator of infant birth LTL, likely through in utero stressors.

MOPEB209

Effects of smoking on telomere length in cohorts of HIV+ and HIV- pregnant women and HIV-exposed uninfected (HEU) and HIV-unexposed uninfected (HUU) infants

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Background: Antiretroviral drugs, HIV proteins, immune activation, and oxidative stress can affect telomerase activity and/or leukocyte telomere length (LTL), a marker of aging and cellular aging and is linked to age-related morbidities. We evaluated the effects of smoking on LTL in cohorts of HIV+ and HIV- pregnant women and HIV-exposed uninfected (HEU) and HIV-unexposed uninfected (HUU) infants.

Results: Maternal smoking in pregnancy, as LTL reflects cellular aging and is linked to age-related morbidities. We evaluated the impact of HIV and cART exposure on LTL by comparing a cohort of HEU and HIV-uninfected (HUU) control infants at birth, over the first 3-6 weeks postpartum period, and over the first three years of age.

Methods: Relative LTL was measured in 324 HEU (0-3y, n=215 had ≥2 blood samples collected) and 308 HUU children (0-3y, single blood sample each) via qPCR. Factors associated with LTL were investigated using linear regression modeling. Longitudinal LTL in HEU was analyzed via a generalized linear model with random intercept and time as factors.

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Methods: Relative LTL was assessed in 89 HIV+ (all on cART) and 58 HIV- pregnant women at 31-40 weeks of gestation, as well as 115 HEU and 91 HUU infants at birth. Mouth swab TL was also measured in 34 HEU and 18 HUU infants. Linear regressions and correlations were used to examine and compare the factors associated with LTL.

Results: Smoking at visit was univariately associated with shorter maternal LTL (p=0.006), although the effect size was greater among HIV+ women (p<0.001). In all infants, male sex (p=0.02) and higher birth weight (p=0.07) were most associated with shorter LTL. In addition, there was a significant (p<0.001) interaction whereby maternal smoking (65% of HIV+ and 43% of HIV-mothers smoked ever in pregnancy) was associated with shorter LTL in HEU and longer LTL in HUU. Given an imbalance in smoking by ethnicity, whereby Aboriginal and Black women were significantly more and less likely to smoke respectively, a sub analysis of White mothers only (n=93, 53% smokers) was performed and showed a similar LTL pattern. An interaction was also seen in infant mouth swab TL (p=0.014) with longer TL in HIV infants exposed to maternal smoking. Among HEU, cART was not related to birth LTL.

Conclusions: Pregnant women who smoke have shorter LTL irrespective of HIV status. In infants, the counterintuitive effect observed in both LTL and mouth swab TL in association with maternal smoking may relate to a physiologic response to intrauterine stress. This smoking in pregnancy effect may be modulated by cART exposure in HEU infants.

MOPEB211
Self-reported HIV risk assessment and risk factors among adolescents from the high HIV prevalence area in the USA
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Background: Adolescents are at risk for acquiring HIV due to high rates of unprotected sex and sexually transmitted infections (STIs). Youth frequently lack awareness about the risk of acquiring HIV. In Washington, DC, with 2.5% overall HIV prevalence, 0.2% of adolescents (13-19 years) and 1.3% of youth (20-25 years) are infected with HIV. This study aimed to evaluate self-reported HIV risk assessment and risk factors among adolescents tested for HIV at the pediatric Emergency Department (ED) located in a community hospital in Washington, DC.

Methods: A self-reported questionnaire with multiple choice answers on HIV risk and risk factors was offered to adolescents (213 years) at the United Medical Center ED during March 2013-August 2014. The questionnaire was distributed after adolescents received their HIV test results. Adolescents with positive HIV test results were excluded from participating in the survey. Descriptive statistics were used for data analysis.

Results: A total of 405 adolescents (median age - 16 years) completed the survey. The majority (70%, n=285) were female and Black (95%, n=385). The majority (63%, n=254) reported being sexually active either currently, in the past, or both. Among adolescents with sexual history, more than half (57%, n=144) reported using condoms “always” or “almost always”. Less than half (45%, n=115) reported that they knew their partner’s HIV status. Almost a third (27%, n=68) of sexually active youth reported at least one prior STI, with 66% reporting chlamydia (n=55) and 23% gonorrhea (n=19), with 15% (n=10) reporting both STIs. The large majority of surveyed adolescents (91%, n=369) did not believe that they were at risk for acquiring HIV.

Conclusions: In an urban area with a high HIV prevalence, majority of tested and surveyed predominantly female adolescents did not believe that they were at risk for acquiring HIV. Although more than half of adolescents with sexual history reported using condoms consistently, almost a third of them had a history of at least one STI. Better understanding of young people’s perception of their risks for HIV and STIs is important in order to develop effective messaging and communication with youth about risks and prevention of HIV and STIs.

MOPEB212
Predicted efficacy of reverse transcriptase and protease inhibitors in pregnant adolescents with perinatally-acquired HIV infection: evidence of limited therapeutic options
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Background: Adolescents with perinatally acquired HIV infection (APH) are a vulnerable population, heavily exposed to antiretroviral treatment (ART), in which prevalence of drug resistance associated mutations (RAMs) is high. We aimed to describe the predicted efficacy of the three historically prescribed ART classes in APH who have transitioned from pediatric hospitals to an adult service during pregnancy.

Methods: Previous and latest genotypic resistance tests from pregnant APH (period 2008-2014) were analyzed in order to estimate prevalence of RAMs and to obtain genotypic sensitivity scores predicted by cumulative genotype. Prevalence of RAMs to NNRTIs, NRTIs and PIs was analyzed according IAS-USA update, 2014. Considering the genotype interpretation system (GIS) of Stanford HIVdb program (version 7.0), the predicted efficacy of each drug was classified within five categories: from susceptible to high-level resistance. The GIS categories “susceptible” and “potential low level resistance” were grouped together as “S” (susceptible), whereas “low level resistance” and “intermediate resistance” were grouped as “I” (intermediate) and “resistant” remaining as “R” (resistant).

Results: During the studied period, 27 treatment-experienced pregnant APH were transitioned. The median (IQR) of age, gestational age, viral load (VL) and CD4 T-cell count were: 18 years (17-19), 8 weeks (5-18), 1534 copies/mL (< 50-12103) and 298µL (223-535), respectively. Genotypic resistance tests were available for 20 of them. Prevalence of RAMs was 84.2% for both NNRTIs and NRTIs, and 73.7% for PIs. The median (IQR) number drugs classified as S was 1 (0-5) for NNRTIs, 1 (0-4) for NRTIs, and 6 (4-7) for PIs. Predicted efficacy of NRTIs is shown in table 1.

Behavioural health outcomes in children and adolescents (including sexual risks, substance use and poor adherence)
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Background: Expanded access to antiretroviral therapy has improved survival of perinatally infected children in sub-Saharan Africa. They are reaching the age of adolescence and facing new challenges on sexual and reproductive health (SRH). This study examined challenges and needs of SRH among HIV-positive adolescents.

Methods: A cross sectional study was conducted at the University Teaching Hospital of Zambia from April to July 2014. In total, 200 HIV-positive adolescents who were already aware of their HIV-positive status were recruited. Structured questionnaires including open-ended questions were administered. Descriptive analysis was done about their basic background, knowledge of HIV and sexual health, their sexual behaviors, and SRH needs. For the participants aged less than 17 years, we obtained parental assents.

Results: A total of 190 adolescents were included in the analysis: 110 (57.9%) girls; and 80 (42.1%) boys. Sixty-three (33.5%) were in relationships with boyfriends/girlfriends at the time of the survey, and 38 (20.4%) had ever disclosed their HIV status to their boyfriend/girlfriend. Of these 38 adolescents, 28 reported supportive relationships with their boyfriends/girlfriends over the time. Regarding sexual and reproductive health issues, they felt comfortable to talk with friends (17.7%) and mothers (16.6%), but 17.1% answered that they were not comfortable to talk to anyone. Pharmacy/dinicospital were the major places to obtain condom (51.4%) and birth control methods (65.5%). About half (49.4%) had concerns about their marriage, such as seeing either active youth reported at least one prior STI, with 66% reporting chlamydia (n=55) and 23% gonorrhea (n=19), with 15% (n=10) reporting both STIs. The large majority of surveyed adolescents (91%, n=369) did not believe that they were at risk for acquiring HIV.

Conclusions: In an urban area with a high HIV prevalence, majority of tested and surveyed predominantly female adolescents did not believe that they were at risk for acquiring HIV. Although more than half of adolescents with sexual history reported using condoms consistently, almost a third of them had a history of at least one STI. Better understanding of young people’s perception of their risks for HIV and STIs is important in order to develop effective messaging and communication with youth about risks and prevention of HIV and STIs.

Transition into adult care
MOPEB212
Predicted efficacy of reverse transcriptase and protease inhibitors in pregnant adolescents with perinatally-acquired HIV infection: evidence of limited therapeutic options
D.M. Cecchin1, I. Zapilda2, S. Fernandez Giuliano2, M. Martinez2, C. Rodriguez2, M.B. Bouza2
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Background: Adolescents with perinatally acquired HIV infection (APH) are a vulnerable population, heavily exposed to antiretroviral treatment (ART), in which prevalence of drug resistance associated mutations (RAMs) is high. We aimed to describe the predicted efficacy of the three historically prescribed ART classes in APH who have transitioned from pediatric hospitals to an adult service during pregnancy.

Methods: Previous and latest genotypic resistance tests from pregnant APH (period 2008-2014) were analyzed in order to estimate prevalence of RAMs and to obtain genotypic sensitivity scores predicted by cumulative genotype. Prevalence of RAMs to NNRTIs, NRTIs and PIs was analyzed according IAS-USA update, 2014. Considering the genotype interpretation system (GIS) of Stanford HIVdb program (version 7.0), the predicted efficacy of each drug was classified within five categories: from susceptible to high-level resistance. The GIS categories “susceptible” and “potential low level resistance” were grouped together as “S” (susceptible), whereas “low level resistance” and “intermediate resistance” were grouped as “I” (intermediate) and “resistant” remaining as “R” (resistant).

Results: During the studied period, 27 treatment-experienced pregnant APH were transitioned. The median (IQR) of age, gestational age, viral load (VL) and CD4 T-cell count were: 18 years (17-19), 8 weeks (5-18), 1534 copies/mL (< 50-12103) and 298µL (223-535), respective-ly. Genotypic resistance tests were available for 20 of them. Prevalence of RAMs was 84.2% for both NNRTIs and NRTIs, and 73.7% for PIs. The median (IQR) number drugs classified as S was 1 (0-5) for NNRTIs, 1 (0-4) for NRTIs, and 6 (4-7) for PIs. Predicted efficacy of NRTIs is shown in table 1.
Concluding NRTIs: 35% remain S to EFV/NVP, 45% S to RPV; 50% and 45% were S and I to ETR, respectively. Considering PIs, 10% and 35% were S and I to NFV; 55% and 20% to RPV; 65% and 15% to TPV; 80% and 20% to DRV, respectively.

Conclusions: Reduced predicted efficacy was observed for most NRTIs/NNRTIs and (in a lesser extent) to PIs, limiting ART options. In this context, prescription of newer drugs with limited experience in pregnancy may be considered.

MOPEB213 Prerequisite knowledge for transition from youth to adult HIV care services among perinatally HIV-infected youth in Thailand

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Method: We interviewed HIV-infected youth aged 14-21 years receiving care at 2 tertiary care hospitals in Bangkok to assess prerequisite knowledge (i.e., 22 questions) important for the transition to adult HIV care. Score was calculated as the percentage of correct answers. We expect a score >80% will allow a smooth transition. Factors associated with a knowledge score greater than median were analysed using logistic regression.

Results: Of 2697 patients, 1827 (68%) were ART-eligible at enrollment, and 1650 (61%) initiated ART. Time, median age at registration slightly increased (Period 1=28 years, Period 2=29 years), Period 3=31 years; p=0.001; the proportion of enrollees who were women increased (Period 1=30%, Period 2=33%, Period 3=37%; p=0.022); and the proportion who injected drugs decreased (Period 1=40%, Period 2=26%, Period 3=22%; p=0.001). Changes were insignificant for the proportion of enrollees with baseline CD4 <100 (Period 1=51%, Period 2=48%, Period 3=46%; p=0.219) or with CD4 >350 (Period 1=18.2%, Period 2=20.8%, Period 3=21.1%; p=0.247), although median baseline CD4 count increased (Period 1=46, Period 2=114, Period 3=132; p=0.0142). The proportion with baseline clinical stages III-IV decreased but not significantly (Period 1=48%, Period 2=46%, Period 3=41%; p=0.402). The proportion of ART-eligible patients who initiated ART increased (Period 1=68%, Period 2=72%, Period 3=85%); p=0.001. Median time between establishing eligibility and initiating ART decreased (Period 1=42 days, Period 2=28 days, Period 3=28 days; p<0.001).

Conclusions: Despite improvement in the proportion of eligible patients receiving ART and the shortened duration between eligibility and initiation, patients were still initiating ART at low CD4 counts. In addition to guideline changes expanding ART eligibility, strengthened interventions- including routine HIV testing for key populations and immediate linkages to and retention in care- are needed to ensure timely ART initiation.

MOPEB214 Late enrollment in care and ART initiation among HIV patients in Ho Chi Minh City, Vietnam

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Background: Vietnam's national guidelines for ART eligibility have changed in accordance with World Health Organization recommendations: before 9/2009 (Period 1), CD4 count <200 cells/mm\textsuperscript{3} or clinical stage IV; 9/2009-11/2011 (Period 2), CD4 <250, <350 and stage III, or stage IV, and after 11/2011 (Period 3), CD4 <350 or stage III-IV. We assessed whether guideline changes were associated with changes in patient demographics and clinical indicators before ART initiation in Ho Chi Minh City.

Methods: We abstracted medical records of 2697 outpatients with initial clinic visits dur- ing 2007-2012 from all 21 community-based, adult HIV clinics using random sampling with probability proportional to clinic size, intra-cluster correlation and weights. We applied OLS regression analysis to test for linear trends across proportions, and the Kruskal-Wallis test for differences in medians.

Results: Of 2697 patients, 1827 (68%) were ART-eligible at enrollment, and 1650 (61%) initiated ART. Time, median age at registration slightly increased (Period 1=28 years, Period 2=29 years, Period 3=31 years; p=0.001); the proportion of enrollees who were women increased (Period 1=30%, Period 2=33%, Period 3=37%; p=0.022); and the proportion who injected drugs decreased (Period 1=40%, Period 2=26%, Period 3=22%; p=0.001). Changes were insignificant for the proportion of enrollees with baseline CD4 <100 (Period 1=51%, Period 2=48%, Period 3=46%; p=0.219) or with CD4 >350 (Period 1=18.2%, Period 2=20.8%, Period 3=21.1%; p=0.247), although median baseline CD4 count increased (Period 1=46, Period 2=114, Period 3=132; p=0.0142). The proportion with baseline clinical stages III-IV decreased but not significantly (Period 1=48%, Period 2=46%, Period 3=41%; p=0.402). The proportion of ART-eligible patients who initiated ART increased (Period 1=68%, Period 2=72%, Period 3=85%); p=0.001. Median time between establishing eligibility and initiating ART decreased (Period 1=42 days, Period 2=28 days, Period 3=28 days; p<0.001).

Conclusions: Despite improvement in the proportion of eligible patients receiving ART and the shortened duration between eligibility and initiation, patients were still initiating ART at low CD4 counts. In addition to guideline changes expanding ART eligibility, strengthened interventions- including routine HIV testing for key populations and immediate linkages to and retention in care- are needed to ensure timely ART initiation.

MOPEB215 Engagement in the HIV care cascade among perinatally HIV-infected patients transferred to an adult HIV clinic in Buenos Aires, Argentina

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Background: Transitioning perinatally HIV-infected adolescents (PHI) patients into adult care is a complex process. In addition, few data of the management of these patients after transition is available. The aim of this study was to characterize engagement in the HIV continuum of care among PHI-patients transferred from pediatric care to an adult HIV care in Buenos Aires, Argentina.

Methods: Retrospective chart review of PHI-patients transferred to our adult HIV care between 2000-2012. Percentages at each step of the cascade (transition, retention in care, on ART and viral load suppression) after 2 years of transition were determined. Bivariate analyses were performed to investigate factors associated with these outcomes.

Results: A total of 70 PHI-patients were transferred to our centre during the study period. Median (range) age: 17 years (9-24). Female sex corresponded to 57%. Twenty seven percent of the patients were orphans. Use of drugs or alcohol was self-reported by 11%. Forty-eight percent of the patients had co-morbidities. The median CD4 T-cell count was 507±57 (3-1390) and 67% had ever had a CD4 category C event. All patients except one were under antiretro- viral treatment at the time of transfer and adherence issues were observed in 36%. Sixty seven percent of the patients were triple antiretroviral treatment (ART) experience including 20% with triple-class ART resistance. Detectable viral load was observed in 52% of the patients. During the first 2 years after transition, 78% were retained in care, 73% continued ART, and 52% had undetectable viral load (72% of those on ART).

Conclusions: Transitioning PHI-patients included in the study were mainly females, orphans and did not have co-morbidities. The median age was 17 years. Female sex corresponded to 57% and 67% had ever had a CD4 category C event. All patients except one were under antiretroviral treatment at the time of transfer and adherence issues were observed in 36%. Sixty seven percent of the patients were triple antiretroviral treatment (ART) experience including 20% with triple-class ART resistance. Detectable viral load was observed in 52% of the patients. During the first 2 years after transition, 78% were retained in care, 73% continued ART, and 52% had undetectable viral load (72% of those on ART).
Assessment of population viral load in epidemiology studies

MOPEC399
Validating a self-report measure for assessing viral suppression in observational studies: an analysis of linked survey and clinical data from the Canadian HIV women’s sexual and reproductive health cohort study

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Background: Assessment of viral suppression is essential toward evaluating progress on Treatment as Prevention (TasP) goals. Without laboratory data measuring viral load (VL), observational studies rely on self-report in surveys but the accuracy remains unclear. We assessed the validity of a self-reported measure of undetectable VL to assess viral suppression among women living with HIV (WLHV).

Methods: We used survey data from WLHV (216 years) enrolled in the Canadian HIV Women’s Sexual and Reproductive Health Cohort Study (CHWOS) in British Columbia (BC), Canada. The only study province (of three) where linkage to clinical data was possible through the BC Centre for Excellence in HIV/AIDS (a population-based registry capturing 100% of VL data in BC). Self-reported undetectable VL was assessed by the question: “What was your most recent VL, undetectable (i.e. below 50 copies/mL) or detectable (i.e. over 50 copies/mL)?” Laboratory measurements of VL ≥ 50 copies/mL (closest to/before study visit) were the criterion for validity analyses. We measured positive and negative predictive values (PPV, NPV) and likelihood ratios (LR+, LR−) of self-reported undetectable VL.

Results: Survey data were linked to clinical data for 99.7% of participants (n=285); 13 were excluded due to missing self-report data. Median age was 45 (IQR: 37-51); 47% identified as Aboriginal, 36% Caucasian, and 6% African, Caribbean, or Black. 31% and 44% reported recent injection drug use and sex work. 83% were currently on ART and 93% enrolled in HIV care. 84% self-reported having undetectable VL while 82% had clinical data indicating suppression. Women reporting recent illicit drug use and current CD4 < 350 cells/mm<sup>3</sup> were significantly less likely to be virally suppressed. PPV was 94% (95% CI:95-99) indicating 94% of women who self-reported being undetectable truly were. LR− was 0.1991 (SE: 0.0636) and LR+ was 12.4264 (SE: 3.2312).

Conclusions: A brief self-reported measure assessing undetectable VL strongly predict true viral suppression among a cohort of WLHV in BC with a high prevalence of laboratory-confirmed viral suppression. This measure can be used in research settings without laboratory data to assess TasP-related goals.

Modelling the epidemiological impact of large-scale prevention programmes: approaches and results

MOPEC400
Impact of ART rollout on risky sexual behavior among HIV-negatives in rural KwaZulu-Natal, South Africa

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Background: Understanding behavioral response to HIV/AIDS management systems is increasingly vital as the global roll-out of antiretroviral therapy (ART) approaches universal coverage. While behavior change of HIV-positive individuals in clinical care has been studied extensively, there is a lack of robust causal inference regarding the impact of public ART programs on the sexual behaviors of HIV-negative individuals. Risk compensation theory suggests
that ART programs would diminish expected negative consequences of risky sexual behavior, yielding riskier sexual behavior in the HIV-negative population.

Methods: The population for this analysis consists of 3,177 individuals from 2003-2011 who are unmarried, HIV-negative, and born after 1983. Data are from the Africa Centre Demographic Information System, a comprehensive population surveillance system, primarily from annual survey, covering a 478km² rural area of KwaZulu-Natal, South Africa. Six ART clinics were offered to ART and HIV-related services in this region between July 2005 and February 2007. While the locations of these clinics is likely to be endogenous to sexual behavior, this analysis takes advantage of plausibly exogenous variation in the timing of clinic opening. Observations are restricted to individuals living within 2km of clinic, utilizing the differences between observations in open and unopened clinics to make a conservative causal estimate of clinic opening on sexual behaviors. Key outcomes include pregnancy and HIV infection rates, using survey data on beliefs regarding ART efficacy as a test of the risk compensation mechanism.

Results: The main results show an 8.4 percentage point (20%) increase in the probability of being ever-pregnant due to local clinic opening dates. However, there was a 0.6-0.9 percentage point (35%) reduction in the probability of testing HIV-positive within 36 months due to the roll-out. Interactions with belief in HIV efficacy are consistent with a risk compensation effect. Men are more likely to be impacted by risk compensation than women after stratifying on gender.

Conclusions: Risk compensation effects in the general population suggest that purely preventative strategies will become more important as universal coverage is approached in the future. Men in particular for slowing the spread of HIV.

STI control to prevent HIV transmission

MOPEC401
Factors influencing prevalence of HIV/AIDS among men who have sex with men (MSM) aged 18-24yrs in Mtwapa Town, Kilifi County, Kenya

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Background: Men who have sex with men (MSM) in Mtwapa Town, Kilifi County are at high risk of HIV infection. Probability sample surveys to determine HIV prevalence among MSM in Mtwapa are needed to inform prevention and care services.

Methods: In 2013, a cross-sectional survey was conducted among MSM aged 18-24 years old using respondent-driven sampling (RDS) in Mtwapa. Consenting MSM were tested for HIV (Fingerstick rapid test). Population-based prevalence and 95% confidence intervals (CI) were estimated using RDS Analysis Tool (RDSAT).

Results: Among 274 MSM, the median age was 20 years (IQR:19-23 years). Fifty percent of MSM reported not selling sex, while 13.2% reported sex work as their “main occupation”, and another 28.4% reported selling sex in the past two months (but not as their main occupation). Overall HIV prevalence was 19.2% (CI: 12.2-26.3%), while among MSM who did not sell sex HIV prevalence was higher (26.6%, CI: 17.2-35.7%). HIV prevalence was higher among MSM who reported sex work as their main occupation (28.3%, CI: 12.1-42.3%) or selling sex in the past two months (26.6%, CI: 17.2-35.7%), than among MSM who did not sell sex (11.6%, CI: 7.5-18.1%).

Conclusions: HIV prevalence among MSM was high than among Kilifi’s general population aged 15-64 years (8.8%; 2010 KAIS) and highest in male sex workers. Health programs need to address concerns and modify services to meet needs of diverse subgroups of MSM. We recommend continued, periodic surveillance to monitor HIV prevalence among MSM in Mtwapa, and expansion to other areas in Kenya.

Male and female condoms and other physical barriers

MOPEC402
Discordance in unprotected sex reporting among African HIV serodiscordant couples

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Background: For HIV serodiscordant couples participating in prevention studies, couple-level data can be compared to evaluate reporting consistency within couples and potentially provide information about reporting accuracy. We examined the frequency of discordance in reports of condom use among HIV serodiscordant couples enrolled in a HIV prevention trial in Kenya.

Methods: Data were from the Partners PrEP Study, a randomized trial of daily oral PrEP for HIV prevention among HIV serodiscordant couples from Kenya and Uganda. At enrollment all couples were sexually active. Participants separately completed an interviewer-administered standardized questionnaire assessing frequency of sex and condom use at quarterly visits. We used descriptive methods to summarize the frequency of unprotected sex and discordant reports and generalized estimating equations to identify correlates of discordant condom use report. We defined couple-level unprotected sex as any self-reported unprotected sex within a partnership during a study visit.

Results: Of the 4747 HIV-1 serodiscordant couples enrolled in the Partners PrEP Study, 97.8% were married with a median of 7 (interquartile range [IQR]: 3-14) years living together and 2 (IQR 1-4) children together. 42.9% of couples reported discrepant condom use at ≥1 visit during study follow-up but only 16.4% of the reports were different by ≥3 acts (figure).

Additionally, 12.1% of follow-up visits had discordant reports about condom use during the last sex act with study partner. Couples with HIV infected female partners (adjusted odds ratio [aOR] = 1.14, 95% confidence interval [CI] 1.01-1.29), currently pregnant (aOR=2.28, 95% CI 2.05-2.53), children together (aOR=1.25, 95% CI 1.03-1.52) and having more sex together (aOR=1.09, 95% CI 1.08-1.1, for each additional sex act), were more likely to have at least one partner report unprotected sex.

Conclusions: Although discordant reports on condom use among HIV serodiscordant partners were frequent, the discrepancies were small and not likely to have substantial effect on perceived level of need for biomedical HIV prevention.
Male circumcision

**MOPEC043**

**Satisfaction and discomfort in PrePex™ device circumcision in Mozambique: programmatic implications**

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**Background:** Device circumcision could reach greater numbers of males with fewer human resources and surgical capacity than conventional surgery. As a result, devices may be important circumcision tools in high priority countries like Mozambique, where shortages of medical providers and infrastructure have limited progress to date. Because device circumcision requires men to wear the device for one week, acceptability among prospective clients is critical. This study describes acceptability of the PrePex™ device in an introductory study in Maputo, Mozambique.

**Methods:** Healthy, HIV-negative males, aged 18-49 years who presented for surgical circumcision at a Maputo clinic were asked to participate in a study examining the acceptability of a circumcision device. Consenting males received medical screening and genital examination to determine that they were in good physical health and eligible for device circumcision. Routine clinical forms and self-administered surveys were used to collect data at various times during the circumcision process. A visual analog scale was used to measure pain intensity. Data were analyzed using statistical software.

**Results:** 504 men received device circumcision between May and July, 2013. Device placement was painless for 98.2% of males. During removal 38.9% reported intense but brief pain and 44.6% moderate pain. Despite that, satisfaction with placement and removal was nearly equal with 91.5% and 93.8% of males very satisfied or satisfied, respectively. Clients were asked about comfort while wearing the device for one week. Most males (51.9%) were very comfortable or comfortable with the device in situ but 38.0% were uncomfortable or very uncomfortable. The most common difficulties with the device in situ were painfull erections (29.1%), urination (16.4%) and hygiene (16.1%). Nearly one-quarter reported no difficulties. By the final clinic visit, 49 days post-device placement, 94.6% were very satisfied or satisfied with the procedure.

**Conclusions:** High levels of satisfaction were reported for device circumcision, despite the pain noted during removal and some specific challenges with the device in situ. Give the programmatic advantages and acceptability among males in this study, Mozambique should consider an integrated service delivery model that combines device circumcision when clinically appropriate as an additional option to conventional surgical circumcision.

**MOPEC040**

**Satisfaction and discomfort in PrePex™ device circumcision in Malawi**


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**Background:** Male circumcision programs in Malawi target more than 2 million procedures over 5 years. Non-surgical devices present an alternative to surgery where health infrastructure and resources are limited. This study aims to assess the safety, feasibility, and acceptability of the PrePex device for adult male circumcision in Malawi.

**Methods:** A prospective single-arm cohort study was conducted at three sites (one urban fixed, one rural fixed, one rural tent) in Malawi. Twelve providers were trained and enrolled, including registered nurses, clinical officers, nurse midwife technicians and a medical assistant. Confidence intervals were corrected for clustering at the clinic-level, and adverse event (AE) outcomes were stratified to incllude/exclude pain measures to be more comparable with previous studies.

**Results:** Among 937 men screened, 129 (13.6%) did not meet inclusion criteria. 13 (1.4%) withdrew before device placement, and 791 (84.4%) men received the PrePex device. The majority of participants were under the age of 30 (88.8%). Moderate and severe AEAs totaled 6.6% including pain [95% Confidence Interval (CI): 3.2-13.0], and 3.5% excluding pain (95% CI: 2.4-5.1). Severe AEs included insufficient skin removal requiring surgical correction (n=4) and early removal (n=4). Among early removal cases, 1 had immediate surgical circumcision, 1 had surgery after 48 hours when swelling subsided, 1 declined surgery, and 1 did not return to our site though presented at a nearby clinic. More than half of men (51.5%) reported odor while the device was in place, however few (2.2%) stated that they would not recommend the device to others due to odor. Median levels of reported pain were 2 [IQR 2-4] during application and removal, and 0 [IQR 0-2] at all other time points. At each visit of the 5 visits, >90% of participants stated that they were satisfied with the procedure and results.

**Conclusions:** Continuous Quality improvement approaches in service delivery impact greatly on the SMC service outcomes.
MOPEC406
Effectiveness of a quality improvement strategy on the quality of voluntary male medical circumcision services: The Ugandan experience

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Background: Ensuring high quality voluntary medical male circumcision (VMMC) services is essential for the realization of the HIV transmission prevention impact of VMMC and increased demand for the service. The objective of this paper is to document Uganda’s experience in improving the quality of VMMC services through integration of a quality improvement (QI) strategy in VMMC services.

Methods: In a before-after design, the quality of VMMC services were assessed at two points in time: at baseline in 2013 and follow-up in 2014, where training in QI approaches and onsite coaching and mentorship of VMMC service providers were included in 21 VMMC sites in 20 districts of Uganda. Improvement in VMMC service quality was measured through observations of 126 VMMC procedures and review of 13,581 and 11,173 client records at baseline and at follow-up, respectively. Percent scores on quality at baseline and follow-up were generated using the Ministry of Health VMMC quality assessment and performance indicator tools and compared.

Results: Overall, the quality of management systems and supplies for VMMC services increased from 44.3% and 52.5% at baseline to 81.9% and 70.1% (p<0.001) at follow-up, respectively. Health education and HIV testing services improved from 63.1% and 61.5% at baseline to 88.5% and 90.3% (p<0.001) at follow-up, respectively. The quality of the surgical technique increased from 75.8% at baseline to 94.8% (p=0.001) at follow-up. Monitoring and evaluation and infection prevention services improved from 58.2% and 73.1% at baseline to 80.9% (p=0.001) and 87.2% (p=0.012) at follow-up. The proportion of VMMC clients with all eligible follow-up visits at sites increased from 76.8% at baseline to 62.1% (p=0.001) at follow-up. The identification of moderate-severe adverse events increased from 0.24% at baseline to 0.69% (p<0.001) at follow-up.

Conclusions: Our findings suggest that integration of a carefully designed QI strategy into VMMC service delivery may help to achieve high-quality VMMC services. Improved client follow-up enables early identification of adverse events. Such measures are needed for increased efficacy of VMMC services and sustainable high demand for the service.

MOPEC407
Satisfaction with receiving voluntary medical male circumcision services in Nyanza, Kenya: a cross-sectional survey

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Background: Male circumcision is an important component of a comprehensive multi-faceted national HIV prevention policy aimed at reducing the risk of HIV acquisition and ultimately reducing HIV in the general population. Though voluntary male medical circumcision (VMMC) services are free-of-charge at all stages of client care, strategically set targets for its minimum package are not being met. The goal of this study was to measure the level of satisfaction among circumcised clients, determine facilitatory and inhibitory factors of VMMC follow-up uptake, and elicit opinions on how VMMC services can be improved.

Methods: Between December 2012 and September 2013, men who received VMMC services at one of five public facilities in Nyanza Province were recruited to participate in a telephone interview between the 21st and 31st day after surgery. An experienced research nurse called once follow-up visit and administered a structured questionnaire. Descriptive analyses were conducted using SPSS. Qualitative data on facilitatory and inhibitory factors and opinions on improving VMMC were coded, grouped, and analyzed using NVivo software.

Results: Of 1653 males screened to participate, 277 eligible participants were enrolled in the study. Almost half of the participants (45%) were between 18 and 25 years of age and 40% had completed secondary education. The most common response was somewhat satisfied with pre-operative counselling (33.9%), theatre services (37.2%), and the discharge process (37.6%). Half (49.5%) of participants were ‘very satisfied’ with the outcome of their surgery. Health education/instruction during counselling (31.4%) was the main motivation for returning for follow-up appointment while occupational engagement and presumption of healing (54.3%) was the main inhibitory factor. Respondents advocated for the introduction of client compensation, nationwide VMMC roll-out, and intensified mobilization to improve service delivery.

Conclusions: Men are generally satisfied with VMMC services; improvement is required to ensure VMMC targets are being met. Several factors were found that facilitate and inhibit the holistic care of clients. This study has highlighted areas that health care partners and policy makers could consider to improve VMMC service provision.

MOPEC408
Scaling up of voluntary medical male circumcision (VMMC) services for HIV prevention in South Western region of Uganda

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Background: Studies have suggested that scale-up of voluntary medical male circumcision (VMMC) to 80% of eligible men in developing countries with generalized HIV epidemics could avert up to 3.4 million new HIV infections and save up to $16 billion in treatment costs by 2025. SouthWest (SW) Uganda has an HIV prevalence of 8.0% and circumcision is not common place among its population. In 2010, the country’s Ministry of Health (MOH) targeted reaching 80% of eligible men (769,469) with VMMC services by 2016 to positively impact HIV prevention. Since 2011, The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) a lead on the USAID-STAR SW project, in partnership with the Uganda MOH, provided support to ensure effective and accessible VMMC services to 48 facilities across all 13 districts in SW Uganda. Program performance reviews conducted by EGPAF to ensure promising practices in program strategy were utilized to ensure program implementers were on track to meet targets.

Methods: A systematic review of monthly data generated from site-level VMMC registers was conducted by EGPAF in 2012. We disaggregated and analyzed data from the VMMC registers by service delivery model: site-based or targeted outreach models over time to determine the contribution of each model to VMMC outcomes. After observing that outcomes yielded more numbers, we then deliberately focused on this model hence the progressively increasing service outputs. Site-based VMMC involves offering those services to clients as they visit a hospital whereas targeted outreach VMMC are offered at lower-level health sites by traveling hospital staff (who visit these outpatient clinics) bringing surgical equipment to provide services to community residents following community sensitization/advertisements in the catchment area of the sites.

Results: The vast majority of circumcisions in SW Uganda were accomplished through targeted outreach: 85% ([193,377/229,277]) of all circumcisions performed in 2011-2014 occurred through targeted outreach. See Table; Progress of VMMC service utilization in SW Uganda (2011-2014)

Conclusions: Targeted outreach significantly contributed to reaching VMMC program targets. This observation has been used to inform district health authorities to create greater buy-in and demand around targeted outreach VMMC. Further analysis is needed to identify challenges around site-based health facility-based circumcision.

<table>
<thead>
<tr>
<th>Period</th>
<th>N of men circumcised in 48 VMMC Site-Based clinical services</th>
<th>N of men circumcised in Targeted Outreach clinical services</th>
<th>Total VMMC Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>1,562</td>
<td>1,279</td>
<td>2,861</td>
</tr>
<tr>
<td>2012</td>
<td>10,849</td>
<td>22,687</td>
<td>33,336</td>
</tr>
<tr>
<td>2013</td>
<td>14,774</td>
<td>66,211</td>
<td>80,985</td>
</tr>
<tr>
<td>2014</td>
<td>8,985</td>
<td>103,210</td>
<td>112,095</td>
</tr>
<tr>
<td>Total</td>
<td>35,090</td>
<td>193,377</td>
<td>228,467</td>
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</table>
MOPEC409
Projected costs and impacts of increasing coverage of 20- to 29-year-olds as voluntary medical male circumcision is scaled up in Zimbabwe

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Background: Most countries scaling up voluntary medical male circumcision (VMMC) for HIV prevention have aimed to increase coverage to 80% among 15–to 49-year-olds. However, VMMC implementers have reported that the majority of clients are ages 10 to 19, with proportions of clients ages 20 and above decreasing over time. This suggests that high coverage among men ages 20 and older may not be achievable. A team from the USAID- and PEPFAR-supported Health Policy Project created more realistic scale-up scenarios based on trends in implementation data from Zimbabwe and examined the potential costs and impacts of increasing efforts to recruit clients ages 20 to 29.

Methods: Zimbabwe VMMC program data were used to examine historical trends in male circumcision coverage by age and project these trends into the future. The projection informed a base scenario supposing that over five years, it would be possible to achieve 80% circumcision coverage among males ages 10-19 and to increase coverage by 25%, 15%, and 10% among males ages 20-24, 25-29, and 30-49, respectively. Two other scenarios assumed that the program could double or triple the increase in coverage among clients ages 20-29 by doubling or tripling the effort (represented as the unit cost in the model), respectively, with a maximum circumcision prevalence of 95% for any age group. The DMNPPT 2.0 model for Zimbabwe was used to project costs and impacts, assuming a VMMC unit cost of $79 and a discount rate of 3%.

Results: Increasing circumcision coverage among men ages 20-29 averts more HIV infections. The number of VMMCs required to avert one infection over 15 years decreases as coverage increases in this age group. Assuming that effort (unit cost) is directly related to the increase in coverage among this age group, the cost per HIV infection averted in the 2x scenario is less than the base and 3x scenarios.

Conclusions: Under these assumptions, doubling the effort to attract clients ages 20-29 leads to increased cost-effectiveness of the program. The overall cost and impact of the program also increase. Programs should measure the relationship between increased effort and increased ability to attract this age group.

MOPEC410
Male circumcision and foreskin cutting practices may explain regional variations in HIV prevalence in Papua New Guinea

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Background: Male circumcision (MC) has been shown to prevent heterosexual HIV acquisiiton in men. Epidemiological evidence from heterosexually driven epidemics indicates that populations with relatively high MC prevalence have relatively low HIV prevalence. Papua New Guinea (PNG) is an extremely diverse nation of 7 million people that speak over 800 languages with myriad socio-cultural practices, including MC and different forms of penile foreskin cutting. PNG has an estimated general adult HIV prevalence of 0.6-0.8% but there are significant variations in prevalence by geographical region and in different sub-populations.

Methods: Self-reported data on male circumcision and penile foreskin cutting were collected from 853 men in four provinces and used to construct maps indicating the prevalence of cutting in each of the country’s four regions. National Department of Health HIV surveillance data were used to construct similar maps indicating variations in HIV prevalence by region.

Results: The prevalence of male circumcision varied from 8-9% in Southern and Highlands Regions, to 13% in Momase, and 23% in New Guinea Islands (NGI). Dorsal longitudinal foreskin slit was the most common form of penile cutting (Momase, 58%, NGI, 50%, Highlands, 45%, and Southern, 42%). The proportion of men without a cut was highest in Southern (50%) and Highlands (46%) Regions, and lowest in Momase (29%) and NGI (27%). Estimated adult HIV prevalence was 1.17%, 1.02%, 0.63% and 0.61% in Southern, Highlands, Momase and NGI Regions respectively. Male circumcision and longitudinal dorsal slit were strongly associated with HIV prevalence and able to explain 95% of the observed geographic variability in HIV prevalence in PNG (p<0.01).

Conclusions: The geographical distribution of HIV infection in PNG appears to be closely correlated with the distribution of male circumcision and other forms of penile foreskin cutting. Given that complete dorsal longitudinal foreskin slit results in an appearance almost identical to that of MC we hypothesise that this form of foreskin cutting may confer a similar level of protection against HIV acquisition in men and thereby help explain the geographical distribution of HIV in PNG.

MOPEC411
Dorsal longitudinal slit of the penile foreskin may protect men against HIV acquisition in Papua New Guinea

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Background: Papua New Guinea (PNG) is a diverse nation with myriad socio-cultural practices, including male circumcision (MC) and different forms of penile foreskin cutting. In earlier research we found that (a) foreskin cutting practices are common and widespread; (b) complete dorsal longitudinal foreskin slit results in an appearance almost identical to that of MC (Figure 1); and (c) variations in HIV prevalence by geographical region are closely correlated with the distribution of penile cutting practices in PNG. These findings led us to investigate the association between penile foreskin cutting and HIV infection in more depth in this setting.

Results: The prevalence of male circumcision varied from 6% in Southern and Highlands Regions, to 14% in Momase, and 76% in New Guinea Islands (NGI). Dorsal longitudinal foreskin slit was the most common form of penile cutting (Momase, 58%, NGI, 50%, Highlands, 45%, and Southern, 42%). The proportion of men without a cut was highest in Southern (50%) and Highlands (46%) Regions, and lowest in Momase (29%) and NGI (27%). Estimated adult HIV prevalence was 1.17%, 1.02%, 0.63% and 0.61% in Southern, Highlands, Momase and NGI Regions respectively. Male circumcision and longitudinal dorsal slit were strongly associated with HIV prevalence and able to explain 95% of the observed geographic variability in HIV prevalence in PNG (p<0.01).

Conclusions: The geographical distribution of HIV infection in PNG appears to be closely correlated with the distribution of male circumcision and other forms of penile foreskin cutting. Given that complete dorsal longitudinal foreskin slit results in an appearance almost identical to that of MC we hypothesise that this form of foreskin cutting may confer a similar level of protection against HIV acquisition in men and thereby help explain the geographical distribution of HIV in PNG.

[Figure 1]

Methods: A prospective study among men attending voluntary HIV counselling and testing (VCT) clinics at six sites in the highlands region of PNG is underway. Following completion of informed consent procedures, participants undergo a face-to-face interview in which socio-demographic, behavioural and clinical information are collected, and a physical examination conducted in which foreskin cutting status is verified and categorised according to the degree of exposure of the glans penis. In addition to onsite HIV testing, participants provide venepuncture and urine specimens for offsite laboratory-based herpes simplex type-2 and syphilis serology, and polymerase chain reaction for chlamydia, gonorrhea and trichomona infections.

Results: Among 524 men enrolled to end-2014, 323 (62.0%) were uncut, 153 (29.2%) had a complete dorsal slit; 38 (7.1%) a partial dorsal slit; and 6 (1.1%) had MC. The prevalence of HIV was 9.3% overall (49/524) and was greatest among uncircum men (36/323, 11.1%). Uncut men and those with a partial cut (in which the foreskin still covers part of or all of the glans in the non-erect penis) were significantly more likely to have HIV infection compared to men with a complete dorsal longitudinal slit or full MC in unadjusted and adjusted analyses (Table 1).
Conclusions: Alternative forms of penile foreskin cutting that result in complete exposure of the penile glans and an appearance similar to MC may protect men against HIV acquisition. The final results of this study (expected end-2015) are likely to have implications for HIV prevention policy in countries where alternative forms of foreskin cutting are prevalent.

**MOPEC412**

**Impact and cost of including adolescents ages 10-19 in programs to scale up voluntary medical male circumcision in South Africa**

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Background: In 2011, the WHO and UNAIDS released a strategic action framework that set a goal of scaling up male circumcision to prevent at least 80% among males ages 15-49 by 2016 in fourteen countries with generalized HIV epidemics and low prevalence of male circumcision. The 15-49 year age group was chosen because it includes the vast majority of sexually active males. As voluntary medical male circumcision (VMMC) programs were scaled up, implementers in these countries found that although the intended demand creation audiences were adults and the majority of clients accessing services were adolescents 10-19.

Methods: A process evaluation was conducted to help interpret VMMC uptake findings from a cluster-randomized trial conducted with 1226 male adolescent Zimbabwean students from March to July 2014. The process evaluation explores perceptions of VMMC's, acceptability and implementability of the MTC+ intervention, influential factors in deciding whether to undergo VMMC, the role of incentives (USD 5 value) in creating demand for VMMC, and to see if there was any evidence of coercion. The process evaluation includes 20 in-depth interviews (IDIs) with participants and 7 IDIs with MTC+ coaches, and structured observation of programme implementation.

Results: IDIs suggest participants enjoyed the educational session because they highly valued hearing their coaches' personal experiences with VMMC and connected with the soccer theme. Logistic regression analyses indicated that participants' decision to undergo VMMC was negatively influenced by their coach's positive beliefs about VMMC, while others did not feel it was influential. The IDIs with participants do not show any evidence of coercion.

Conclusions: This study provides strong evidence of MTC+’s effectiveness and acceptability in Bulawayo schools. If the intervention’s effectiveness remains consistent at scale, the MTC+ intervention could generate substantial new VMMC demand among adolescent males and should be included in a package of effective demand creation tools.

**MOPEC413**

**A sport-based intervention to increase uptake of voluntary medical male circumcision among adolescent male students in Bulawayo, Zimbabwe: process evaluation**

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Background: Three randomized controlled trials have shown that VMMC reduces female-to-male transmission of HIV by 50-60%. Mathematical models estimate that, between 2011 and 2025, more than 3.3 million new HIV infections (570,000 in Zimbabwe alone - 42% of the projected new infections) could be averted through increased scale-up and uptake of VMMC. Despite progress in supply scale-up, Zimbabwe is falling well short of its target of 80% VMMC coverage. In this context, Grassroot Soccer developed “Make the Cut+” (MTC+), a short, scalable intervention facilitated by circumcised “coaches” and targeting 14-19 year-old male students in secondary schools in Bulawayo, Zimbabwe. MTC+ consists of a 60-minute soccer-themed educational session and logistical, behavioral reinforcement in the form of follow-up phone calls, coach accompaniment to the clinic, and small soccer-based incentives.

Methods: A process evaluation was conducted to help interpret VMMC uptake findings from a cluster-randomized trial conducted with 1226 male adolescent Zimbabwean students from March to July 2014. The process evaluation explores perceptions of VMMC’s, acceptability and acceptability of the MTC+ intervention, influential factors in deciding whether to undergo VMMC, the role of incentives (USD 5 value) in creating demand for VMMC, and to see if there was any evidence of coercion. The process evaluation includes 20 in-depth interviews (IDIs) with participants, 7 IDIs with MTC+ coaches, and structured observation of programme implementation.

Results: IDIs suggest participants enjoyed the educational session because they highly valued hearing their coaches’ personal experiences with VMMC and connected with the soccer theme. Logistic regression analyses indicated that participants’ decision to undergo VMMC was negatively influenced by their coach’s positive beliefs about VMMC, while others did not feel it was influential. The IDIs with participants do not show any evidence of coercion.

Conclusions: This study provides strong evidence of MTC+’s effectiveness and acceptability in Bulawayo schools. If the intervention’s effectiveness remains consistent at scale, the MTC+ intervention could generate substantial new VMMC demand among adolescent males and should be included in a package of effective demand creation tools.
Conclusions: While men who are 25 years and above are accessing MMC services, they may be at risk of being identified with an AE post-circumcision. It is possible that individuals who do not speak the local language may not fully understand the post-procedure instructions. Tailored age appropriate counselling in different languages on sexual abstinence post-circumcision is recommended for those accessing MMC services.

Results: In 2014, 70,047 patients started ART in Brazil, 27% more than the 55,721 patients who initiated ART in 2013. Approximately 36% initiated ART with CD4 count higher than 500 cells/mm³, what represented a twofold increase of the proportion observed in 2013. Consequently, the median CD4 count at treatment increased 26%, from 345 in 2013 to 439 cells/mm³ in 2014. Moreover, viral suppression rate among patients who started ART with CD4 count higher than 500 cells/mm³ in 2014 was 92%, higher than the average of 88% observed in the same year.

Conclusions: One year after TaSP implementation in Brazil, the highest increase in the amount of PLWHA starting ART in Brazilian history could be observed. Similarly, early ART initiation was significantly improved. Moreover, this study showed a higher suppression rate in patients who started ART with CD4 count above 500 cells/mm³ than the average in 2014, that refutes the idea that these patients would present lower levels of adherence to treatment. By implementing innovative national strategies, Brazil shows that it may not only succeed in achieving the 90-90-90 goals by 2020 but also contribute to the end of the world epidemic levels of HIV/AIDS by 2030.

MOPEC415
Improving quality of voluntary medical male circumcision services thorough mentorship and coaching: an experience of East Central Uganda

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Background: The World Health Organization and United Nations Program on AIDS recommend voluntary male medical circumcision (VMMC) to be part of comprehensive HIV prevention package. VMMC is known to reduce the risk of HIV infection by 60% and therefore provides a vital avenue for averting new HIV infections especially the sexually active individuals. To achieve optimum benefit and successful scale of VMMC, there are minimum quality indicators that must be in place to ascertain safety and confidence among the beneficiaries. However, the baseline quality improvement assessments conducted in 2013 at 22 health facilities in East Central Uganda showed that adherence to Ministry of Health (MoH) quality improvement indicators for VMMC services was less than 60% as opposed to the acceptable standard 80% and above.

Methods: From 2013 through to 2014, The Strengthening TB and HIV/AIDS Responses in East Central Uganda (STAR-EC) with funding from USAID conducted onsite monthly mentorships and coaching at 22 VMMC health facilities that offer static and outreach VMMC services. The objective was to ensure that set MoH quality improvement standards are adhered to and sustained. The quality improvement areas on which coaching and mentoring focused on included: management systems; supplies; equipment; environment; registration and utilization of information; education and communication materials; individual HIV testing and counseling; adherence to standard male circumcision; infection control; monitoring and evaluation.

Results: Ministry of Health quality standards for VMMC services improved from below 60% to over 80% in all quality indicators. The VMMC teams developed capacity to conduct continuous self-assessment to sustain quality. There was improvement in day two post circumcision follow up of the beneficiaries by health workers from 40% to over 90% all the 22 health facilities were able to competently respond to any emergency due to the availability of fully constituted emergency kits. Post circumcision adverse events have been maintained at the acceptable limit of less 2%. Conclusions: On-site health facility mentoring and coaching is an effective and cost effective model of improving quality of VMMC services. This also provides a platform for monitoring and evaluating quality of VMMC services in resource limited settings.

Treatment as prevention

MOPEC416
Assessing TaSP implementation one year after the publication of Brazilian national guidelines

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Background: Brazil was the first developing country and the third country in the world to adopt the concept of Treatment as Prevention (TaSP) in its national guidelines. Published in the end of 2013, the new national guidelines presented the recommendation of stimulating antiretroviral therapy (ART) initiation for all people living with HIV/AIDS (PLWHA) irrespective to CD4 count or clinical condition. The objective of this study is to assess TaSP implementation one year after the publication of Brazilian ART guidelines.

Methods: A multiple cross-sectional study was made by analyzing data on antiretroviral dispensation and routine monitoring laboratory tests from two national information systems. Patients who were 18 or more years of age and had the first ART dispensation in life between 2009 and 2014 were selected. Increase rate of new patients on ART, last CD4 count before ART initiation and viral suppression rate (below 1000 c/mL) were analyzed.

Results: In the early arm and 9 participants in the delayed arm failed ART. Time to ART failure and ART failure, potentially increasing the risk of late transmission events. Further studies are needed to evaluate the relationships between VL, time to VS, ART failure, and HIV transmission when ART is used for HIV prevention.

Conclusion: In HPTN 052, early antiretroviral therapy (ART) prevented 96% of linked HIV infections in serodiscordant couples. In this setting, HIV transmission can occur after ART initiation before viral suppression (VS) or after ART failure. We analyzed VS and ART failure in HPTN 052.

Methods: Data through May 2011 (trial unblinding) was analyzed for 1,036 participants who had a viral load (VL) ≥400 at ART initiation (early arm: N=632, CD4 350-550 at ART initiation before viral suppression (VS) or after ART failure. We analyzed VS and ART failure in HPTN 052. Factors associated with a shorter time to ART failure and ART failure, potentially increasing the risk of late transmission events. Further studies are needed to evaluate the relationships between VL, time to VS, ART failure, and HIV transmission when ART is used for HIV prevention.
MOPEC418
Reconciling the individual and community benefits of treatment as prevention through optimizing an HIV testing program
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**Background:** Treatment as Prevention (TasP) provides benefits to individuals and communities, which may be shared disproportionately depending on how TasP is implemented operationally. We sought potential conflicts between individual and community TasP goals through a resource allocation analysis conducted to optimize the HIV testing program in Vancouver, British Columbia.

**Methods:** We carried out resource allocation simulations using a validated system dynamics model of the HIV care continuum in Vancouver. (doi:10.1007/s10729-014-9312-0). The model incorporates the major local testing programs, including high-cost/high-efficiency targeted testing and low-cost/high-efficiency routine testing in high-prevalence settings (HPS), both serving key populations of men who have sex with men (MSM) with 15% prevalence of HIV and the socially linked injection drug user and street-based female sex worker (IDU-FSW) populations with 18% prevalence of HIV. Relatively low-cost/low-efficiency routine testing in acute care serves these key populations as well as the general population with 0.1% prevalence of HIV. The cost of a targeted test is approximately 7 times the cost of a routine test. The optimal strategies for allocating a fixed budget were determined by incrementally reallocating resources until minimum morbidity, mortality or incidence was achieved. We considered HIV morbidity and mortality to represent individual outcomes and HIV incidence to represent community outcomes.

**Results:** Morbidity, mortality and new infections were all minimized when resources were predominantly allocated to routine testing. However, to minimize morbidity and mortality, resources had to be predominantly dedicated to routine testing in acute care, potentially avert 320 AIDS cases, 99 deaths, and 238 new infections. In contrast, minimizing incidence would require 44% of the budget to be allocated to routine testing in HPS and the rest to acute care; this strategy could avert 123 AIDS cases, 65 deaths, and 277 new infections. Further simulations showed that improving linkage to care in HPS to match acute care rates could harmonize individual and community benefits in HPS.

**Conclusions:** Understanding that individual and community benefits of TasP could be shared unequally is important for operational planning and policy. Analysis of the HIV care continuum as a system can uncover important inconsistencies, while optimization techniques can help make better use of scarce resources.

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MOPEC419
Can targeting treatment as prevention to female sex workers in a concentrated HIV epidemic setting lead to local HIV elimination: a modelling study
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**Background:** Burkina Faso has a concentrated HIV epidemic where female sex workers (FSW) are thought to drive HIV transmission. In such settings, targeting antiretroviral treatment (ART) to FSWs could be an efficient strategy for reducing HIV transmission to low levels. The aim of this study was to compare the impact and efficiency of different targeted ART-based prevention strategies.

**Methods:** A dynamic deterministic HIV transmission model was developed using data from the Yerelon FSW cohort in Bobo-Dioulasso and general population surveys obtained from 1987 to 2010. The model categorises individuals into subgroups on the basis of gender and sexual behaviour and stratified FSW into occasional and full-time FSWs. Compared to current ART provision (status quo/SQ), the model estimated the proportion of HIV infections averted (%HIA) or incremental life-years-gained (LYG) per additional person-year of ART (PYA) over 20 years from prioritizing ART to different subgroups, or expanding eligibility to all HIV-infected individuals. The model also estimated the impact of past increases in condom use.

**Results:** Modelling suggests that the scale-up of condom use within commercial sex averted 45% of past HIV infections. Continuing current levels of ART (SQ) over the next 20 years averts 35-47% of new infections compared to no ART, leading to local elimination by 2037. The most rapid decline in incidence is achieved by increasing the annual recruitment on to ART to 80% of all HIV-infected individuals (44-71 %HIA compared to SQ, over 20 years) with local elimination being achieved by 2016. If FSWs were targeted at the same recruitment rate, then a smaller impact (4-35 %HIA is achieved, with local elimination occurring by 2027; however, targeting FSWs is more efficient in terms of LY/GPYA per 100PYA, respectively). Importantly, condom use within commercial sex needs to be maintained at high levels (>80%) for HIV elimination to occur with expanded ART provision to FSWs.

**Conclusions:** Increasing FSW recruitment onto ART could be an efficient prevention strategy for eliminating HIV transmission in concentrated epidemic settings, but should not be undertaken at the expense of existing interventions for FSWs, particularly condom promotion.

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Vaccines

MOPEC420
Parents’ uptake of human papillomavirus vaccine for their children: a systematic review and meta-analysis
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**Background:** Human papillomavirus (HPV), among the most common STIs worldwide, is a causal agent in genital warts, cervical, anal, penile and oral cancers, with morbidity among MSM and persons living with HIV much higher than the general population. We synthesized results from quantitative cross-sectional investigations of parents’ uptake of HPV vaccine for their children to understand rates and correlates of parents’ uptake of HPV vaccine for their children.

**Methods:** We conducted a systematic search of the scientific literature across multiple electronic databases to locate empirical studies that examined rates and/or correlates of parents’ uptake of HPV vaccine for their children. Standardized data extraction forms were used including descriptive information, methods, outcomes/key findings. We performed meta-analysis on studies examining similar correlates of HPV vaccine uptake and calculated effect sizes for each variable, with a random-effects model to compensate for clinical and methodological diversity between studies, following PRISMA guidelines.

**Results:** Out of 284 articles collected, 32 studies (n=334,823) from six countries met inclusion/exclusion criteria, the majority (n=29) from the US. Parental uptake of HPV vaccine for their children ranged from 1.0%-89.0%: weighted mean (WM)=12.8 (SD=21.6), with girls’ uptake (WM=49.9; SD=16.3) higher than boys’ (WM=16.6; SD=6.6; p<.0001). Correlates of uptake included healthcare provider (HCP) recommendation (n=0.54 [95% CI: 0.30-0.72]), parental preventative check-up (n=0.38 [95% CI: 0.21-0.52]), safety concerns (n=0.30 [95% CI: 0.41-0.19]), belief in vaccines (n=0.23 [95% CI: 0.07-0.33]), perceived HPV vaccine benefits (n=0.45 [95% CI: 0.24-0.62]), logistical barriers (n=0.27 [95% CI: 0.42-0.10]), vaccine covered...
by health insurance (n=0.23, 95% CI: 0.03-0.47), HPV vaccine awareness (n=0.25 [95% CI: 0.21-0.29]), HPV knowledge (n=0.11 [95% CI: 0.01-0.21]), and urban vs. rural (n=0.15 [95% CI: 0.02-0.27]).

Conclusions: Low-to-moderate parental HPV vaccine uptake for their children, even lower for boys, and the primacy of HCP recommendation and parental preventive check-ups suggests that parents’ interactions with the healthcare system, particularly HCP, present important opportunities to increase children’s HPV vaccine uptake. Information to address HPV vaccine safety and efficacy, along with interventions to broaden insurance coverage (including boys), reduce vaccine cost, and mitigate logistical barriers may increase uptake.

MOPEC421
Willingness to participate in future HIV vaccine trials among adolescents and young adults (AYA) from the AYAZAZI study in Soweto, South Africa

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Background: South Africa has the highest HIV burden globally; 139,000 new infections occur among 15-24 year olds annually. With a 4.9% HIV incidence among adolescents and young adults (AYA), participation of AYA will be critical in preventative HIV vaccine trials conducted in South Africa. We measured willingness to participate (WTP) in HIV vaccine trials among AYA.

Methods: Baseline interviewer-administered survey data were analyzed for AYA (16-24 years) enrolled in AYAZAZI, a youth-centred, inter-disciplinary cohort study aimed at linking socio-behavioral, structural, clinical, and biomedical data to understand HIV acquisition risk among AYA. AYAZAZI is based at the Perinatal HIV Research Unit, in Soweto, South Africa and began enrollment in November 2014. Study procedures include: a survey, clinical screening and bloodwork. WTP in HIV vaccine trials was assessed using a 3-point Likert scale [very willing, neutral and very unwilling] and compared by gender using Pearson Chi-squared test of proportions. Reasons for WTP in vaccine trials are presented. Statistical analyses were conducted using STATA v.12.

Results: We enrolled 111 participants, median age 18 (IQR: 17-21), 55% female. Forty nine percent were ‘very willing’ to participate in HIV vaccine trials, 21% reported a neutral response, and 22% were ‘very unwilling’. There was no difference in WTP in HIV vaccine trials by gender (p = 0.59). The leading reason for WTP amongst ‘very willing’ participants (n = 59) was “to make a difference and to contribute to new HIV knowledge” (n = 44, 75%). Other reasons included learning about HIV (n = 8) and access to free healthcare (n = 4). The main reason amongst ‘very unwilling’ participants (n = 27) was “being scared of becoming ill” (n = 20, 74%).

Conclusions: Half of participants in a youth-focused cohort reported WTP in future HIV vaccine trials with no significant differences by gender. WTP is motivated by altruistic intentions. Recruitment of AYA in future HIV vaccine trials should emphasize participants’ ability to make a long term difference in decreasing HIV incidence through an HIV vaccine trial. With a large proportion of unwilling participants reporting fears of “becoming ill”, vaccine research efforts should engage AYA in trial planning and communication efforts.

Strategies for identifying key populations

MOPEC422
‘Meeting a sex partner downtown’ as a risk factor for HIV and syphilis infection among MSM and trans women in Lima, Peru: a marker for larger sexual networks?

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Background: Syphilis and HIV are endemic among lower-income MSM and transgender women (TW) in Lima, where current prevention strategies have had low impact. Lima’s population of 10 million has substantial sprawl, but also has a central hub sector with important social gathering locations for the working class, including clubs, bars and bath houses catering to MSM and TW. The objective of this analysis was to determine if meeting a sex partner in downtown Lima is associated with recent STI/HIV infection among MSM and TW.

Methods: High-risk MSM and TW who attended one of two STI clinics in Lima from June 2013 to May 2014 were invited to participate. Data on demographics, sexual risk behaviors and where they met sex partners in the last three months were collected using a computer-based questionnaire. Serologic testing for HIV and syphilis infection was conducted. Associations between recent HIV (reporting an HIV negative test within 6 months) or recent syphilis diagnoses (RPR >1:8) and reporting having met a recent sex partner in downtown Lima were analyzed using and multivariable Poison regression to calculate adjusted prevalence ratios (aPR).

Results: A total of 253 MSM and TW reporting recently meeting a sex partner were surveyed, among these participants 45 (18%) had recent syphilis, 5 (2%) had recent HIV and 2 (1%) had recent HIV/syphilis co-infection. Among participants, 37% recently met a sex partner downtown. Condomless anal sex, number of sex partners, being a sex worker and being a TW were similar in both groups and were not associated with recent syphilis/HIV infection (all p-values>0.05).

Having recent syphilis or HIV infection was higher among MSM/TW who met a recent sex partner downtown (aPR 1.41, 95% CI 0.8-2.5) compared to those who had not met a partner downtown, adjusted for age and sex role.

A. Recent Syphils/HIV infection by MSM and TW residence in Lima.

B. Recent Syphils/HIV infection by where MSM and TW met sex partner.

Conclusions: Meeting a sex partner in downtown Lima indicates links to sex partners outside of participants’ neighborhoods, suggesting broader, more diverse sexual networks. The association between higher prevalence of recent syphilis/HIV infection and reports of meeting sex partners in downtown Lima should be explored with ethnography and potentially lead to prevention strategies focused on this risk configuration.

MOPEC423
Transpinay: understanding the Philippine transgender women towards developing transgender-specific HIV prevention programs and related health services

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Background: Unlike other neighboring Southeast Asian countries, the Philippines do not have a localized term to refer to transgender (TG) persons. In fact, the common local terms “bakla”, “bading” and “bayot” are negatively used to refer to TG women. Even the Philippine Integrated HIV Behavioral and Serological Surveillance (IHBSS) do not disaggregate data for MSM and TG but are lumped together as one population, which creates both a socio-political and behavioral risk issue.

Thus, it is important to look at how TG women themselves define and understand the concept of TG in order to provide a context in developing TG-specific HIV prevention programs and related health services.

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Methods: The method used was facilitating a self-administered questionnaire to forty-six (46) self-identified TG women, and conducted four (4) focus group discussions to TG women members from community-based organizations (CBOs) in Metro Manila, Cebu City and Davao City.

Results: The findings revealed that majority of the respondents/participants, being affiliated with a CBO, defines TG as persons whose gender identity and/or expression does not conform with their sex assigned at birth. Their differentiation of a TG woman from a transsexual (TS) is that the latter is related more to the concept of body modifications such as hormone replacement therapy, collagen injection and implants. Some TG CBOs coined “transpyriy,” “transwomen” and “binabae” as a local term for TG women rather than referring to them as “bakla”. Lastly, in identifying TG women clients in peer education programs, peer educators can use qualifier questions or criteria but always respect the target clients’ gender self-identification - both strategies should complement each other.

Conclusions: The study concludes that the use of local, indigenous and peer terms should be utilized in order to reach the unaware TG women community. Trans-specific health services should include both empowerment of their TG identities and addressing risky behaviors such as “versatile” sexual role and engaging in any form of body modifications, especially those who self-inject hormones and collagens, which is a potential risk to HIV. Lastly, members of TG CBOs should always be part of the consultative process in developing a comprehensive package of trans-health services and programs.

Use of the internet, social media, mobile phones and other e-devices for prevention

MOPEC424

Text messages increased HIV testing among young women in Kenya: a pilot study

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Background: More than half of all HIV infected individuals in Kenya are unaware of their status with young women carrying a disproportionate burden of incident HIV infections. We sought to increase HIV testing in young Kenyan women via a text messaging (SMS) intervention.

Methods: We conducted a randomized quasi-experimental study via SMS to increase HIV awareness among women 18-24 years old who had not tested for HIV in the preceding 12 months. We randomized women attending four technical training colleges in central Kenya. Women at two colleges received weekly SMS on HIV related topics with an option to text back questions to more information while women at the 2 control colleges did not receive any messages. Monthly 9-question SMS surveys were sent to all participants for 6 months to collect data on HIV testing, sexual behavior and HIV risk perception. We used multivariate Cox proportional hazards regression analysis to detect differences in the incidence of HIV testing among women in the intervention group compared to women in the control group.

Results: We enrolled 600 women between September 2013 and March 2014; 300 in each study arm. On average, women were 20 years of age (IQR 19-22). 68% had ever had sex in their lifetime and 73% had never tested for HIV. A total of 355 women reported testing for HIV within the 6 months of follow up: 67% were among the intervention arm and 51% were among the control arm representing a 52% increase in reported HIV testing among women in the intervention arm (95% CI 1.17-1.98, p=0.002) after adjusting for age, number of sex partners, condom use and HIV risk perception.

Conclusions: Use of HIV interventional text messages significantly increased rates of HIV testing among young Kenyan women in this pilot study and should be widely scaled up to have a substantial public health impact.

MOPEC425

Playing it safe: a game-based intervention to prevent HIV among young men who have sex with men in Mexico City

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Background: Gamification modifies attitudes towards activities that individuals are un-motivated to undertake by embedding them in game-like environments, awarding points for targeted outcomes, and using ‘leaderboards’ (relative rankings) and non-financial rewards to create an atmosphere of supportive competition or collaboration. ‘Serious’ games increase participants’ knowledge and self-efficacy skills. We are developing a ‘serious’ game integrated in an online gamification platform to motivate young men who have sex with men (MSM) in Mexico City to learn about HIV/AIDS and get tested for HIV and syphilis, a first in developing settings.

Methods: The intervention is being developed based on findings from six iterative focus group discussions (FGDs) with 42 MSM aged 18-40 years from Mexico City, conducted in 2014-2015. Through prototype testing, FGDs inform the story, design, and specific game elements, and ensure that the intervention is engaging, motivating, and culturally relevant.

Results: We found that young MSM are highly interested in a web-based intervention exclusively for MSM, and positively reacted to gamification elements and principles. The FGDs informed the game element development process and adapted it for the Mexican context. In the game, players’ objectives include persuading virtual partners to have sex, then figuring out how to sexually satisfy them; during this process they learn about the HIV risks associated with different sex acts and practice talking about HIV/AIDS. In addition to the game, the gamified intervention includes recruitment of peers, quizzes, an online forum, and real-world actions (HIV and syphilis testing). Via the gamification platform, these activities are rewarded using a point system and badges for pre-determined accomplishments (e.g., HIV testing, higher scores on quizzes). Participants are motivated to participate and excel by comparing their scores to those of other participants via a leaderboard.

Conclusions: Iterative FGD data helped develop an HIV prevention intervention that leverages men’s sexual curiosity to engage in a playful environment that also communicates pro-health and pro-social messages. The intervention will be piloted for 6 months among 300 MSM; we will assess participants’ engagement, the acceptability and effect of the intervention on participants’ level of knowledge about HIV/AIDS, self-reported safe sexual behaviors, and uptake of testing for syphilis and HIV.

MOPEC426

Variations in recruitment yield, costs, and speed and participant diversity across internet or social media platforms in a global study of HIV/AIDS and HIV testing knowledge

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Background: For a global, internet-based study on HIV/AIDS and HIV testing knowledge among English- or Spanish-speaking, we compared:

(1) the yields, speed of costs of recruitment across 17 internet or social media platforms; and

(2) participant diversity among participants recruited from these platforms.

Methods: English- or Spanish-speaking persons worldwide of any age self-identifying as HIV uninfected were recruited over a six-week period from July to August 2013. Recruits were solicited from internet or social media platforms in English and Spanish to the study website through:

(1) free postings on 13 platforms,

(2) paid advertising or postings on 3 platforms (Amazon Mechanical Turk, Google, and Find-participants); and

(3) separate free postings and paid advertisements in sequential time periods on Facebook.

Conclusions: Use of HIV interventional text messages significantly increased rates of HIV testing among young Kenyan women in this pilot study and should be widely scaled up to have a substantial public health impact.
How effective are innovative strategies that use communication technology in scaling up HIV testing and engaging MSM in HIV awareness?

**A case study from Thailand**

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**Background:** Thailand has faced a rapidly growing proportion of new HIV cases among men who have sex with men (MSM) over the past decade. The HIV testing rate among the MSM population, estimated to contribute 40% of the country's new HIV cases during 2012-2016, is very low at 29%. Only 7% of MSM reached through traditional outreach under Thailand’s Global Fund Round 8 Program received HIV testing. In 2011, The Thai Red Cross AIDS Research Centre launched ‘Adam's Love’, Thailand’s official MSM health project. An innovative model, adamslove.org offers 60% HIV/STI education and 40% entertainment in English and Thai. The campaign features over 300 expert advice videos, a comprehensive HIV prevention package, an entertaining YouTube video series gaining over 1 million views to encourage HIV testing, fashion photography and integrated social media and web message boards for health advice. Video coverage of celebrities getting tested are posted on Adam’s Love social media networks that have gone viral among the MSM community. Billboards are placed in strategic locations promoting safe sex and HIV testing messages. The campaign is linked with The Thai Red Cross AIDS Research Centre, community drop-in centres like RSAT and SWING, and 5 private hospitals in Bangkok to make HIV/STI testing easily accessible.

**Results:** Between Sep 2011 - Dec 2014, Adam’s Love website received 147 million hits, engaged 7,031,618 total visitors (21% repeat visitors), with 8,263,071 page views an average visit duration of 4.58 minutes per visitor. YouTube videos gained over 1 million views for HIV testing, fashion photography and integrated social media and web message boards for health advice. Video coverage of celebrities getting tested are posted on Adam’s Love social media networks that have gone viral among the MSM community. Billboards are placed in strategic locations promoting safe sex and HIV testing messages. The campaign is linked with The Thai Red Cross AIDS Research Centre, community drop-in centres like RSAT and SWING, and 5 private hospitals in Bangkok to make HIV/STI testing easily accessible.

**Conclusions:** Adam’s Love has demonstrated its feasibility in engaging MSM in HIV awareness and testing. Online outreach and innovative strategies can initiate the interest and uptake of HIV/STI testing among MSM in Thailand.

**MOPEC428**

**You care about us:** exploring use of mobile phones to improve retention in care and facility delivery in Tabora, Tanzania

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**Background:** The Supporting Attendance for Facility Delivery and Infant Health (SAFI) Study, launched in November 2014 by EGFPAW, was designed to test interventions to increase adherence to clinic visits, the rates of facility-based delivery, the proportion of HIV-exposed infants (HEI) receiving nevirapine after birth, and the proportion of HEI tested for HIV within 8 weeks of age. Formative research explored the feasibility and acceptability of two interventions: mobile communication using HIV-neutral SMS appointment reminders, and mobile banking systems for transport reimbursement through cell networks in rural areas, a low-literacy population.

**Methods:** Semi-structured in-depth interviews were conducted in 13 health facilities in Tabora, Tanzania. Participants included HIV-positive (n=16) and HIV-negative (n=19) women, and health care workers (n=23) purposely selected for maternal and postnatal care. Audio recordings were transcribed and translated into English. Data were analyzed using MAXQda with comparisons made between groups.

**Results:** Sharing mobile phones is common, often within families. Sample SMS reminders were perceived as helpful and indications of “caring” sentiments from the health facility, with comparisons made between groups. Very few days before a scheduled visit, on the day of the appointment, and again a few days later. Lack of transport money meant women walked to the clinic or waited until they had money. Even small amounts of money to cover transport costs or to buy food to eat while at the facility could incentivize attendance. Most women reported having their own mobile banking accounts or access to one to receive and send money.

**Conclusions:** Results suggest that SMS appointment reminders would be received well and read by most women. Additionally, mobile banking is commonly used, and would be feasible for reimbursing transport costs. These interventions, demonstrating promise in promoting visit adherence, are well-suited for implementation and evaluation in larger-scale operations research.

**MOPEC429**

M-Health, e-Health innovations and social media platforms to optimize HIV/STI test and treat strategies: what is the evidence?

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**Background:** In the field of HIV/STI, innovative Mobile health (m-Health), internet-based (e-Health) and media (i.e., social media, soap operas) based intervention strategies offer novel, creative, out of the box solutions to access, engage, inform, educate, test, treat and link hard to reach populations to care. However, evidence to inform their scale up is limited. A systematic review was conducted to evaluate all innovations to fill this gap.

**Methods:** Two reviewers independently retrieved 1640 citations from databases (i.e., MEDLINE, EMBASE, Cochrane Central, Web of Science). From 40 studies, data on study design, and metrics (patient-centered-acceptability, preference and adherence) and implementation-centered-feasibility and impact) were abstracted.

**Results:** About 75% (3140) studies reported data on HIV, 18% on chlamydia and 3% for each HPV, HSV 2 and Syphilis. About 34 studies evaluated m-Health, 3 evaluated e-Health, and 3 a combination of the two. Within m-health 83% (3130) evaluated a short mes-
MOPEC430
Structures, users, benefits, and barriers of social media for communication about HIV prevention and care: a systematic review

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Background: Conventional public health interventions for HIV prevention are limited in their ability to educate, link to care, and reach the public, particularly members of vulnerable groups who are most affected by HIV and have greater needs for services. Social media has the potential to address these limitations and extend the reach of HIV prevention and care. Lacking in the literature is an examination of the various structures, users, and approaches to using social media to communicate about HIV. The objective of this study was to conduct a systematic review exploring the use of social media to communicate about HIV prevention and care.

Methods: We searched seven databases to locate peer-reviewed studies: additional studies were identified by searching references of systematic reviews. PRISMA guidelines were followed. Study quality was assessed using a tool recommended by the Cochrane Collaboration.

Results: Thirty-five studies met inclusion criteria (figure 1). The majority of studies analyzed the use of pre-existing social media platforms, rather than creating new platforms (83%). Most studies engaged users in high-income countries (79%), the remaining in middle and low-income countries. Most studies included users age 18-40 (88%). Users included people living with HIV/AIDS and individuals from vulnerable groups, including racial and ethnic minorities, men who have sex with men, and low socioeconomic groups. Social media was used to discuss a diverse range of topics related to HIV including information on prevention and treatment, HIV testing, medication adherence, patient notification, and experiences living with HIV. Benefits of using social media to communicate about HIV included greater access to medical information and healthcare providers, increased social and emotional support, and a high level of anonymity, which may promote disclosure and discourse about stigmatized behaviors. Barriers included technology issues, costs, lack of physical interaction and privacy concerns. Studies reported high user satisfaction—platforms were easy to use, useful, and provided access to a diverse range of users.

Conclusions: Growing evidence supports the use of social media as a tool for engaging a range of diverse individuals in a collaborative discourse about HIV prevention and care. More research is needed to understand how social media affects outcomes related to HIV.

MOPEC431
Active and interactive advertising: social media as a recruitment tool for an HIV vaccine trial in Philadelphia, Pennsylvania

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Background: Online and mobile phone based social networking applications have been shown to be valuable tools for recruitment of subjects to interventional clinical trials. During a 3-year recruitment period we utilized multiple online modalities including “active” (email and interactive directed marketing), and “passive” (static side bar ads and online billboards) recruitment. We report more success with active rather than passive methods when recruiting MSM to a phase 2b HIV vaccine trial.

Methods: The University of Pennsylvania HIV Vaccine Trials Unit has utilized passive online recruitment methods including Facebook and Craigslist since July 2010. In December 2011 and October 2012 we began active recruitment with a Web Based Marketing Company (WBMC) and the mobile phone app GRINDR respectively. To analyze the ability of online recruitment methods to engage eligible participants we compare active and passive strategies employed during recruitment for HTN 505.

Results: Online recruitment strategies successfully populated approximately 37% (71/191) of this HIV vaccine trial. While Facebook and Craigslist were employed for 33 months each, WBMC ran for 6 months and GRINDR for 17 24-hour periods. Passive recruitment via Facebook generated 11.1 (365/33) and Craigslist 6.5 (214/33) phone screens per month of use. Active recruitment using WBMC garnered 18 (108/6) and, GRINDR produced 130.5 (233/0.56) phone screens per month. Differences in enrollment by recruitment method followed a similar pattern. Number of enrols per month of use for Facebook and Craigslist were 0.97 (32/33) and 0.36 (123/33) respectively. Active recruitment through WBMC resulted in 1.8 (11/6) while GRINDR returned 8.96 (16/0.56) enrols per month. All online recruitment methods produced recruits who were not significantly different by demographics or risk.

Conclusions: Recruitment via online venues and mobile phone apps is likely to continue to grow. We found that active online recruitment in the form of email and interactive directed marketing through the mobile phone app GRINDR was more successful at engaging MSM than passive recruitment via Facebook and Craigslist. Similarly, more enrols resulted from active recruitment than passive recruitment strategies.

MOPEC432
Utilization of biometric and mobile technology in a community-based combination HIV prevention study

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Background: Various methods exist to recruit and uniquely identify study participants, particularly during follow-up periods. In a low-resource study setting the technological options are limited. Our study, Gender-Specific Combination HIV Prevention for youth in high burden settings (MP3 Youth), in rural western Kenya utilizes biometric technology to uniquely identify participants (youth aged 15-24). We assess the feasibility of using biometric technology for
Integration of HIV prevention services (into reproductive health and STI / care and treatment / other programmes)

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**Background:** Women in sub-Saharan Africa face 2-3 fold higher risk of HIV acquisition during pregnancy/post-partum than non-pregnant women. Home-based HIV testing of their male partners has potential to reduce HIV transmission to women and infants. Evaluating costs of such programs could inform policy-makers as they implement interventions within budget constraints.

**Methods:** We estimated incremental annual costs of providing home-based partner education and HIV testing (HOPE) to couples as part of routine antenatal care in Kisumu, Kenya. Costs were collected from the HOPE Study, a randomized controlled trial where couples received HOPE intervention or standard of care. Couples also received information on facility delivery, exclusive breastfeeding, family planning, and male circumcision. We conducted time and motion studies to estimate number of staff needed for efficient scale-up and to separate research time from program services. Costs and utilization were collected from budgets, government price lists, and staff interviews. Costs (2012 US dollars) collected from a payer perspective were divided into: staff, transportation, equipment, supplies, buildings and overhead, and startup. Capital items were assumed to have 5 years of useful life with 3% discount rate.

**Results:** Costing was conducted onsite in June 2014. Average time to administer the HOPE intervention was 1 hour per couple. Accounting for travel time and home location, we estimated 7,740 couples can be tested annually assuming a program of 12 health advisors and 3 clinic nurses. The incremental cost of adding the HOPE intervention to antenatal care was $30.37, $34.39, and $35.97 for couples testing concordant HIV-negative, HIV-discordant, and concordant HIV-positive, respectively. Staff salaries represented the bulk of costs (65-75%). Under a task shifting scenario, using community health workers reduced costs to $16.89, $21.00, or $20.91 depending on couple status.

**Conclusions:** Home-based testing and education of couples during pregnancy has potential to decrease HIV-associated morbidity and mortality and improve maternal and child health indicators at a cost of $30-36 per couple tested. Task shifting reduces costs to $17-21 per couple tested. These estimates can inform mathematical models evaluating cost-effectiveness of the HOPE program. Our costs are similar other community-based (home and mobile) HIV testing programs found to be affordable in sub-Saharan Africa.
MOPEC435
Partner notification services to identify and refer people living with HIV for care and treatment in Cameroon 2007-14
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Background: Since 2007, the Cameroon Baptist Convention Health Board (CBCHS) has assisted health facilities and community-based HIV testing programs in development of HIV partner notification (PN) services in the Northwest and Southwest Regions of Cameroon with the support of the minister of health as a public health intervention.

Methods: From 2007-14, CBCHS trained 63 health advisors (HA) (nurses, laboratory technicians, social workers, and chaplains) from 16 CBCHS facilities and 53 HA from 26 non-CBCHS facilities (governmental, faith-based and private facilities). HA interview consenting HIV-positive persons (index cases) on their sexual partners in the last two years, to find their sexual partners and inform them of their HIV-exposure. HA collect data on all consenting index cases and their partners which are entered into an Epi-info database for evaluation. HA contact partners, ask about risk of infection, provide pre-test counseling and offer HIV testing in their home or at any agreed upon location. HA educate both index cases and partners on HIV prevention and risk reduction, and refer HIV-positive partners to HIV care and treatment.

Results: From 2007-14, HA interviewed 16,537 consenting HIV-positive persons who provided information on 18,685 sexual partners. HA notified 11,762 (63%) of these partners, of whom 8,421 (72%) were HIV-positive. Of partners tested, 4365 (52%) were HIV-positive, of whom 2713 (62%) enrolled into HIV care (Table 1). Of 2483 persons newly diagnosed with HIV in eight CBCHS facilities, 790 (31.8%) received PN services.

Conclusions: PN HIV prevention in resource-limited settings identifies many partners of HIV-positive persons who otherwise may not be traced, tested, and referred for care and treatment. Significant challenges in PN include HA availability to interview index persons and to contact partners and the inaccurate contact information provided by index cases for their partners.

MOPEC436
Validation of the Denver HIV risk score for targeting HIV screening in Vancouver, British Columbia
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Background: Clinical prediction rules (CPRs) have been shown to potentially reduce the number of individuals who receive unnecessary testing. The Denver HIV risk score is a CPR developed for targeting HIV testing and validated in U.S. clinical settings (Haukoos et al, 2012; PMID: 22431561). The final logistic regression model of the Denver HIV risk score included age, gender, race/ethnicity, sex with a male, vaginal intercourse, receptive anal intercourse, injection drug use, and past HIV testing, and values ranged from -14 to 81. We aimed to validate the risk score in patients attending two publicly funded STD clinics in Vancouver, British Columbia.

Methods: We conducted a multisite, observational, cross-sectional study. Applying the same inclusion criteria and methods used in the derivation of the Denver HIV risk score, we examined electronic records (2000-2012) from 47,175 clinic visits at two sexual health clinics in Vancouver. Each clinic visit was assigned a score based on the variables included in the Denver HIV risk score. Patient visits were stratified into 5 risk groups according to their score: very low (<20), low risk (20-29), moderate risk (30-39), high risk (40-49), and very high risk (≥50). The model’s calibration and discrimination for predicting an HIV diagnosis were examined by the area under the receiver operating characteristic curve (AUC) and the Hosmer-Lemeshow (H-L) statistic. We examined the sensitivity and proportion of patients that would need to be screened at different cutoffs of the risk score.

Results: The prevalence of HIV infection was 0.46% in these clinics. Validation demonstrated good performance: the AUC was 0.80 (95% CI: 0.79-0.81) and the H-L χ2=88.8, 8 df, p<0.05. HIV prevalence within each risk group was: 0% (very low risk), 0.05% (low risk), 0.23% (moderate risk), 0.85% (high risk) and 1.23% (very high risk). HIV testing is recommended for scores of ≥20. The risk score identified HIV cases with a sensitivity of 96% and a fraction screened of 41%.

Conclusions: The Denver HIV risk score performed well in these STD clinic settings in Vancouver, accurately identifying individuals at increased HIV risk, and may be useful for providing individualized estimates of risk as part of routine HIV screening.

MOPEC437
Provider’s role in comprehensive sexual health screening and education for YBMSM aged 15-19
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Background: Young Black men who have sex with men (YBMSM) in the US and abroad are most impacted by high STI/HIV rates. Access to and utilization of accurate comprehensive sexual health information may be limited for YBMSM due to stigma associated with race/ethnicity and gay identity during key milestones of sexual development. Health care providers are uniquely poised to provide sexual health information for YBMSM. We sought to examine experiences of provider-related sexual health care in a sample of YBMSM.

Methods: 50 YBMSM recruited via snowball sampling, venue-based outreach. Adolescent/STD clinics, and Internet social network advertisements (n=185) participated in brief ACASI and 90-minute in-depth interviews about first same-sex sexual experiences/sexual health. Interviews were transcribed verbatim and double coded. Data was analyzed using categorical and contextualizing analytic methods.

Results: Mean age was 17.6 years (SD=1.3). Most (62%, N=31) self-identified as gay or bisexual (34%, N=17). Mean number of lifetime partners 13.3 (SD=2.0, Median=8.5). Mean age at first sex 13.9 (SD=2.6). Most (N=42/84%) had prior HIV test. Nine (18%) reported prior STI diagnosis and three (6%) were HIV-positive.

Talking About Sex - Participants were more comfortable talking about sexual orientation (92%) than first same-sex (96%) and more comfortable sharing sexual health information in research interviews than with medical providers (96%).

Sexuality - Participants had mean Outness Inventory (OI) of 37.2 (SD=16.1) and high OI-score (≥75th %tile) was associated with positive feelings about sharing information about first same-sex. Sexual Health Care - Most (76%, N=38) saw a provider within 6 months. Only 46% (N=23) reported receiving HPV vaccination, 28% (N=14) described anal douching before sex. None described discussing anatomy or sexual health with provider. YBMSM described three needs for comprehensive sexual health - targeted clinical services incorporating mental, minority and sexual health; developmentally appropriate sexual education (regarding anatomy, sexual position, relationships); and support services that connect YBMSM with other gay/bisexual men.

Conclusions: This work suggests providers may be missing opportunities to provide YBMSM with adequate sexual health information. Comprehensive sexual health that addresses clinical care, sexual education and support services for YBMSM and administered by providers is needed.
Efficacy of structural interventions and social protection

MOPEC438
Social, socio-economic and associated clinical benefits of ART exposure among HIV-infected people who use illicit drugs in Vancouver, Canada

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Background: Among people living with HIV/AIDS (PLHIV), there is extensive documentation of the direct clinical benefits of engagement in HIV care. However, very little is known about the possible social, socio-economic and associated clinical benefits of engagement in HIV care, particularly for people who use illicit drugs (PWUD), and whether these benefits are relevant at different stages of the HIV cascade of care, such as initiation of antiretroviral therapy (ART).

Methods: We used longitudinal data from a prospective cohort of community-recruited HIV-positive PWUD, in Vancouver, Canada, a setting of free and universal access to all HIV treatment and care. Participant data were linked to comprehensive HIV clinical monitoring and ART dispensation records. We developed a series of generalized linear mixed effects models, adjusting for potential confounders, to examine whether initial exposure to ART was associated with social, socio-economic and ancillary clinical benefits, including relationship initiation, transitioning out of homelessness, entering employment, and initiating a romantic relationship (AOR: 2.24; 95% confidence interval [CI]: 1.50-3.35); initiating a romantic relationship (AOR: 2.19, 95% CI: 1.23-3.89) and enrolling in addiction treatment (AOR: 3.59; 95% CI: 1.90-6.75).

Results: Between December 2005 and November 2013, of the 755 eligible study participants, 247 (32.7%) self-reported as women and 421 (55.8%) as Caucasian, with 128 (17.0%) initiating ART for the first time during the study period. In final multivariate models, newly initiating ART was positively and significantly associated with transitioning out of homelessness, entering employment, ceasing involvement in high-risk income generation (e.g., street-based income generation, sex work, drug dealing or other illegal activities), and enrolling in addiction treatment.

Conclusions: These findings demonstrate that initiating ART is associated with initiating other transitions whose benefits could support both the clinical management of HIV and improved quality of life across social, socio-economic and drug use dimensions. These results point to the potentially critical role that engagement in HIV care can have in clinical and non-clinical domains of the lives of PHA who use illicit drugs, and supports the scale-up of early initiation of ART among this population.

Combination prevention approaches

MOPEC439
The role of male circumcision and antiretroviral drugs in the evolution of the HIV and HSV-2 epidemics in Orange Farm (South Africa) between 2002 and 2012 (ANRS-12126 -12285)

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Background: Over the past several years, antiretroviral drugs (ARVs) have been used to prevent AIDS, and male circumcision (MC) has been used to prevent HIV among men in Eastern and Southern Africa. We aimed to quantify whether MC and ARVs have impacted the HIV and HSV-2 epidemics, between 2002 and 2012 in Orange Farm, a typical township of South Africa where ARVs are available since 2005 and where MC roll-out has been conducted since 2008.

Methods: Data were collected in four independent cross-sectional surveys conducted in 2002, 2007, 2010 and 2012 from a total of 10,941 participants aged 18-49y. Age at first sexual intercourse, condom use and number of sexual partners were self-reported. Blood samples were tested for HIV, ARVs and HSV-2. Untreated HIV was defined as the prevalence of HIV-positive and ARV-negative participants. Time trends of factors extrapolated over a 10-year period, and contribution of MC to changes in HSV-2 and untreated HIV were computed using age-adjusted linear regression models. The preventive effect of ARVs on the HIV epidemic was estimated by comparing trends in untreated HIV prevalence and in HIV prevalence after excluding all those testing ARV-positive, a proxy of what would have been the HIV prevalence without ARVs in the community.

Results: We observed limited relative changes in sexual behaviors (< ±15%). There was a relative increase in MC prevalence of <9% (95%CI: 7% to 11%), and there was a relative increase in ARVs prevalence of >7% (95%CI: 5% to 11%), among HIV-positive men, and of >123% (+106% to +139%) among HIV-positive women.

Conclusions: These findings demonstrate that initiating ART is associated with initiating other transitions whose benefits could support both the clinical management of HIV and improved quality of life across social, socio-economic and drug use dimensions. These results point to the potentially critical role that engagement in HIV care can have in clinical and non-clinical domains of the lives of PHA who use illicit drugs, and supports the scale-up of early initiation of ART among this population.
**MOPEC441**

Combination prevention intervention: a tool for increasing access to safer sex products and services and improved safer sex negotiation among non-brothel based female sex workers in rural North Eastern Nigeria

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**Background:** Non-brothel based female sex workers operating in the difficult to reach rural areas. These interventions were conducted in the rural communities of Ikole, Ikalar and Uhurrah in Donga Local Government Area of Taraba state, North East Nigeria. It is estimated that 70% of female sex workers in the rural areas are not exposed to learning about safer sex practices and products and services.

**Methods:** With funding from USAID, MSH's Pro ACT project provided small grants to Community Based Organizations to conduct combination prevention interventions targeting non-brothel based female sex workers in difficult to reach rural areas. These interventions were conducted in the rural communities of Ikole, Ikalar and Uhurrah in Donga Local Government Area of Taraba state, North East Nigeria. A total of 45 non-brothel based FSWs were reached with 7 interventions of combination behavioral, structural and biomedical interventions using peer education approach over a period of 12 months.

**Results:**
- After twelve months, average monthly reported cases of unplanned pregnancy declined from 1 pre interventions to 0 post interventions.
- Average monthly reported cases of STIs declined from 7 pre interventions to 2 post interventions.
- FSWs voluntarily demanding for safer sex commodities increased from 9 pre interventions to 37 post interventions.
- Reported cases of new STI infections declined from 1 pre interventions to 0 post interventions.

**Conclusions:** Combination Prevention Intervention when strategically tailored to address the HIV prevention needs of FSWs operating in hard to reach rural areas leads to multi-dimensional positive results. Thus, there is need to strategically design HIV prevention interventions targeting FSWs operating in difficult to reach areas using combination prevention intervention.

**MOPEC442**

What will it take to achieve virtual elimination of HIV transmission in South Africa?

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**Background:** Virtual elimination of horizontal and mother-to-child HIV transmission in South Africa (SA) has been suggested, but there have been few systematic investigations of which interventions are most likely to be most critical to reducing HIV incidence up to 2035.

**Methods:** A mathematical model was developed to simulate the population-level impact of different HIV interventions in SA. Probability distributions were specified to represent uncertainty around 34 intervention parameters, and a set of 1000 parameter combinations was randomly generated by sampling from these distributions. For each of the 1000 parameter combinations, the model calculated expected incidence up to 2035. Correlation coefficients (r) were calculated to assess the sensitivity of the model outputs to each intervention parameter.

**Results:**
- HIV incidence in SA adults (ages 15-49) is expected to decline from 1.4% in 2011-12 to 0.23% by 2035, though with wide ranges of uncertainty (95% CI: 0.05-0.50%).
- The intervention parameters most strongly correlated with future adult HIV incidence are the relative risk of HIV transmission after initiating ART (r=0.81), the level of condom use in non-marital relationships (r=0.40), the reduction in unprotected sexual HIV following diagnosis (r=0.40), the uptake of medical male circumcision (r=0.18) and the year of pre-exposure prophylaxis introduction among youth (r=0.14).

**Conclusions:** Modelled expected HIV incidence is expected to decline from 1.4% to 0.23% by 2035. Correlation coefficients indicate that the model is most sensitive to parameters related to ART uptake, condom use and male circumcision. Reducing pre-partum and intra-partum transmission to infants

**MOPEC443**

Prevalence and correlates of Mycoplasma genitalium among HIV-infected pregnant African women and implications for MTCT

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**Background:** Many sexually transmitted infections (STIs) increase risk of mother-to-child transmission (MTCT) of HIV, but the role of Mycoplasma genitalium (MG) is not known. We determined prevalence and correlates of MG infection in a cohort of HIV-infected pregnant women and determined whether MG infection was associated with MTCT.

**Methods:** Between 1999 and 2005, 510 HIV-infected Kenyan women were enrolled and followed in a perinatal MTCT cohort and received short-course zidovudine for PNCMTCT. Infant perinatal infection was determined at birth and 4 weeks of age by HIV DNA PCR. In this case-cohort design, prevalence and correlates of MG were evaluated in a random sub-cohort. The MG-MTCT association was evaluated in the sub-cohort plus all additional perinatal MTCT cases from the parent cohort.

**Results:** In our random sample of 220 women, 47 women (21.4%) had detectable MG in cervical samples collected at birth and 4 weeks of age. MG-MTCT association was not observed in the sub-cohort, but could not be evaluated in the larger perinatal MTCT cohort.

**Conclusions:** MG-MTCT association was not observed in our cohort, but future studies are needed to elucidate the role of MG in MTCT.
**MOPEC444**

**Higher than expected HIV prevalence and risk factors for newly diagnosed versus known HIV infection in an antenatal clinic in Western Kenya**

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**Background:** In generalized epidemics, high HIV testing and counselling (HTC) rates are essential to track HIV disease burden and monitor antiretroviral therapy (acART) scale-up. New diagnoses and increased antiretroviral coverage may accelerate progress towards elimination of mother-to-child HIV transmission (EMTCT). Understanding the current prevalence and risk factors for HIV infection among women at the first antenatal care (ANC) visit may inform EMTCT strategies.

**Methods:** This was a nested cross-sectional study conducted among pregnant women at first ANC visit participating in a randomized trial comparing home-based versus clinic-based couple education and HTC. Women were interviewed and then offered HTC if they were not known to be HIV infected. HIV infected women were categorized as “known HIV positive” if they knew their status prior to pregnancy; and “newly diagnosed HIV positive” if they had no prior HTC or their previous test was negative. Proportions of newly diagnosed, known, and overall HIV positive women were determined and compared to regional and national HIV prevalence. Using logistic regression we determined risk factors for overall, newborn and known HIV diagnoses.

**Results:** Of 600 women, 107 (17.8%) were HIV infected. This is greater than twice the national and regional HIV prevalence, which are 5.8% and 15% respectively. Majority of HIV infected women were newly diagnosed (n=60, 56%) compared to known HIV positive (n=44%), HIV negative women had a median age of 24 (interquartile range 21, 28) years. Compared to HIV infected women, HIV infection during the first ANC visit was higher if their gravidity age was > 25 years (Odds ratio [OR] 2.5; 95% confidence interval [CI] 1.61-3.87), if partners age was >30 years (OR 1.92; 95% CI 1.24-2.97) and parity higher (OR 1.20; 95% CI 1.05-1.37). Risk was lower among those with > secondary education (OR 0.39; 95% CI 0.18-0.79). Newly diagnosed HIV positive women were less likely to report previous HIV testing (OR 0.28; CI 0.12-0.63) while known HIV positive women were more likely to report more lifetime sexual partners (OR 1.48 95% CI 1.21-1.80).

**Conclusions:** In this high-HIV burden, low-resource setting, HIV prevalence including newly diagnosed is higher than the national or regional prevalence. To achieve EMTCT novel strategies aimed at increasing individual and couple HTC before pregnancy are needed.

**MOPEC445**

**Successes and failures of vertical HIV transmission prevention efforts in Canada: evidence from the Canadian Perinatal HIV Surveillance Program (CPHSP)**

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**Background:** The CPHSP collects data annually on HIV infected mothers and their infants from 22 Canadian pediatric and HIV centres across the country. The objective of this report was to describe factors associated with VT in Canada since 2004, post-implementation of routine prenatal HIV testing programs in all provinces/territories.

**Methods:** All children born in Canada to HIV-infected mothers from 2004-2013 in the CPHSP database were reviewed. VT rates are based on data of MP delivered in Canada and identified within 3 months after birth; infants identified beyond 3 months of birth are tracked separately.

**Results:** Among 1966 MIPs, 1984 (99%) were identified antenatally or within 3 months of the child’s birth. Of those, 93% were prescribed antenatal combination antiretroviral therapy (acART), 95% >4 weeks before delivery, and 85% ≤4 weeks before delivery. Intrapartum intravenous zidovudine was administered to 88% of mothers and 34 weeks of antiretroviral prophylaxis was given to 96.4% of neonates. The VT rate for this cohort was 1.7% (33 infants); the rate was 14.6% with no acART, 8.6% with ≤4 weeks of acART before delivery and 0.12% with >4 weeks of acART before delivery. Of two VT cases that occurred despite >4 weeks of acART, one was associated with poor maternal adherence, the other with incomplete virologic suppression despite good adherence. An additional 12 infected infants were identified after 3 months of age. Eight of these 12 mothers were Canadian born (4 white, 4 Aboriginal) and 11/12 delivered in provinces with opt-out antenatal screening programs. On multivariate analysis of all 1996 MIPs, receipt of opn/≤4 weeks versus >4 weeks of acART was significantly associated with earlier year of birth, province/territory of birth and maternal risk acquisition category (28.4% IDU; 11.6% sex; 12.3% other) (adj p<0.01).

**Conclusions:** VT continues to occur in Canada despite a free universal access health-care system. The observations that 12/45 infected infants were identified after 3 months of age and that 11/12 of those were in provinces with opt-out prenatal screening programs suggest that lack of access to routine prenatal care is a major issue contributing to ongoing VT in Canada.

**MOPEC446**

**HIV positivity among HIV exposed infants and turnaround time (TAT) for EID results in Iringa and Njombe regions: analysis of results from DNA-PCR laboratory and follow-up on ART initiation**

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**Background:** Njombe and Iringa regions have the highest HIV prevalence in Tanzania. Effective and quality pediatric HIV treatment requires early diagnosis, prompt initiation of ART, and frequent monitoring to ensure retention in care. According to UNAIDS 2013 Global Report, the percentage of infants born to HIV infected mothers who becomes HIV infected is 15%. Further studies report that without ART, 52% of perinatally HIV-infected infants and 26% of postnatally HIV-infected infants will die within 12 months. The main objective of this analysis was to ascertain effectiveness of PMTCT interventions as well as TAT at various health delivery and testing points.

**Methods:** Data for all EID samples received between June 2013 and February 2014 were obtained from zonal DNA-PCR laboratory. The collected data had all information from when the sample was collected, age of the infant at sample collection, date of birth of the infant, date at which the results were out at the DNA-PCR laboratory and HIV test outcome. Further more follow-up was made to the facility level for those infants diagnosed HIV+ to determine if and when they were started ART.

**Results:** Between June 2013 and February 2014 a total of 1357 samples were tested at Mbeya DNA-PCR laboratory of which 70 samples (5%) tested positive for HIV. Follow up of these tested positive for HIV revealed that 31 infants (4%) were already initiated on ART, 12 infants (17%) had already died before the results while 27 (38%) infants were still being tracked by volunteers for ART initiation. Turnaround time calculations revealed an average of 41 days between DBS collection to when results reached health facilities. Further more follow-up was made to the facility level for those infants diagnosed HIV+ to determine if and when they were started ART.

**Conclusions:** Between June 2013 and February 2014 a total of 1357 samples were tested at Mbeya DNA-PCR laboratory of which 70 samples (5%) tested positive for HIV. Follow up of these tested positive for HIV revealed that 31 infants (4%) were already initiated on ART, 12 infants (17%) had already died before the results while 27 (38%) infants were still being tracked by volunteers for ART initiation. Turnaround time calculations revealed an average of 41 days between DBS collection to when results reached health facilities.

**Conclusions:** Mother to child HIV transmission is showing decline in Tanzania as shown by this analysis, 5% against 15% reported by UNAIDS global report 2013. This decline could be attributed by increase in ART coverage among pregnant and lactating mothers but also efforts by health care workers in ensuring mothers have knowledge on optimal infant feeding practices. ART initiation for HIV diagnosed infants is still a challenge. To increase enrolment of infants into ART, special strategies to strengthen mother-baby pair facility/community link up need to be instituted.
Reducing post-partum transmission in infants

MOPEC447
Systematic review of perinatal HIV transmission from breastfeeding for up to twelve months when the mother has viral suppression with combination antiretroviral therapy

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Background: The reduction of perinatal HIV transmission to <1% when pregnant women are given antiretroviral therapy (ART) in the absence of breastfeeding and birthing complications has been a key breakthrough of modern infectious disease prevention. However, there remains limited comprehensive knowledge of the current risk associated with breastfeeding. We undertook a systematic review to determine the risk of perinatal transmission through breast milk among women on combination ART (cART). Understanding this risk is paramount given the discrepancies in global guidelines, and heightened concerns of breastfeeding in high-income countries among communities where formula feeding may not be acceptable, feasible, affordable, sustainable or safe.

Methods: We searched electronic databases for relevant observational studies and randomized controlled trials (RCTs) without restriction to publication date, language or study jurisdiction. To increase sensitivity, we reviewed reference lists of identified studies and review articles, and hand-searched selected journals to ascertain recently published articles. Included studies reported cART use among HIV-positive pregnant women prior to delivery with stated viral load responses, who then breastfed for any length of time with reported perinatal HIV transmission rates to the infants. Two reviewers independently extracted methodological characteristics and outcomes and assessed risk of bias. Meta-analytic techniques calculated rates of HIV transmission among breastfed infants in included studies.

Results: Of 5270 citations, 10 studies met the eligibility criteria (three RCTs and seven observational studies) of which five were included in the meta-analysis, with a sample size of 1623 women. The transmittion rates were 2.6%, 95% CI [2.3 - 2.9] at one month, 3.6%, 95% CI [2.7 - 4.6] at three months; 4.0%, 95% CI [3.1 - 5.2] at six months; and 5.1%, 95% CI [4.0 - 6.5] at twelve months. Transmission rates increased by 1.1% in the early perinatal breastfeeding period (one to six months). Late transmissions increased by 1.1% from six to twelve months.

Conclusions: Though limited by a predominance of observational studies, our findings suggest an overall HIV transmission risk attributable to breastfeeding of at least 2.2% during the early perinatal period with heightened risk during the first year when the mother is on cART. This data can facilitate counseling for mothers experiencing difficulty adhering to formula-only guidelines in high-income settings.

Strategies to increase HIV testing in pregnant women and their partners

MOPEC449
Invitation cards during pregnancy enhance male partner involvement in prevention of mother to child transmission (PMTCT) of human immunodeficiency virus (HIV) in Blantyre, Malawi: a randomized controlled open label trial

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Background: Male involvement (MI) is vital for the uptake of Prevention of Mother to child transmission (PMTCT) of Human Immunodeficiency Virus (HIV) interventions. Partner notification (PN) is among the strategies identified for MI in PMTCT services. The purpose of this ran- domized controlled trial was to evaluate the efficacy of an invitation card to the male partners as a strategy for MI in PMTCT services by comparing the proportion of pregnant women that were accompanied by their partners between intervention and the non-intervention study groups.

Methods: Pregnant women attending antenatal care without a male partner at South Lunzu and Mpetamba health centres were enrolled in the study from June to December 2013. In an intention-to-treat analysis, we compared all participants that were randomized in the invitation card group with the standard of care (SoC) group. Risk ratios (RR) with 95% confidence intervals (CI) were computed to assess the efficacy of the invitation card.

Results: Of the 462 randomized women, 65/230 (28.26%) of the women in the invitation card group reported to the antenatal care clinic with their partners compared to 44/232 (18.97%) women in the SoC group. In an unadjusted intention to treat analysis women in the invitation card group were 50% more likely to be accompanied by their male partners than those in the SoC group RR: 1.49 (95% CI: 1.06 - 2.09); p = 0.02. Our random effects analysis showed that there was no clustering by recruitment with an inter cluster correlation coefficient (ICC) of 1.98 x 10^{-7} - 0.96 x 10^{-7} p = 0.403.

Conclusions: An invitation card significantly increased the proportion of women who were accompanied by their male partners for the PMTCT services. An invitation card is a feasible strategy for MI in PMTCT.

MOPEC450
Improving PMTCT service uptake through integration into maternal, neonatal and child health week in a high prevalence setting

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Background: In Nigeria, PMTCT coverage was 27% in 2013. A key challenge is low ANC coverage which limits the potential reach of HCT among pregnant women. Biannual 1-week campaigns are conducted to increase uptake of maternal, neonatal and child health (MNCH) services and these are known to be well utilized. We hypothesize that integrating HCT for pregnant women into MNCH week will boost PMTCT coverage.

Methods: MNCH campaign was conducted in Benue State (highest HIV prevalence state) on 8-12 December 2014 and the implementation was integrated in 288 health facilities in 13 of 23 Local Government Areas (LGAs). Strategies for mobilizing pregnant women for ANC were developed for the period. About 600 volunteers were trained to collect basic data from respondents with the aid of questionnaires and support health workers in providing HCT in accordance with national guidelines. All pregnant women accessing ANC were offered HCT, using the opt-out approach. Those testing positive were enrolled in PMTCT and linked with volunteers to follow them up to ensure retention. The feasibility of integration of HCT was measured by the number of pregnant women receiving HCT and those enrolled in PMTCT services. The results were also compared with 2013 PMTCT programme data.

Results: 50,271 pregnant women (median age 25 years) had ANC during the MNCH week; this represented 135% and 86% respectively of the population seen in the selected LGAs and the State in 2013. Of these, 50,269 had HCT; this represented 129% and 82% respectively of those tested in the selected LGAs and the State in 2013. 1,063 of the tests were positive, 54% of these were new positives and enrolled in PMTCT. All enrolment in PMTCT will be tracked for retention in care till delivery. 31% of pregnant women seen were first time ANC clients in their current pregnancy with 59% of these beyond first trimester.

Conclusions: Service uptake in 13 LGAs in 5 days (70% pregnant women population) exceeded 80% uptake for the entire State in a year. This suggests that integrating HCT into MNCH campaigns is feasible as an additional strategy to improve access to PMTCT and move Nigeria towards eMTCT earlier.

MOPEC451
A rapid structured assessment of health facilities for PMTCT scale up in four states in Nigeria with high prevalence

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Background: Access to PMTCT services in Nigeria remains low at less than 18% despite the presence of many Health Facilities (HF) across Kaduna, Benue, Gombe and Kogi States, where HIV prevalence is higher than National prevalence of 4.1%. The aim of this study was to assess HF in these states for scale up of PMTCT program. Center for Integrated Health Programs (CIHP) with funding from CDC implemented a Health Care Facility Assessment in four (4) Nigerian states.
Methods: The health facility assessment was conducted within a four day period in all the states concurrently from February 10 to 13 2013. The exercise was jointly conducted by the State Ministry of Health, Local Government and CHF. A total of 661 health facilities were listed in all the states, 815 (17%) were said to be providing PMTCT pre assessment. 3, 846 health facility were included in the study involving private health facilities and mission centers. All the facilities in states one state provide HIV testing for pregnant women with a fee. More than one-quarter of the PHCs record very low volume of ANC uptake (2.5 in a month). A half of the health facility assessed need facility upgrade.

Conclusions: The assessment revealed a huge number of HF with MNCH services without PMTCT services. The assessment using LGA structures was innovative and cost effective, as over a thousand health facilities were assessed within four days with an opportunity to have evidence based listing of facilities and status, while institutionalizing ownership to promote sustenance of the PMTCT program.

MOPEC452
Partner antenatal attendance associated with partner HIV testing among pregnant women in Kisumu, Kenya

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Background: HIV testing among couples prevents horizontal and vertical transmission and facilitates linking individuals to care. Evidence suggests that male involvement in antenatal care facilitates HIV testing; however, male antenatal clinic attendance is low in Kenya and elsewhere. In this study, we identify factors associated with male partner HIV testing.

Methods: The Home-based Partner Education and Testing (HOPE) study is a randomized clinical trial of pregnant women and their partners, determining whether home visits result in higher HIV testing uptake among partners than invitations to attend the antenatal clinic. Results presented here come from a screening questionnaire completed at enrollment. All pregnant women attending the Kisumu District Hospital Antenatal Clinic from October 2012 to May 2013 were verbally consented, screened for eligibility and asked about previous pregnancies as well as HIV testing. Correlates of partner HIV testing, including past partner antenatal attendance, female and partner age, female education, household income, individual income, gravida, number of living children with partner, and duration living together, were examined using multiple logistic regression with α-level of 0.05.

Results: In total, 1,105 women were screened, 85 (7.7%) of whom were accompanied by their partner. Overall, 673 (81%) women reported their partner had been HIV tested, 617 (91.7%) were aware of their partner’s status, and 73 (13.9%) partners were positive. Among 511 women reporting a previous pregnancy with their current partner, 131 (25.6%) partners attended at least one antenatal visit during the preceding pregnancy. In a multiple logistic regression model, partners who attended any antenatal clinic visits during the preceding pregnancy were 4.11 times as likely to have been HIV tested compared to those did not (95% CI: 2.24-7.59). Additionally, household monthly income level (OR=1.42, 95% CI: 1.11-1.83) and female education level (OR=1.27, 95% CI: 1.02-1.57) were significantly associated with partner HIV testing. There were no other significant correlates of partner testing.

Conclusions: While partner antenatal attendance was low, it was positively associated with HIV testing in previous pregnancies. Strategies to increase partner attendance could boost HIV testing during the antenatal period and need to be considered for pregnant couples in areas with high HIV prevalence.

MOPEC453
Where are pregnant women who were not tested for HIV? The use of IQSMS in identifying pregnant women for HIV testing, Tanzania experience, Tanzania

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Background: The Local Partners Excel in Comprehensive HIV & AIDS Service Delivery (LEAD) project, funded by the Centers for Disease Control under PEPFAR, supports prevention of mother-to-child transmission (PMTCT) services at 293 facilities in Tanga region, Tanzania. HIV testing and counselling of pregnant women is a major initiative to reduce transmission of HIV from mother to child. Lack of HIV testing kits caused some of the women not to be tested on time which resulted in missed opportunity for early identification of infected babies. LEAD project used International Quality Short Message Software (IQSMS) to identify pregnant women from all facilities in Tanga who were not tested for HIV.

Methods: The IQSMS software uses health providers’ mobile phones to send monthly reports of HIV test kits stock status and number of pregnant women tested and not tested from each facility to a server via SMS. The monthly reports submitted to the server are analysed and women not tested identified. A call-back campaign, jointly implemented by program officers, nurses and clinicians based on reports retrieved from the IQSMS, encouraged women who were not tested to return to facilities to be tested.

Results: Between January and March 2013, a total of 18,683 pregnant women attended antenatal clinics from 293 facilities for the first time, among them 15,877(84%) were tested for HIV while 2986 (16%) were not tested due to lack of HIV test kits. Between April and September 2013, the test kits stock improved and by the use of IQSMS, Out of 2965 women who were not tested (2750(92%) were identified and tested for HIV and 234(8%) were not traced. There was improvement in testing when data collected among pregnant women who attended for the first time in the clinic between April and September 2013, a total of 36,118 pregnant women attended clinic and all of them 100% were tested for HIV.

Conclusions: Through the use of IQSMS, stakeholders at the facility- district, regional- and national/levels obtained up-to-date information that can quickly identify pregnant women who have not yet been tested for HIV to be tested when HIV test kits become available.

MOPEC454
Systematic HIV-testing in delivery rooms is feasible: a pilot program through 8624 consecutive deliveries in Burundi, East Africa

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Background: Burundi associates high HIV prevalence (1.3% in 15-49 years old) and limited resources in a post conflict area. In 2012, according UNAIDS, 54% of HIV-infected pregnant women will receive antiretrovirals during pregnancy, but access to HIV- testing is poor. Testing for HIV during pregnancy is recommended by national guidelines, free of charge. Methods: As HIV testing was poorly proposed in public healthcare settings, we have implemented a systematic testing in the delivery room of Bujumbura’s main hospital. Testing is systematically proposed by community workers, who perform a rapid pre-test counseling. If a woman is diagnosed previously unknown HIV-positive, with no prior access to the PMTCT program, she’s proposed immediate lamivudine/tenofovir/efavirenz intake and a free 72H hospitalization to perform active counseling, a doctor’s visit, and to schedule protected breast-feeding. Results: From April 2012 to June 2014, there were 9624 deliveries, and 76% of women were tested for HIV before intervention, less than 10% of mothers were tested during delivery; one month after the onset of the intervention, 65% of women were tested, and 98% in June 2014. 105 women were tested newly positive (1.8% of women with previous unknown status). Four hundred and fifty seven women were previously diagnosed for HIV, thus the global prevalence at delivery was 6.5%. Among previously unknown HIV-infected women, there was a high prevalence of unemployed, singles with unknown father or unmarried, and women who had no medical follow-up during pregnancy. In these late-diagnosed women, lost to follow-up after delivery was very high, with 23% of women never returning to the healthcare setting, three babies and 2 mothers died, among those who were not lost for follow-up.

Conclusions: Systematic testing in delivery rooms is feasible and should be encouraged if we want to be on the path of ETME. Special care must be emphasized for the women who are diagnosed during delivery, because of their high risk of lost to follow-up. Delivery is their unique occasion to be in touch with healthcare workers. Community and healthcare support for adherence, juridical or psychological assistance is critical to lower lost to follow-up, infant and mother mortality and mother-to-child-transmission.
MOPEC455
Infant HIV outcomes and timing of presentation to prenatal care: contribution of HIV seroconversion during pregnancy
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Background: Mother to Child HIV-1 Transmission (MTCT) is rare in women who receive combination antiretroviral therapy (cART) throughout pregnancy but women who undergo primary HIV-1 infection during gestation or are undiagnosed until delivery are at high risk of HIV transmission.

Methods: HIV MTCT rates at a tertiary HIV referral institution in southern Brazil were evaluated over 7.5 years. Infant outcomes were determined for mothers who received antiretrovirals throughout pregnancy and mothers identified with HIV only at delivery. Rapid HIV testing was performed during labor in women with negative HIV results ≥ 1 month prior to admission or with unknown HIV-1 diagnosis. Neonatal infection was ascertained using RNA PCR over several time points.

Results: Between 1/2006 to 7/2013, 48,560 deliveries occurred at our institution, 1,873 (3.4%) in HIV-infected women. Data was available for 1,132 HIV+ pregnant women who continued postnatal follow-up at our hospital. Infant outcomes were available for children of 949 women (83.8%) who were accompanied for HIV exposure. Women either received prenatal care and cART during pregnancy (n=781) or were only identified as HIV-infected at delivery (n=371). As seen in the table, HIV MTCT was over 10 times more frequent among women identified during labor as compared to women receiving cART (p < 0.001). Rates of miscarriage were two-fold higher in women not on cART during pregnancy (p = 0.02), while rates of early infant death and loss to follow-up were similar in both groups. Forty-two women identified at delivery (11.3% of late presenters) had documented HIV seroconversion during pregnancy. HIV MTCT rate 19%. None of the women followed postpartum at our institution breastfed. The incidence of HIV-1 seroconversion in pregnancy was 0.9/1,000 (CI 95% 0.6-1.2/1,000).

Conclusion: In southern Brazil, an area of high HIV-1 prevalence, seroconversion during pregnancy is not unusual, and carries a high MTCT risk. Women not on cART have higher rates of miscarriage as compared to treated patients. Early infant death among HIV-exposed children was higher than in the general population (2% vs 1.5%). Loss to follow-up of HIV-affected mother-infant pairs is still a significant problem in our setting.

Increasing coverage and quality of PMTCT programmes

MOPEC457
Characteristics and outcomes of women initiating ART during pregnancy versus breastfeeding in Option B+ in Malawi
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Background: Malawi adopted the PMTCT strategy ‘Option B+’ in 2011, providing lifelong ART for all HIV-infected pregnant and breastfeeding women. We explore differences in characteristics and outcomes of women initiating ART during pregnancy versus breastfeeding.

Methods: We conducted a retrospective cohort analysis of women initiating ART during pregnancy or breastfeeding in Zomba District, southern Malawi, from January 2012 to September 2013. Data were extracted from the Zomba District Observational Cohort Study database, a surveillance project collecting information from standard Ministry of Health ART monitoring tools.

Results: 2965 women were included: 1993 (67.2%) initiated ART during pregnancy, 972 during breastfeeding. 54.4% of women were between 21-30 years old. Younger women (< 30 years) were 1.3 times more likely to initiate in pregnancy (vs. breastfeeding) than older women (aOR 1.32, 95%-CI 1.1-1.6; p=0.00).

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MOPEC458
Dramatic improvements in uptake of prevention of mother to child HIV transmission services in Zimbabwe, 2012-2014
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Background: Prevention of mother-to-child HIV transmission (PMTCT) requires an integrated cascade of services for pregnant and breastfeeding women and their infants. We compared uptake of maternal PMTCT services among women with a recent birth in Zimbabwe in 2012 and 2014 using community-based data.

Methods: We analyzed serial cross-sectional data from the evaluation of Zimbabwe’s accelerated implementation of the 2010 WHO PMTCT guidelines. Using multi-stage cluster sampling, eligible women were randomly sampled in 2012 and 2014 from the catchment areas of 157 facilities offering PMTCT services in Harare, Manicaland, Mashonaland Central, Mata-beleland South, and Mashonaland West. Eligible women were 16 years old and biological mothers of infants (alive or deceased) born 9 to 18 months before the survey. Participants were tested for HIV infection and interviewed about health service utilization during pregnancy and breastfeeding.

Results: Overall, 8,800 and 10,225 mother-infant pairs were interviewed in 2012 and 2014, respectively. The uptake of reproductive health services increased significantly among all pregnant and postpartum women, including attendance at ≥1 antenatal care (ANC) visit during pregnancy (94% to 96%), ANC visits (64% to 71%), receiving HIV test results (92% to 93%), institutional delivery (77% to 84%), postnatal visit attendance (92% to 95%), and use of [Figure. Utilization of services in the PMTCT cascade among HIV-infected women and their HIV-exposed infants]
a modern contraceptive method (77% to 84%). Among women who were HIV-infected (2012: 12.7%, 2014: 12.1%), the proportion reporting initiation of antiretroviral therapy (ART) before pregnancy or an antiretroviral prophylactic regimen increased significantly from 59% to 69% (p< 0.01, see Figure), as did the proportion reporting antiretroviral prophylaxis for their HIV-exposed infant (83% to 71%, p< 0.01). Coverage of cotrimoxazole increased 25 percentage points and early infant diagnosis increased 13 percentage points. Among infants with complete testing data, the proportion who were HIV-infected (2012: n=97 (8.5%), 2014: n=99 (9.1%)) and on ART did not change significantly (19% to 25%, p=0.31).

Conclusions: Zimbabwe’s accelerated PMTCT program had large and positive impacts on service uptake in a two-year period. Nevertheless, these data from women in the community indicate gaps in the PMTCT cascade where further efforts are needed to increase engagement and retention in PMTCT services as Zimbabwe approaches virtual elimination of MTCT.

MOPEC459
Acceptability of prevention of mother to child transmission of HIV Option B+ among HIV-infected pregnant and breastfeeding women in Chiradzulu District, Malawi

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Background: In 2011, Malawi became one of the first countries in the world to adopt the Option B+ Prevention of Mother-to-Child Transmission of HIV (PMTCT) antiretroviral treat- ment (ART) programme, which entails lifelong ART for all Human Immunodeficiency Virus (HIV) infected pregnant and breastfeeding women. However, the acceptability of lifelong treatment, especially to healthy women, has not been examined. Therefore the objective of this study was to assess the acceptability of PMTCT Option B+ among HIV infected pregnant and breastfeed- ing women in Chiradzulu District.

Methods: We conducted a cross sectional qualitative study using in-depth interviews (IDIs) with 32 pregnant and breastfeeding women at Chiradzulu District Hospital in Malawi. Eligible study participants were women who had just been initiated on Option B+ regimen (n=10), those that had been on the regimen for 3 to 6 months (n=12) and postnatal women transitioning from the PMTCT programme to the adult ART programme (n=10). IDIs were recorded and then transcribed in verbatim. Data was analyzed manually using thematically content analyses.

Results: We found that Option B+ PMTCT regimen was highly acceptable among preg- nant and breastfeeding women regardless of their health status or duration of treatment. Most women were in favor of Option B+ mainly because they viewed the regimen as being beneficial in preventing frequent illnesses, prolonging life, and enabling a longer period of breastfeeding. However, a few women were not in favor of Option B+ because of the need to take daily medi- cations for the rest of their lives.

Conclusions: Option B+ regimen was highly acceptable to HIV+ women due to expecta- tion of improved health status for themselves and their infants. These benefits seem to out- weigh concerns about long duration of treatment and ART side effects.

MOPEC460
Same day integration of HIV diagnosis and treatment with antenatal care affects retention in Option B+ prevention of mother to child transmission services in Zomba District, Malawi

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Background: Early programmatic data from Malawi show considerable variation between health facilities in retention on ART of Option B+ women. We studied whether full integration of HIV testing and counseling (HTC) and ART initiation on the same day during antenatal care (ANC) impacted on retention on ART compared with partial integration: HTC at ANC with refer- ral for ART initiation. We also investigated whether any difference in retention was due to the impact of having diagnosis and ART initiation on the same day.

Methods: A retrospective cohort study of pregnant women seeking ANC at all rural primary health facilities in Zomba District, Malawi was conducted using data extracted from standard- ized ANC and ART registers, and ART master cards and linked by patient identifiers. Descriptive information on the organization of Option B+ service delivery at each health facility, accounting for the degree of integration of ANC, HTC and ART, was identified by the Zomba District Health Office.

Results: Between October 2011 and March 2012 a total of 10,168 women were newly registered at ANC, in 23 rural health facilities. Twelve health facilities provided HTC and ART on the same day at ANC (Model 1) to 3,842 women and 11 provided only HTC at ANC and referred to an ART clinic for treatment (Model 2) to 6,386 women. There was no difference in uptake of HTC or ART between the models. For those who started ART, there was a significantly higher loss-to-follow-up in Model 1 (22%) vs. Model 2 (8%), p< 0.001. Multivariable analysis (adjusted for mothers age, gravidity and model of care applied) showed that initiation of ART at ANC on the same day was associated with reduced retention on treatment both 3 months [aOR=1.62 (95% CI 1.04-2.51)] and 6 months after starting ART [aOR=1.94 (95% CI 1.15-3.29)].

Conclusions: Retention on ART was higher in those who were referred to start ART from ANC vs. starting ART in ANC. HIV diagnosis and treatment on the same day appears to be associated with reduced retention on treatment. Reduced retention related to implementing test and treat on the same day needs further evaluation.

MOPEC461
Predictors and outcomes of perinatal HIV transmission at regional referral hospitals implementing Option B plus in Uganda

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Background: HIV transmission to the infant (MTCT) occurs in at least 30% of perinatal pairs. Prevention of mother to child transmission (PMTCT) programs are effective if a continuum of care is provided for HIV infected pregnant women and their exposed infants. This study assessed predictors of HIV transmission and clinical outcomes among HIV-exposed infants in care at ten regional referral hospitals in Uganda.

Methods: Retrospective chart review for exposed infants enrolled at Early infant diagnosis care points at ten Regional referral hospitals was conducted. All records of HIV-exposed infants enrolled between October 2012 and September 2013 were included. Trained midwives and data personnel collected data using a structured data extraction format. Data were then entered into to EPI- DATA Version 3.5.1 statistical software and analyzed by STARTA version 12.0. Both bivariate and multivariate analyses were carried out to identify associations.

Results: A total of 2,657 infant records were included in the analysis. The median age of infants at enrolment was 2.6 months. A total of 207(7.8%) were HIV infected and 82% initi- ated on ART. Not breast feeding status at enrolment (AOR = 2.75, 95% CI: 2.23, 10.1), lower health facility delivery (AOR = 2.83, 95% CI: 1.53, 5.23), not receiving infant Nevirapine at birth (AOR = 2.57, 95% CI: 1.29, 5.09), and mother not in care (AOR = 4.08, 95% CI: 1.09, 14.8) were significantly and independently associated with maternal to child transmission of HIV in this study. Sixteen percent of the exposed infants had stopped breast feeding with median duration 8 months IQR (5-8) and 56% of these received a second HIV test. Mother-baby pairs active in care were 75%.

Conclusions: Perinatal HIV transmission is high. Predictors were: None-breast-feeding status by first PCR test. No Nevirapine receipt, mother not being in care and delivery at a health facility other than the RRH. Only half of the children that have stop breastfeeding received a 2nd DNA-PCR test indicating losses in care. Three quarters of HIV exposed infants and their mothers are still active in care.

MOPEC462
Male partner involvement improves uptake of prevention of mother to child HIV transmission services in Kenya

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Background: Male partner involvement, such as antenatal clinic (ANC) attendance, may increase uptake of prevention of mother-to-child transmission of HIV (PMTCT) services. We assessed the prevalence and correlates of male ANC attendance and the effect of male involve- ment on PMTCT-related outcomes in Kenya.

Methods: We conducted a cross-sectional survey of male-infant pairs in 141 maternal child health (MCH) clinics throughout Kenya between July and December 2013. Structured questionnaires and MCH checklists were used to gather information on maternal and partner ANC attendance, antiretroviral drug (ARV) use, skilled delivery, contraceptive use, infant HIV testing, ARV prophylaxis, and infant HIV-1 status. Multivariable logistic regression models ad-
justed for clustering effect at the clinic level, geographic region, maternal and paternal characteristics were used to compare maternal and infant outcomes by male ANC attendance, and to identify correlates of male ANC attendance.

**Results:** Among 2521 mother-infant pairs attending MCH, 960 (33.7%) reported male ANC attendance. Male ANC attendance was similar in HIV infected (55 male partners of 460 women) and uninfected (786 male partners of 2270 women) women [aOR (95%CI)=1.05 (0.65-1.74)]. Maternal HIV disclosure [aOR=4.2 (2.2-8.2)], shorter relationship duration [aOR=1.39 (1.1-1.77)], higher maternal education [aOR=1.8 (1.5-2.2)], earlier gestational age at first ANC [aOR=1.32 (1.0-1.66)], and absence of intimate partner violence [aOR=1.64 (1.2-2.2)] were significantly associated with higher male ANC attendance. Male ANC attendance varied significantly by geographic region with higher rates in Central compared to Western Kenya [aOR=3.30 (1.78-6.10)]. Among HIV+ women, male ANC attendance was significantly associated with higher maternal uptake of ARVs for PMTCT [aOR=4.36 (1.5-12.05)], ≥4 maternal ANC visits [aOR=1.68 (1.41-1.96)], skilled delivery [aOR=1.54 (1.21-4.58)], and contraceptive use [aOR=1.55 (1.16-2.08)]. Among HIV infected women, partner attendance had no discernible effect on infant HIV status [aOR=0.96 (0.35-2.65)], likelihood of infant HIV testing [aOR=1.08 (0.72-1.65)], or infant nevirapine use [aOR=0.74 (0.23-2.74)], although power to detect associations in HIV exposed infants was low.

**Conclusions:** Male partner attendance was associated with increased maternal uptake of MCH and PMTCT services. Further efforts to increase male ANC attendance such as national awareness campaigns or incentives for men may be useful.

**MOPEC463**

Male partner participation in antenatal clinic services is associated with improved mortality and HIV-free survival among infants of HIV-positive women in Nairobi, Kenya: a prospective cohort study

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**Background:** Male involvement in PMTCT in sub-Saharan Africa is recommended however evidence supporting improved outcomes with participation is limited. This prospective study investigated the relationship between male ANC/PMTCT involvement and infant HIV-free survival.

**Methods:** From 2009-2013, HIV-infected pregnant women were enrolled from six clinics in Nairobi, Kenya and followed with their infants until six weeks postpartum. Women were screened for consent for partner involvement. If females consented, men were encouraged to attend through invitation letters. Standardized questionnaires were used to survey all participants. Males who failed to attend antenatal had questionnaires provided for self-completion postnatally. Informed consent was obtained from all subjects.

**Results:** Among 830 enrolled women, 519 (62.5%) consented to male participation and 138 partners (28.2%) attended the ANC. For the 363 (73.8%) women whose partners failed to attend, 63 (16.4%) were surveyed via outreach. Partner attendance was more likely in couples in monogamous relationships that had previously discussed PMTCT interventions and if men reported prior HIV testing, awareness that vertical transmission was possible and that their partner was HIV-positive. In multivariate analysis only male report of prior HIV testing was associated with attendance (aOR=3.7; 95%CI:1.5-8.9, p=0.003). Thirty-three (6.6%) of 499 in couples in which men had previously undergone HIV testing and partner involvement was associated with improved infant HIV-free survival. Promotion of male HIV testing and engagement in ANC/PMTCT services may improve infant outcomes in similar settings and warrants further study.

**MOPEC464**

An innovative approach to triple elimination of mother to child transmission of HIV, syphilis and hepatitis B in Viet Nam

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**Background:** Elimination of mother-to-child transmission (EMTCT) is a global target. Vietnam has a concentrated HIV epidemic and high prevalence of hepatitis B virus (HBV) infection. Prevention of mother-to-child-transmission (PMTCT) has focused only on HIV. This operational research aims to demonstrate an innovative model of integrated PMTCT of HIV, HBV and syphilis to inform policy change toward more comprehensive approach to eliminate new infection of HIV, HBV and syphilis among infants.

**Methods:** This study was implemented in all 18 communes in Pho Yen district, Thai Nguyen province between October 2012 to December 2014. Pregnant women (PW) were offered HIV, HBV and syphilis testing during antenatal visits. PW diagnosed with HIV, HBV and syphilis and their infants were offered interventions, including antiretrovirals (ARV), syphilis treatment, and HBV immunoglobulin (HBIG) for infants in addition to HBV vaccine. Infants were tested for HIV, HBV and syphilis at age 7 and 12 months.

**Results:** Among a total of 3,498 PW, 98.6% were tested for HIV, HBV and syphilis. Prevalence of HIV, HBV and syphilis were 0.17%, 8% and 0.03%, respectively. Five out of six HIV positive women received ARV. All HIV exposed infants underwent early infant diagnosis of HIV had negative results. One woman diagnosed with syphilis infection in week 24 of gestation received treatment and her infant was uninfected. Among PW infected with HBV, 45.5% were HBeAg and 52% HBeAb positive. Overall, 76% HBV-exposed infants received the birth-dose immunization (within 24 hours) which was higher than the overall birth-dose coverage (33.5%) in the same district during the same period. Among 143 HBV-exposed infants born in 2013, 28 were HBeAg positive (19.6%). The multivariate analysis showed that not receiving HBIG was strongly associated with increased risk of infant HBV infection (AOR 4.95% CI:1.6-12; P=0.004).

**Conclusions:** This study suggested triple EMTCT is feasible. However, PMTCT of HBV needs further effort and investment. Our findings suggest that investment in HBV screening for PW could increase uptake of hepatitis B birth-dose among exposed infants and HBIG could reduce the risk of HBV infection for infants.

**MOPEC465**

National estimates of mother to child transmission of HIV-1 at 6 weeks and 9 months in Kenya

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**Background:** To reach targets for elimination of perinatal HIV infection, Kenya has expanded prevention of mother-to-child transmission of HIV (PMTCT) coverage. We evaluated PMTCT program effectiveness and factors influencing MTCT in a nationwide survey.

**Methods:** We conducted probability-proportional-to-size sampling of 120 clinics in Kenya, July-December 2013. Staff surveyed mother-infant pairs attending 6-week and 9-month immunizations, offered HIV testing to HIV-uninfected mothers, and collected blood spots from infants of HIV-infected mothers for HIV DNA testing. Transmission risk (TR) was calculated by dividing number of DNA-positive infants by infants at risk at each time point. Multivariable regression models weighted for survey design and clinic-level clustering compared exposures between HIV-infected and uninfected infants.

**Results:** Among 2521 mother-infant pairs surveyed, 1502 attended 6-week and 1019 at 9-month visits. Overall, 2422 (94.7%) reported HIV test in pregnancy or prior HIV diagnosis, of whom 200 (7.4%) were HIV-infected, 86 (0.47%) diagnosed in pregnancy. Of 200 infants born to mothers with known HIV, 188 underwent HIV testing, of whom 7.2% (95% CI: 3.7-13.5%) were HIV-infected. HIV-TR was 8.8% (CI: 4.0-18.3%) in the 6-week cohort and 4.8% (CI: 1.3-15.6%) in the 9-month cohort, including mothers with incident HIV since pregnancy. Nine-month postpartum HIV-TR was 8.7% (CI: 1.2-22.0%). Mothers of HIV-infected infants were less likely to know their CD4 count (18.6% vs. 58.5%, p<0.001) or disclosed their status to male partners (24.5% vs 80.6%, p<0.001) than mothers of uninfected infants. Infected infants were more likely to be female (82.3% vs. 17.8%, p<0.003). Overall, 69% of HIV-infected mothers received antiretroviral drugs (ARVs) during pregnancy, 65% at delivery, 64% postpartum; 93% of
utilization rates of women who received the ABC in their most recent pregnancy. Women to identify barriers to service uptake, problem solve using existing community resources.

**Results:** In November 2014, a cross-sectional survey of women who received the ABC during their most recent pregnancy in Rushinga District was conducted. Service uptake related to each ABC Goal during recent (with ABC) and previous (without ABC) pregnancies was documented using a structured, pre-tested questionnaire.

**Conclusions:** Rural women who received the Action Birth Card and planned for service use in their recent pregnancy demonstrated higher reported uptake of services along the PMTCT cascade compared to both previous pregnancies and national data. Implementation of this low-cost, effective intervention should be expanded to enhance existing efforts by the Ministry of Health and Child Care to increase demand and uptake for services along the PMTCT Cascade. Service goals in the ABC should be extended to postnatal services in the PMTCT cascade and the impact upon health and development outcomes of mother-baby pairs explored.

**MOPEC467**

**Awareness, utilization and access to HIV and maternal health care services for pregnant women in two high HIV prevalence districts of India: a baseline evaluation**

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**Background:** Mother-to-child transmission is the single most important source of HIV infection in children. However, utilization of antenatal care (ANC), which is an important entry point for preventing Mother-to-Child Transmission of HIV, remains low in India. A baseline survey was carried out to understand knowledge, perceptions, practices and barriers related to early HIV testing, care and support among pregnant women, and their community members.

**Methods:** Cross-sectional and mixed methods were used. Quantitative data were collected from 1108 pregnant or recently delivered women in Nagpur and Adivalab districts through structured questionnaires. These included 19 women living with HIV. Qualitative data were gathered through in-depth interviews (IDIs) and focus group discussions (FGDs) with identified stakeholders including ASHAs, ANMs, Doctors, Integrated Counselling Testing Centre (ICTC) counsellors and Panghatay volunteers. Data were collected between March and April 2014.

**Results:** Awareness of complete antenatal care (ANCs) package was only 28% in Adivalab whereas it was 53% in Nagpur. Only 38% of women in Nagpur and 33% in Adivalab went for HIV testing in the second trimester of pregnancy. Around 28% women were not aware of any place where HIV testing could be done. Notably, 12 out of 19 women living with HIV reported that they had late ANC registration and came to know about their “positive status” as late as six months of their pregnancy. Five HIV positive women reported that they were not currently under ART. Qualitative data on barriers revealed that local norms and traditional beliefs did restrict many women to visit health facility for HIV screening during first ANC. Further, frontline functionaries reported limited availability of HIV rapid testing in remote areas, notion of stigma and lack of motivation by community health workers also acted as barriers for uptake of services.

**Conclusions:** Poor uptake of ANC services and HIV testing during pregnancy results from both community and facility level barriers in the intervention districts. The study indicates that there is a need to motivate frontline community health workers, and to support pregnant women to access ANC and early HIV testing.

**MOPEC468**

**Timing of maternal HIV diagnosis and uptake of PMTCT in Kenya**

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**Background:** Prevention of mother-to-child transmission (PMTCT) services/coverage has been scaled up in Kenya over the last decade aiming at eliminating perinatal infection. With expanded PMTCT and HIV care programs, more women are diagnosed with HIV prior to pregnancy. We compared characteristics of mothers diagnosed with HIV prior to those diagnosed in pregnancy and examined uptake of PMTCT interventions in these groups in a national survey.

**Methods:** We conducted a cross-sectional study enrolling mother-infant pairs at week 6 and month 9 immunizations from 140 maternal child health clinics selected by probability-proportional-to-size sampling in Kenya, between July and December 2013. Maternal socio-demographic characteristics, HIV status, uptake of PMTCT services, and maternal and infant clinical data were collected by standardized questionnaire. Blood spots were collected for infant HIV DNA testing and maternal HIV rapid testing. Chi-square tests were used to compare uptake of PMTCT services between mothers diagnosed before and during pregnancy. All analyses account for clustering at the clinic-level.

**Results:** Among 2891 mother-infant pairs surveyed, 438 HIV-positive mothers were enrolled, of whom, 306 (61.4%) had HIV diagnosis before pregnancy and 192 (38.6%) had HIV diagnosis during pregnancy. Mothers diagnosed during pregnancy were younger (median, 26.2

**Proportion of women who made use of services in pregnancies with and without Action Birth Card were compared by Chi-square analysis. To explore potential influence of temporal bias upon service uptake between pregnancies, utilization during the recent pregnancy was compared with national data over a similar period.

**Results:** Among 174 women interviewed, average age was 26.9yrs (range 16-40yrs) and average number of pregnancies 2.5. Women demonstrated significantly higher service uptake during their recent pregnancy using the ABC planning tool compared to previous pregnancy without ABC for all ABC utilization indicators (p<0.005), with the exception of 4+ ANC (p=0.07). Women who used ABCs during their recent pregnancy also demonstrated higher rates than national figures over the same time period.
MOPEC469
Why did it stop? Barriers and facilitators to acceptance of and retention in the Option B+ program in Lilongwe, Malawi

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Background: Despite the early success of Malawi’s Option B+ program, early loss-to-follow up remains a challenge. Few studies address how women make treatment decisions and their reasons for dropping out of care. This study compares the experiences of women in care and those not in care and examines how women decide whether to start and stay on ART. We aim to identify the key factors that lead to ART refusal, default, and retention.

Methods: We conducted in-depth qualitative interviews with HIV-positive women who initiated ART through Option B+ in Lilongwe, Malawi (N=62). We included those successfully retained in care (N=27) and those who refused/defaulter ART (N= refuse14; default 21). Open-ended interviews were used to understand women’s experiences through the PMTCT cascade. We explored potential barriers and facilitators to acceptance/retention in Option B+. Data was analyzed in Atlas.ti using an inductive approach based on grounded theory methodology.

Results: Women who refused ART were concerned with immediate initiation. Half of the women who refused felt healthy and wanted to wait until their health declined or try alternate forms of healing first (7/14). Others expressed that they wanted to wait because they needed time to process their newfound status (4/14). The main reasons women gave for defaulting forms of healing first (7/14). Others expressed that they wanted to wait because they needed time to process their newfound status (4/14). The main reasons women gave for defaulting forms of healing first (7/14). Others expressed that they wanted to wait because they needed time to process their newfound status (4/14).

Conclusions: Successful retention is related to how women conceptualize early ART initiation in light of their perceived health. Interventions that provide early support for patients experiencing side effects may be helpful.

PMTCT services for marginalized groups

MOPEC470
Mother to child transmission of HIV amongst adolescents: findings from three national surveys, South Africa, 2010, 2011-12 and 2012-13

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Background: Globally, nearly 16 million births occur annually to adolescents (15 to 19 years), mostly in developing countries. These contribute to higher maternal or infant morbidity/mortality. Noting the new global call for better adolescent health, we sought to quantify access to HIV-related care and risk of early mother-to-child transmission of HIV (MTCT) amongst adolescents in South Africa where HIV prevalence is high and 30% of teenage girls report ever being pregnant.

Methods: Data from three national, cross-sectional, facility-based surveys, conducted in 2010, 2011-12 and 2012-13, were analysed. Stratified, multi-stage, probability proportional to size sampling methodology, with random sampling of facilities and consecutive or systematic sampling of participants (couples with infants aged 4-8 weeks receiving their 1st DTP immunization) was conducted. Interviews gathered data on maternal socio-demographics, ante- and postnatal care and uptake of prevention of MTCT (PMTCT) services. Infant dried blood samples were tested for HIV antibodies and total nucleic acid to determine HIV exposure and infection, respectively. During analysis mothers were grouped into adolescents (<20 years) or adults (>20 years). Data were weighted for sample realisation and population live births.

Results: Data from 4704 adolescents (1646 from 2010, 1680 from 2011-12 and 1388 from 2012-13) and 25253 adults (8536 from 2010, 8426 from 2011-12 and 8291 from 2012-13) were analysed. Overall, adults utilized PMTCT interventions 3 times more than adolescents (unadjusted odds ratio, OR, 3.36, 95% confidence interval, CI, 2.95-3.83). This did not differ significantly by survey. Early MTCT amongst adolescents compared with adults was 7.2% (CI:4.2-12.1%) versus 3.2% (CI:2.6-4.0%) in 2010, 5.8% (CI:3.1-10.5%) versus 2.5% (CI:1.9-3.2%) in 2011-12 and 6.7% (CI:3.4-12.9%) versus 2.4% (CI:1.9-3.1%) in 2012-13. The OR for MTCT in adolescents compared with adults, across all surveys was 2.99 (CI:1.17-7.88), adjusted for PMTCT intervention, maternal education, knowledge of partner’s HIV status, CD4 cell count conducted, maternal income source, survey year and infant birth weight. Between 2010 and 2012-13 early MTCT reduced significantly in adults but not in adolescents.

Conclusions: Adolescents have lower coverage of PMTCT services and significantly higher early MTCT compared with adults. Adolescent-focused services are urgently needed to improve PMTCT service coverage for adolescents and reduce adolescent MTCT.

Integration of family planning and HIV services

MOPEC471
Unplanned pregnancies and unmet family planning needs among HIV-1-discordant couples in Nairobi, Kenya

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Background: HIV-1-discordant couples face a complex set of decisions surrounding fertility desires and contraceptive practices. The vertical and horizontal transmission risks associated with conception and pregnancy can be substantially mitigated if pregnancies are planned
and couples are aware of their options. We sought to describe unplanned pregnancies among a cohort of HIV-1-discordant couples and identify factors associated with these pregnancies. Methods: HIV-1-discordant couples in Nairobi, Kenya were followed quarterly for up to 2 years. In 64.2% of the couples, the woman was the HIV-positive partner. Pregnancy status was assessed via self-report at study exit and risk factors were assessed via questionnaires given at multiple time points during the study. Logistic regression was used to determine associations between risk factors and unplanned pregnancy. Results: Of 402 women in stable heterosexual HIV-1-discordant relationships, 76 (18.7%) reported having been pregnant during the study, and of the 70 women who responded to the question, 39 (55.7%) reported that the pregnancy was unplanned. Contraceptive use (excluding condoms) was low; current usage at baseline was reported by 7 (17.9%) women with unplanned pregnancies, 4 (12.9%) women with planned pregnancies, and 87 (20.9%) women who did not become pregnant. Among those who reported a planned pregnancy, only 3 (8.7%) reported taking action to reduce the risk of HIV-1 transmission. The likelihood of an unplanned pregnancy was not significantly different between HIV-1-infected women (51.1%) and uninfected women (66.7%) (p=0.23). Women who reported planned pregnancies were also more likely to report unprotected sex (OR=4.7, 95% CI 1.6 to 13.6; p=0.004), and HIV-infected women were almost twice as likely as uninfected women to report any unprotected sex during the study period (30.8% vs. 15.9%, p<0.001). Baseline desire for additional children (p=0.06), number of living children (p=0.045), any reported unprotected sex at baseline (p=0.07), and baseline contraceptive use (p=0.28) were not associated with the likelihood of an unplanned pregnancy.

Conclusions: Unplanned pregnancies were common among HIV-1-discordant couples, while usage of hormonal or other modern contraceptives was low. The results stress a need to consider fertility desires of discordant couples and take action to provide both highly effective contraception and safer conception counseling.

**MOPEC472**

**Uptake of highly effective contraception among HIV-infected postpartum women: results from a national survey**

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**Background:** Uptake of postpartum contraception is critical to prevent unintended pregnancies and promote healthy births. However, pregnancy prevention is an important component of preventing mother-to-child HIV transmission. We measured contraceptive use and correlates of highly effective contraception (HEC) among HIV-infected postpartum Kenyan women. **Methods:** We conducted a nationally representative cross-sectional survey of women attending 9-month infant immunization visits at 120 MCH clinics in Kenya between July and December 2013, with a survey sample oversampling HIV-positive mothers at 30 clinics. Study staff administered questionnaire assessing self-reported contraceptive practices and maternal characteristics. Maternal HIV-positive status was confirmed with clinic records, or determined through rapid testing for women with unknown status.

Factors associated with HEC were analyzed using logistic regression accounting for clinic-level clustering. HEC was defined as using injectables, oral contraceptives (OCs), implants, tubal ligations, or intrauterine devices (IUDs). **Results:** Among 238 HIV-infected women surveyed, median age was 28 years. 194 (81.5%) were married, median relationship duration was 6 years and 156 (65.6%) reported using contraception at 8-months postpartum. The majority (73.9%) of women were breastfeeding. Most (93.3%) women did not want children in the next 1-2 years. Among these women 141 (68.5%) reported contraceptive use: 32 (22.7%) used condoms alone while 109 (77.3%) used HEC [67 (61.5%) injectables, 8 (7.3%) OCs, 21 (19.2%) implants, 4 (3.7%) tubal ligations, 2 (1.8%) IUDs, and 7 (6.5%) dual methods (condoms plus HEC)]. Women who were more educated (p=0.002), received contraceptive counseling earlier, and delivered at a facility were more likely to use HEC (Table 1). HEC use during the prior pregnancy was significantly associated with current postpartum HEC use (p<0.002).

**Conclusions:** In this national survey, 65.6% of HIV-infected postpartum women who did not desire pregnancy in the next 1-2 years were using HEC and use of dual methods was rare. Unmarried and less educated women, and women who had not received contraceptive counseling were less likely to use HEC, which suggests these women need tailored contraceptive counseling. However, effective strategies to improve contraceptive counseling and uptake, including long-acting reversible contraception and dual methods, are needed for all HIV-infected postpartum women.

**MOPEC473**

**Loneliness and perceived social support in mothers living with HIV in Ontario**

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**Background:** HIV-related stigma results in isolation, poor perceived social support and barriers to health care. The perinatal period adds challenges, potentially increasing the sense of isolation experienced by women living with HIV (WLWH). Correlations between loneliness, depression, and poor coping styles amongst WLWH have been described, but not in the context of motherhood. The analysis identified correlates of lower perceived social support and loneliness in mothers living with HIV (MLWH).

**Methods:** The HIV Mothering Study is an observational study that explored the psycho-social experiences of MLWH. Data collected at 12 months postpartum (n=62) measuring depression, HIV stigma, race and gender-based discrimination, loneliness and perceived social support were analyzed. Univariable and multivariable linear regression were used to determine the correlates of loneliness and perceived social support at 12 months postpartum, with a priori correlates of interest being stigma, depression, discrimination, number of children, age, and race. Covariates with p values < 0.1 were included in the multivariable model and backward stepwise elimination was carried out until a best-fit model was reached.

**Results:** The median age of the cohort was 33 years, consisting mainly of African/Black women (65%); 42% of participants were not in a relationship, and 25% had no previous children. All psychosocial variables (HIV stigma, depression, racism, and gender discrimination) were highly correlated to perceived social support and loneliness (r=0.39 to 0.774), and were significant covariates in univariate analysis (p<0.10). In multivariable analyses, depression was a significant covariate of perceived social support (β=0.399, p<0.05) and depression (β=0.599) and HIV stigma (β=0.241) were significant covariates of loneliness (p<0.05). Loneliness and perceived social support were highly negatively correlated (r=-0.736, p<0.0005).

**Conclusions:** Understanding the relationship between depression, isolation, and social support in the context of HIV and motherhood is essential for optimal maternal and child health. Multivariable regression revealed that depression was a significant factor in low perceived social support whereas discrimination and stigma were significant factors of loneliness. Screening and treating depression, as well as destigmatization may be optimal ways to reduce loneliness and improve perceived social support in MLWH.
MOPEC474
Breastfeeding did not have negative impact on body mass index of HIV-infected mothers in 4 African countries

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Background: In socio-economic deprived settings breastfeeding is a key survival strategy to infants born to HIV-infected women. HIV-infection is known to cause wasting in people infected. Breastfeeding further increases energy demands. Our objective was to explore the impact of breastfeeding on changes in Body Mass Index (BMI).

Methods: The data were collected in the ANRS 12174 trial (clinical trial no NCT00640263) in Burkina Faso, South Africa, Uganda and Zambia. We ran a linear mixed model with BMI as the dependent variable and exclusive and predominant breastfeeding (EPBF) duration as the key explanatory variable.

Results: Among 1225 participants, 97% initiated BF in the first week of infant’s life for a mean duration of 5.9 (95% CI 5.8-6.0) and a median of 6.6 months (Interquartile range: 0.9). The mean (standard deviation) age, BMI, CD4 count, and HIV viral load at baseline (day 7) were respectively 27.4 (5.4) years, 24.5 (4.5) kg/m², 579 (198) cells/µl and 39000 (336000) copies/ml. The hemoglobin concentration (week 14 post-delivery) was 12.1 (1.5) g/dl.

For each additional month of EPBF, there was a non-significant decrease in BMI of -0.08 (95% CI: -0.24; 0.08) kg/m² (table 1), and the total mean reduction was 0.50 (95% CI: -1.42; 0.47) kg/m². The mothers’ HIV-1 viral load, disease stage, hemoglobin concentration, the marital and occupational status, breastfeeding initiation time child gender as well as the study treatment arm were not statistically significantly associated with the BMI change.

Conclusions: According to our findings breastfeeding practice did not have a negative impact in HIV-infected women’s BMI. EBf should be widely advised for infants born to HIV-infected women in poor resource settings where formula is not safe.

MOPEC475
Postpartum transfer of care among HIV-infected women who initiated antiretroviral therapy during pregnancy: a cohort study

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Background: The movement in prevention of mother-to-child transmission (PMTCT) programmes to integrate antiretroviral therapy (ART) provision into antenatal care has created the need to transfer women to general ART clinics after delivery for ongoing care. While there are widespread concerns around ART adherence and loss to follow-up after delivery, there are few data describing this postpartum step in the HIV care cascade for women starting ART in pregnancy.

Methods: We examined postpartum transfer between ART services in a cohort of voluntarily suppressed women who had started ART in pregnancy and were transferred from an integrated antenatal ART clinic to general ART clinics from May 2012 - September 2013. Before transfer, women completed a brief questionnaire and post-transfer engagement in care at an ART clinic was assessed via routine laboratory records and telephonic follow-up.

Results: During the study period 279 postpartum women were transferred to ART clinics (median age, 28 years; median duration of ART use at transfer, 30 weeks). Overall, between 74% and 91% of women had evidence of attending an ART clinic after delivery, depending on the outcome definition. The median time from transfer to reported engagement in ART care and first laboratory assessment was 8 weeks and 22 weeks, respectively. In a logistic regression model adjusted for age, CD4 cell count and being diagnosed with HIV in the current pregnancy, additional weeks on ART prior to transfer improved the odds of engagement in care at an ART clinic after transfer (OR 1.04 95% CI 1.00-1.07, p=0.033).

Conclusions: Postpartum transfer of ART care is an important step in the HIV care cascade for PMTCT programmes but one that has received little attention. Even in this cohort, women who were adherent at the time of transfer, up to 26% of women had no evidence of engaging in care at an ART clinic post-transfer, suggesting this is a vulnerable step in the HIV care cascade. To ensure the benefits of ART for both maternal health and PMTCT, retention is required across all steps of the cascade, including transfer of ART care after delivery.

Prevention addressing gender inequalities

MOPEC476
Knowledge, attitudes and experiences of violence among adolescent girls: a baseline assessment in the Soweto township of South Africa

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Background: South Africa has one of the highest rates of sexual violence against girls ages 12 to 17, with more than a third of girls experiencing sexual violence before the age of 18. There is an urgent need for effective interventions that address the intersections of violence and HIV among adolescent girls. In May 2014, Grassroot Soccer conducted a baseline assessment with 200 girls aged 11-16 to better understand the practices, attitudes, knowledge, and experiences of girls related to gender, intimate relationships and violence.

Methods: A 164-item questionnaire was administered to grade 8 female learners in 4 schools in Soweto, Gauteng (n = 200; mean age = 13.51) on mobile phones using Open Data Kit (ODK) software. For the analysis, SPSS version 18 was used for simple frequency distribution and cross tabulation. Self-efficacy, gender-equitable beliefs (measured using a modified Gender Equitable Men scale), justification of violence, and HIV knowledge were analyzed by age distribution (11-13 years = 48%; 14 years = 38%; 15-16 years = 13%).

Results: Respondents aged 11-13 had higher gender-equitable beliefs (21%) than the older age cohorts (Table 1). Respondents in the younger cohorts had higher perceived self-efficacy (11-13 years = 25%; 14 years = 32%) than the oldest cohort (15-16 years = 15%). The mean level of HIV-related knowledge decreased with age (11-13 years = 3.53; 15-16=3.22). 31% of all respondents reported intimate partner violence (IPV) as unacceptable; justification of a boyfriend’s violent behavior increased with age (11-13 years = 18%; 15-16 years = 33%). 47% of all respondents identified street, 24% school, and 17% home as high-risk areas of violence. 48 respondents (42%) reported experiencing IPV, and 126 (63%) reported experiencing non-partner violence in the last 12 months. 62% of respondents who had experienced violence reported disclosure of experience to parents. 58% of respondents shared IPV experiences with mothers; 2% with fathers. 31% and 36% respectively reported to police for IPV and non-partner violence.

Age of respondents | Percent of respondents with low gender-equitable beliefs (no. of respondents) | Percent of respondents with moderate gender-equitable beliefs (no. of respondents) | Percent of respondents with high gender-equitable beliefs (no. of respondents) | Total percent of respondents (total no. of respondents)
|---|---|---|---|---|
11-13 years | 18.6 (18) | 60.8 (59) | 20.6 (20) | 100.0 (97)
14 years | 21.1 (16) | 60.5 (46) | 18.4 (14) | 100.0 (76)
15-16 years | 25.9 (7) | 66.7 (18) | 7.4 (2) | 100.0 (27)
Total | 20.5 (39) | 61.5 (123) | 18.0 (36) | 100.0 (200)

[Table 1: Level of gender-equitable beliefs by age]

Conclusions: Findings indicate that older girls reported lower gender-equitable beliefs, self-efficacy, and HIV-related knowledge, and higher justification of a boyfriend’s violent behavior than younger girls. These data demonstrate high experiences of violence and absence of the father when disclosing violence among girls. Creating a safe space and integrating linkages to support services, family, and schools is important.
MOPEC477
Gender norms, masculine gender-role strain and HIV risk behaviors among men in rural South Africa
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Background: Theory suggests that gender norms and the related construct of masculine gender-role strain (MGRS) influence HIV risk behaviors among men. Evidence supports a link between inequitable gender norms and HIV risk in the African setting. MGRS, defined as the psychological strain men experience from trying or failing to live up to masculine expectations, has rarely been examined as a predictor of risk behaviors in HIV prevention research.

Methods: We examined associations between men’s gender norms and MGRS and sexual partner concurrency, intimate partner violence (IPV) perpetration and alcohol abuse using data from a household survey of 579 183-5 year-old men residing in the rural Agincourt Health and Socio-demographic Surveillance Site, South Africa. To measure gender norms we used the Gender Equitable Men’s Scale. To measure MGRS we used a multi-dimensional scale we developed for the South African context.

Results: Prevalence of concurrency in the last 12 months was 38.0%, 13.4% of men reported perpetrating IPV in the last 12 months, and 19.9% abused alcohol. In multivariate analyses that controlled for demographic characteristics, more inequitable gender norms was significantly associated with an increased odds of concurrency (AOR 1.31, 95% CI: 1.07-1.62, p<0.01), IPV perpetration (AOR 1.41, 95% CI: 1.04-1.87, p=0.02), and alcohol abuse (AOR 1.40, 95% CI: 1.04-1.87, p=0.02). Higher MGRS was also associated with an increased odds of concurrency (AOR 1.26, 95% CI: 1.06-1.50, p=0.008), IPV perpetration (AOR 1.48, 95% CI: 1.17-1.88, p<0.001) and alcohol abuse (AOR 1.58, 95% CI: 1.22-2.03, p<0.001). Analyses of the specific relationships between different MGRS sub-dimensions and study outcomes from descriptive analyses of associations between concurrency and subordination to women (p=0.04), IPV perpetration and restrictive emotionality (p=0.006), and alcohol abuse and success, power, competition (p=0.008).

Table 1. Multivariate logistic regression results

<table>
<thead>
<tr>
<th>Sexual partner concurrency</th>
<th>Intimate partner violence perpetration</th>
<th>Alcohol abuse</th>
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<tr>
<td>(AOR 95% CI)</td>
<td>(AOR 95% CI)</td>
<td>(AOR 95% CI)</td>
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<tr>
<td>Inequitable gender norms</td>
<td>1.31 (1.07-1.62)</td>
<td>1.40 (1.04-1.87)*</td>
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<tr>
<td>MGRS sub-dimensions</td>
<td>1.26 (1.06-1.50)**</td>
<td>1.58 (1.22-2.03)***</td>
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Conclusions: Men with more inequitable gender norms and higher MGRS are more likely to engage in HIV risk behaviors in this setting. HIV prevention programs to transform gender norms should be coupled with strategies to reduce the strain men experience around fulfilling expectations of themselves as men. Research is needed to identify effective strategies to reduce MGRS, currently lacking worldwide.

MOPEC478
Factors associated with living with HIV between men and women in people living with HIV/AIDS in Guangzhou, China
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Background: Previous studies have shown gender differences in factors associated with depression among the general population, but few studies have examined such differences in people living with HIV/AIDS. This study aimed to explore the rates of depression and associated factors between men and women among people living with HIV/AIDS.

Methods: We conducted a cross-sectional survey by convenient sampling from March to June, 2013 in Guangzhou, China. Center for Epidemiological Studies Depression scale (CES-D) was utilized to measure depression of 409 PLHWA, including 286 men and 123 women. 16 was the cut-off point for depression. Chi-square tests and multivariate unconditional logistic regressions were performed to explore the related factors with depression.

Results: The average age of PLHWA was 39.4 years for male and 36.0 years for female; about 54.9% female and 48.9% male PLHWA were married/cohabitation (P<0.027), 54.9% male and 25.0% female had middle school education or higher (P<0.001). The rate of depression was 48.2%, with 49.0% for male and 46.3% for female. Multivariate Logistic regressions showed that for male PLHWA, HIV-related stigma was significantly associated with depression (OR=3.222, CI: 1.880-5.522), whereas self-efficacy was negatively associated with depression (OR=0.938, CI: 0.896-0.980). For female PLHWA, the risk of depression was significantly higher when the husband was HIV-infected (OR=2.645, CI: 1.033-6.775) and was significantly associated with depression, whereas social support was negatively associated with depression (OR=0.937, CI: 0.139-0.771).

Conclusions: The rates of depression were high for both male and female PLHWA in Guangzhou, China. There were gender differences in factors associated with depression. Future interventions targeting PLHWA to improve mental health need to take into account gender differences. Strategies to reduce HIV-related stigma, help improve self-efficacy for male PLHWA and strengthen social support for female PLHWA are likely to have the potential to reduce depression and improve mental health among PLHWA.

Reproductive choices and interventions for women (including discordant couples)

MOPEC479
High levels of unmet need for family planning among HIV-infected women participating in an open HIV community cohort study in rural Tanzania: implications for HIV prevention and service integration
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Background: Unmet family planning (FP) needs contribute to HIV transmission and un-wanted pregnancies. This study investigated factors associated with unmet FP need in rural Tanzania.

Methods: Data on sexual and reproductive health needs and HIV service use were collected using structured questionnaires during the 2012 round of a community-level HIV surveillance study, covering a population of approximately 30,000 persons. HIV voluntary counseling and testing services were available during surveillance rounds, and at the local health centre from 2005. Antiretroviral therapy was also available from 2005. FP services were available at the local health centre, but were not integrated with HIV services. Women of reproductive age were defined as having unmet FP need if they were married or sexually active in the past two years and were not using modern contraception. Cross-tabulations were used to describe the distribution of unmet FP need, contraceptive prevalence and fertility intentions by HIV status, and by HIV diagnosis and treatment status. Logistic regression was used to identify factors independently associated with unmet FP need.

Results: 8.8% (199/2258) of included women were HIV-infected, of whom 52% knew their status, 38% reported modern contraceptive use. Unmet FP need was 64% overall and highest among HIV-infected women receiving HIV care (figure 1). Factors independently associated with unmet FP need included age, marital status, area of residence, education, income source, etc.
parity, and HIV and treatment status. Demand for FP (unmet FP need plus current contraceptive use) was 70% among HIV-negatives and 74% among HIV-positives, while the proportion of demand satisfied (FP use/demand) was 19% and 18% among HIV-negatives and HIV-positives respectively, reflecting low contraceptive use. Among women with unmet FP need, 49% of negatives and 43% of positives reported past, or intended future FP use.

### MOPEC480

**Pregnancy incidence and outcomes in women receiving tenofovir-based PrEP in the VOICE trial**


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**Background:** Reproductive aged-women are a primary target for antiretroviral pre-exposure prophylaxis (PrEP) for HIV prevention. Understanding exposure effects of PrEP in the periconception period is vital to assessing drug safety. While oral tenofovir disoproxil fumarate (TDF) and emtricitabine/TDF (FTC/TDF) are FDA approved PrEP medications, the efficacy of 1% tenofovir vaginal gel (TFV) is yet to be established. We assessed pregnancy incidence and outcomes among women assigned to these products in the VOICE trial.

**Methods:** VOICE was a five-arm, double-blinded, randomized, placebo-controlled trial of daily oral TDF, oral FTC/TDF and vaginal TFV for HIV pre-exposure prophylaxis (PrEP) vs. oral placebo. Pregnancy incidence was performed monthly and if positive, study product was withheld. Pregnancy incidence was calculated per 100 person-years of follow-up and compared across arms using an Andersen-Gill proportional hazards model. Risks of ART initiation regardless of clinical/immunological criteria. Proportion of ART-uptake within one-month of an HIV clinic visit were compared between reporting quarters (PMTCB+), and between patients with high (>350) and low (<350) CD4 levels (PMTCB+EAA).

**Results:** Overall, 665 women were eligible for ART under PMTCB+. ART-uptake at CD4=350 increased in consecutive quarters from 60% (Q1-2013) to 92% (Q2-2014) (p<0.01), and it was higher than in CD4<350 group (86%; p=0.03) at the end of the pilot. Six of 9 facilities had uptake levels >80%. In the first 3 months of EAAA implementation, 287 clients initiated ART of which 203 (71%) were already enrolled into ART care and 84 (29%) were new HIV+ cases (p=0.01). Among new HIV+ cases with one-month minimum follow-up time (n=99), ART-uptake was 63% for CD4≤350 and 73% for CD4>350 (p=0.17).

**Conclusions:** Differences in pregnancy incidence and outcomes did not differ across arms. Specifically, neither the use of tenofovir-based medication nor the presence of gel in the vagina impacted early loss rates. Study product adherence was suboptimal; therefore, further analyses integrating data on drug detection in the periconception period are ongoing. However, the present analyses suggest that tenofovir-based PrEP exposure, including a vaginal formulation, is safe in the periconception period.

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**Population-based intervention studies**

MOPEC481

**Treatment as prevention (TasP) in rural Swaziland: initiating the change towards universal treatment in the public health sector**

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**Background:** Antiretroviral therapy (ART) is an effective HIV prevention tool to reduce both viral load and HIV transmission in HIV+ patients. Swaziland, the country with the highest HIV prevalence globally, developed a Treatment as Prevention (TasP) framework for population HIV incidence reduction. However, evidence is scarce on the feasibility of TasP interventions under routine programmatic conditions. In 2013, the Ministry of Health and Medecins Sans Frontieres (MSF) launched TasP pilot projects in the Shiselweni region to assess feasibility of rapid ART expansion beyond current WHO treatment eligibility criteria.

**Methods:** ART-uptake of two consecutively implemented TasP strategies was analysed in a decentralized health zone with a network of 9 rural health facilities. The PMTCB+ option B (PMTCB+B+) was scaled-up between Jan 2013 to Jun 2014, and followed by phase-in of Early Access to ART for all (EAAA) from Oct 2014 to Dec 2014. Under EAAA, all HIV+ clients aged ≥15 years are eligible for ART initiation regardless of clinical/imunological criteria. Proportion of ART-uptake within one-month of an HIV clinic visit were compared between reporting quarters (PMTCB+), and between patients with high (>350) and low (<350) CD4 levels (PMTCB+EAA).

**Results:** Overall, 665 women were eligible for ART under PMTCB+. ART-uptake at CD4=350 increased in consecutive quarters from 60% (Q1-2013) to 92% (Q2-2014) (p<0.01), and it was higher than in CD4<350 group (86%; p=0.03) at the end of the pilot. Six of 9 facilities had uptake levels >80%. In the first 3 months of EAAA implementation, 287 clients initiated ART of which 203 (71%) were already enrolled into pre-ART care and 84 (29%) were new HIV+ cases (p=0.01). Among new HIV+ cases with one-month minimum follow-up time (n=99), ART-uptake was 63% for CD4≤350 and 73% for CD4>350 (p=0.10).

**Conclusions:** High levels of ART-uptake are needed for TasP to reduce HIV transmission at population level. Early challenges in PMTCB+ implementation were overcome resulting in acceptable ART-uptake levels after scale-up. Early one-month treatment uptake under EAAA was acceptable and comparable with uptake levels in lower CD4 strata. Phase-in of TasP interventions appeared feasible in the public health sector but it may need time and efforts to achieve acceptable treatment uptake.
Economic-based HIV interventions (i.e., micro-capital/cash transfer/contingency management/housing/poverty reduction programmes)

**MOPEC482**

The impact of a multisectoral agricultural and finance intervention on nutritional and HIV health outcomes in rural Kenya

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**Background:** Food insecurity and HIV/AIDS outcomes are inextricably linked in sub-Saharan Africa. We report on health and nutritional outcomes of a multisectoral agricultural intervention trial aimed to improve food insecurity and health outcomes among HIV-infected rural Kenyan adults.

**Methods:** The intervention included:

i) a human-powered water pump,
ii) a microfinance loan (~$125) to purchase the farm and farm commodities, and
iii) education in sustainable farming practices and financial management.

Two health facilities in the Nyariga Region of Kenya were randomly assigned as intervention or control, HIV-infected adults on antiretroviral therapy (n=140) ages 18-49, with access to surface water and land were enrolled beginning in April 2012, and followed quarterly for one year. Data were collected on food security, dietary intake, anthropology, CD4, and viral load measurements. Differences in change between study groups were compared statistically to the baseline from difference between intervention and control arms.

**Results:** We enrolled 72 and 68 participants in the intervention and control groups respectively. At baseline, participants at the two sites were similar in age, gender, education, marital status, and food security, but incomplete viral suppression and low diet diversity were more common in the intervention group. At 12 months follow-up, participants enrolled in the intervention arm of this multisectoral agricultural intervention had statistically significant improvements in nutritional status and food security. At baseline, participants in the intervention arm of this multisectoral agricultural intervention had statistically significant improvements in nutritional status and food security.

**Conclusions:** Participants in the intervention arm of this multisectoral agricultural intervention had demonstrated significant improvements in nutritional and health outcomes compared to controls. Lifestyle interventions may be a promising approach to tackle the intersecting problems of food insecurity and HIV/AIDS morbidity.

**MOPEC483**

Economic incentives to increase demand for voluntary medical male circumcision in Kenya: qualitative interviews with participants in a randomized controlled trial


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**Background:** Interventions to increase demand for medical male circumcision are urgently needed in eastern and southern Africa. Despite promising evidence that economic incentives can promote uptake of health interventions, few studies have sought to identify why incentives are—or are not—effective.

**Methods:** As part of a randomized controlled trial in Kenya that found incentives to be effective in increasing male circumcision uptake, we conducted in-depth interviews with 45 circumcised and uncircumcised participants to explore how the incentives influenced circumcision uptake. An inductive, thematic analysis was conducted to identify patterns in decision-making.

**Results:** Financial concerns, particularly the prospect of lost wages, continue to be an important consideration for many adult men. Economic incentives in the form of food vouchers conditional on becoming circumcised were found to be effective because they partially compensated participants for the transportation and opportunity costs such as lost wages associated with getting circumcised. Many circumcised participants stated the economic incentive was influential because (a) it offset associated costs and increased their willingness to get circumcised; or (b) it ‘nudged’ them towards doing something that they had previously been intending to do. Moreover, we found that offering even higher amounts could increase male circumcision uptake without being coercive. For the majority who chose not to get circumcised, the incentive amounts were perceived as either being inadequate relative to their expected circumcision-related costs or not addressing their non-economic barriers to VMMC uptake.

**Conclusions:** This study provides important insights into how economic incentives influence men’s decision-making about VMMC. Men explain a detailed thought process by which they weighed the costs and benefits of becoming circumcised and assessed whether the voucher was sufficient to outweigh the costs incurred through loss of income and transportation. The vouchers offered were not effective for addressing all men’s concerns and demand generation strategies other than economic incentives are needed to address the array of circumcision-related concerns men have. However, they were an important tool for increasing circumcision uptake among some adult men and warrant further consideration in future VMMC demand creation efforts.

**Assessing impact/cost-effectiveness of structural interventions**

**MOPEC484**

Evaluating the impact of health system strengthening on HIV and sexual risk behaviors in Nigeria

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**Background:** Evaluating the impact of health system strengthening on disease and behavior change outcomes provides evidence of returns on investment in health. The Enhancing Nigeria’s Response (ENR) to HIV/AIDS project began implementation of a health systems strengthening (HSS) program in seven states in Nigeria in 2008. We evaluated the impact of HSS on HIV prevalence and sexual risk behaviors in the project states.

**Methods:** Between 2007 and 2012, two rounds of HIV bio-behavioral surveys were conducted in Nigeria and evaluated in a cross sectional analysis. Contiguous states with similar socio-cultural characteristics and no presence of HSS programs (non-HSS) served as comparative groups. Chi-square was used to evaluate differences over time while logistic regression was used to assess the impact of the HSS program on HIV and risk behaviors.

**Results:** A total of 4,856 and 11,712 respondents were surveyed in 2007 and 2012 respectively with females accounting for 47% and 50% in 2007 and 2012. Overall, change in HIV prevalence between 2007 and 2012 was 6.3% vs. 5.3%(p<0.113) and 3% vs. 5.1%(p<0.001) in the HSS and non-HSS states respectively. Overall change between 2007 and 2012 for HIV and non-HSS states respectively was 19.5% vs. 34.2%(p<0.001) and 17.1% vs. 32.8%(p<0.001) for ever testing for HIV; 4.9% vs. 7%(p<0.001) and 5.0% vs. 4.7%(p=0.545) for comprehensive HIV knowledge; 59.3% vs. 58.7%(p=0.959) and 29.4% vs. 45.2%(p=0.121) for ever testing for HIV; 4.9% vs. 7%(p=0.001) and 5.0% vs. 4.7%(p=0.545) for consistent condom use with casual partners; 43.7% vs. 49.2%(p=0.064) and 38.5% vs. 39.7%(p=0.739) for consistent condom use with boy/girlfriends over 12 months. When controlled for age, gender, HSS intervention, location (rural vs. urban) and year (2007 vs. 2012),
MoPec485
Model the impact of needle and syringe program on HIV incidence: how to gain more
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Background: Sharing syringes by people who inject drugs (PWID) is an important mode of global transmission of HIV. Since 2002, needle-syringe programs (NSPs) have been one of the core public health strategies aimed at reducing the sharing of syringes in Iran. However, the impacts of NSPs in developing settings have not been systematically studied. The objective of this study is to estimate the impact of NSPs on HIV incidence in PWID in Kermanshah, Iran.

Methods: We used Wilson et al. mathematical model to forecast the incidence of HIV among PWID with sufficient and insufficient client-level coverage of NSPs. We parameterized and calibrated the model using behavioral and epidemiological data collected in an empirical study of 470 active injecting drug users living in Kermanshah in 2014. Other parameters such as risk of HIV transmission per injection with a shared injection, and effectiveness of syringe cleaning were obtained from literature. We applied Monte Carlo simulation (10,000 runs) to capture the uncertainty (simulation interval - SI) in the results given the uncertainty in the parameters.

Results: Given the output of the model, we found that among PWID with sufficient coverage of NSPs the HIV incidence is 1.02%, while in those with insufficient coverage it's increased to 4.06% (relative difference 337%, SI95% 272.4-451.9%). By decreasing the percentage of sharing from 18% (in PWID with insufficient NSPs coverage) to 10%, the HIV incidence will be dropped to 0.9% (SI95%, 0.4-1.3%).

Conclusions: We found a large impact of NSPs on reducing the HIV incidence among active drug injectors if they have been provided sufficient needles and syringes. The coverage of NSPs needs to be increased to observe such significant impact.

Gender sensitization, empowerment and violence reduction
MoPec486
Understanding the violence cycle and the impact of structural interventions reducing different forms of workplace violence perpetrated against female sex workers: implications for HIV prevention
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Background: Recent and past exposure of female sex workers (FSWs) to workplace violence (e.g. by police, clients) continues to be high and frequently global, facilitated by criminalization of sex work, stigma and perspectives of FSWs as transgressing gender norms. Increasing evidence suggests sexual/physical violence may be associated with lower client condom use and increased HIV risk. Understanding the violence cycle and impact of reducing violence is critical to designing structural HIV interventions to support FSWs health and human rights. We assess the impact of violence prevention and influence of violence dynamics on violence outcomes among FSWs in Vancouver.

Methods: A dynamical deterministic compartmental model was developed, comprehensively representing multiple violence pathways. We assumed women began sex work prior to experience of workplace violence (police harassment, client physical violence (CPV) or client sexual violence (CSV)). Over time SWs could independently experience different forms of workplace violence multiple times. Data for model parameters came from a community prospective cohort (An Evaluation of Sex Workers’ Health Access, AESHA). The model reflected data suggesting increased risks of PH or CSV following CPV (IR or IRCH, respectively), and of CSV following PH (IRCH). We used Wilson et al mathematical model to forecast the incident of HIV among FSWs in AESHA.

Results: We found a large impact of NSPs on reducing the HIV incidence among active drug injectors if they have been provided sufficient needles and syringes. The coverage of NSPs needs to be increased to observe such significant impact.

Research designs in epidemiology
MoPec487
What is the effect of including online-recruited seeds within an in-person bio-behavioural study of men who have sex with men (MSM) employing respondent-driven sampling (RDS)?
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Background: Respondent driven sampling (RDS) is an increasingly popular method for recruiting MSM in research. “Seeds” (initial participants) are purposively selected in-person or online and given a determined number of coupons to assist with study recruitment. We aimed to discover differences between...
Research designs in prevention research

MOPEC488
Implementing electronic coupons within respondent-driven sampling (RDS) to improve recruitment of men who have sex with men (MSM) in Vancouver, British Columbia

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Background: Respondent driven sampling (RDS) has been utilized in HIV research for selecting and connecting with under-represented communities like men who have sex with men (MSM). RDS ‘seeds’, primary participants who are equipped with a selected number of vouchers via email or paper to continue recruitment. The objective of this study was to explore the impact of online and electronic RDS innovations on differences between MSM who redeemed electronic versus paper coupons.

Methods: Participants were MSM aged ≥16 years, recruited using RDS from February 2012 to February 2014 to complete a self-administered computer-based survey. Seeds were selected online (e.g., Grindr; social media) or offline (e.g., community agency, social group) and recruitment coupons were electronic or paper. All analyses used RDS weights. Manual backward-stepwise multivariate logistic regression was used to examine factors associated with redeeming an electronic versus paper coupon.

Results: Of 596 participants recruited from seeds into the study, 93 redeemed electronic coupons (15.6%) and the remaining 503 redeemed paper coupons. Men who redeemed online coupons were more likely to be within a recruitment chain started by an online seed (91.4%) compared with men who redeemed paper coupons (84.4%; odds ratio (OR)=1.97, 95% Confidence interval: 1.18, 3.27). MSM who redeemed an electronic coupon were more likely to be currently HIV-positive compared with paper versus not (adjusted odds ratio 1.26, 95% Confidence Interval 1.46-6.59), to be homeless versus stably housed (AOR=4.48[1.39-13.32], to have come out as gay more recently (e.g., within 1-4 years versus ≥11 years, AOR=2.53[1.10-5.81]), to be out at work versus not (AOR=3.88[1.44-10.45]), to be out to their male guardian versus not (AOR=2.53[1.14-5.62]), to prefer not to have anal sex versus receptive anal sex (AOR=4.97[1.37-18.01]), to be in a relationship ≥1 year versus < 1 year (AOR=0.03[0.01, 1.02]), to ask partner’s HIV status < 50% of time versus >50% of time, and recruitment coupons were electronic or paper. All analyses used RDS weights.

Conclusions: While offline seeds were more productive recruiters, electronic innovations allowed for a diverse set of seeds that recruit chains that differ from in-person and offline recruited seeds.

MOPEC489
Effect of antiretroviral therapy on diarrhea incidence and stool pathogens among HIV-infected individuals in rural Uganda: a prospective population-based cohort study

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Background: Diarrhoea is a common problem in people with untreated HIV infection, especially with increasing immunosuppression. We examined the effect of ART on diarrhoea and stool pathogens among HIV-infected individuals in rural Uganda.

Methods: In a cohort of HIV-infected and uninfected participants followed from 2005-09, stool microscopy (modified Zehl Neelsen stain) was done at quarterly visits and whenever participants presented with diarrhoea, and diarrhoea samples were cultured. HIV-infected participants had regular CD4 cell count measurements. We identified pathogens and compared diarrhoea incidence in three groups of participants: HIV-uninfected, HIV-infected not yet on ART, and those on ART. Random effects Poisson regression models were used to account for repeated events and adjustment: made for covariates (HIV and ART status).

Results: 282 diarrhoea events occurred: 28 among 205 HIV-uninfected, 127 among 262 HIV-infected not yet on ART and 97 among 283 HIV-infected on ART. ART 44 events (15.6%) yielded positive stool pathogens and 95 (33.7%) yielded positive non-pathogenic organisms. The proportions of participants with pathogenic and non-pathogenic organisms were highest among HIV-infected individuals not on ART. The commonest pathogens (number of isolates) were: Giardia lamblia (22), Shigella (13) and cryptosporidiosis (4). Pathogens (number of isolates) isolated from HIV-infected individuals not yet on ART were G. lamblia (13) and Shigella (9), and among HIV-infected participants in ART G. lamblia (8) and Shigella (6).

Compared with an incidence of 0.50 per 100 pyr [95%CI 0.20-1.40] among HIV-uninfected participants, diarrhoea incidence was modestly increased among HIV-infected individuals on ART for up to 2 years (AHR 2.37 [95%CI 0.68, 8.24]) and much higher among not yet on ART (adjusted relative rate [ARR]) 8.00 [95%CI 2.89, 25.07]). Diarrhoea incidence was higher at CD4 cell counts less than 250 (p<0.001).

Conclusions: Pathogenic and non-pathogenic organisms were most commonly isolated from HIV-infected individuals not yet on ART. ART reduced the risk of HIV-related diarrhoea.

MOPEC490
A comparison of strategies to recruit Black men who have sex with men with undiagnosed HIV infection and/or suppressed viral load

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Background: HIV prevalence among US Black men who have sex with men (BMSM) is nearly 4-fold higher than among White MSM and evidence suggests that BMSM are less likely to be aware of HIV infection and to be in care. Identifying effective strategies to find such individuals is a national priority. We compared the effectiveness of respondent-driven sampling (RDS), community-based (CB), web-based (WB), and hybrid (HYB) recruitment methods to identify BMSM with undiagnosed HIV and/or suppressed HIV infection.

Methods: From July 2012 to December 2014, RDS (a chain referral sampling method in which participants receive incentives for recruiting members of their social networks) was used to enroll BMSSM at risk for HIV infection in a study of testing, linkage, and retention in care. RDS was supplemented with CB outreach and WB recruitment beginning in August 2013. All participants enrolled through CB and WB methods were offered incentives to recruit their associates via RDS; these enrolled associates are referred to as HYB-CB and HYB-WB, respectively. Rapid HIV testing was done; participants with reactive tests had confirmatory testing and HIV RNA viral load measured. Participants with viral load < 200 copies/ml were considered virally suppressed (VS). Associations were tested using Chi-square, Fisher’s exact, and Wilcoxon rank-sum tests.

Results: 1552 eligible BMSM were enrolled and tested for HIV over 29 months. Median age was 43 years; 27% of participants were Latino, 3% transgender and 63% identified as bisexual. Overall, 7% were HIV-infected. HIV infection was associated with recruitment method, with highest prevalence among those recruited via HYB-WB, albeit with low yield (p<.001), younger age (p=.041), being transgender (p=.002), homosexual/gay identity (p<.001), and more than high school education (p<.019). Of HIV-infected participants, 45% were VS at enrolment. There was no significant difference in VS by recruitment method (p=0.369) (see table).
MOPEC491

Estimating the population-level impact of methamphetamine use on HIV acquisition among men who have sex with men using population attributable risk percent: a powerful and underused planning tool

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Methods: We used data from multiple sources, including the National HIV Surveillance System (NHSs), National HIV Behavioral Surveillance (NHBs), Seattle Gay Pride survey, and the KC STD Clinic. We defined the number of MSM at risk of acquiring HIV as: the number of male KC residents 15 years and older times 0.054, minus the number of MSM living with HIV (Table). Data on methamphetamine use were available from NHSs and STD Clinic patients recently diagnosed with HIV. Gay Pride, STD Clinic, and NHSs data provided age-standardized estimates of the proportion of HIV-uninfected MSM who used methamphetamine in the last year. PAR% was calculated as the estimated population incidence minus the estimated incidence in non-methamphetamine-users divided by the estimated population incidence.

Results: The overall 2013 incidence of HIV among MSM was 474 per 100,000 people at risk. The estimated incidence of HIV for methamphetamine users (25% of recent HIV infections) was 1,984 per 100,000. Among MSM who did not report using methamphetamines in the last year, HIV incidence was estimated as 377 per 100,000 (relative risk = 5.3, 95% CI = 3.7 - 7.3). Estimates of methamphetamine use among HIV-negative MSM ranged from 3% (Gay Pride) to 10% (NHBs). These led to an estimated PAR% of 20%. With 87% of KC HIV diagnoses occurring among MSM, we estimate that methamphetamine use among MSM might be associated with 2% of HIV infections.

Conclusions: Methamphetamine use contributes substantially to ongoing HIV transmission among MSM. KC HIV prevention programs might consider incorporating PAR% for prevention decisions. KC HIV prevention will benefit from methamphetamine prevention and harm reduction interventions.

MOPEC492

Cohort study as a comprehensive approach to evaluate the impact of HIV prevention interventions on risk behavior change and HIV seroconversion among PWIDs in Ukraine

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Background: HIV prevention program among PWIDs has been implemented in Ukraine since 2004. 60% PWID of 310,000 estimated are covered annually with prevention services. The comprehensive HIV prevention package includes condoms and syringes provision, medical/social specialist counseling, informational-educational activities, HIV, HCV and STI testing. So far, no study on impact of available prevention activities on HIV incidence among PWIDs has been done in Ukraine.

Methods: The study is a 2-year research which implies a combination of retrospective analysis of programmatic data and prospective multi-center cohort study conducted in 11 randomly chosen cities, which represent regions with all levels of HIV prevalence among PWIDs. A cohort of 2,200 PWIDs HIV-negative, who are clients of HIV prevention program, was recruited by using respondent-driven sampling. HIV incidence and risk behavior change are the main study outcomes, measured at baseline and every 6-month follow-ups by using interviews and HIV rapid tests which will be confirmed with additional lab assays on dry blood spot samples.

Data, collected within the cohort study, is linked to programmatic data collected with a help of SYREX database which tracks each client and services s/he received for the analysis. The impact will be assessed in both retrospective and prospective part using time-to-event statistical methods based on frequency of services utilization by clients.

Results: The preliminary analysis of the prospective data showed that out of 2143 PWIDs covered with HIV prevention packages, 28 PWID's seroconverted within first 6-months and additional 16 new HIV cases were detected in the 12-months follow-up. All new cases are associated with risky injection behavior during the last injection 3.6% vs 1.9% (p< 0.01) and during last 30 days 6.5% vs 10.1% (p< 0.01). Retrospective data analysis identified main patterns of services utilization: occasional clients, minimal package clients, regular testers, regular clients and secondary exchangers.

Conclusions: The study documents the impact of available prevention services on risk behavior change and HIV incidence in the prospective cohort of PWIDs in Ukraine. This will, for the first time, enable to make an evidence-based decision with regard to the most effective activities to be included into the National AIDS Programme.

Ethical and human rights issues in prevention research

MOPEC493

Barriers to and strategies for reducing the length of informed consent forms in HIV prevention research

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Background: Sufficient understanding of a research study is necessary for potential research participants to make informed decisions about enrolling. Yet, long informed consent forms (ICFs), which are commonplace in HIV-related research, are a barrier to understanding research and place an unnecessary burden on both potential participants and study staff. Limited data are available on barriers to and strategies for reducing the length of ICFs in HIV prevention research.
Methods: We partnered with two active HIV prevention studies within the HIV Prevention Trials Network (HPTN) to identify barriers to and strategies for reducing ICF length. We conducted 100 in-depth interviews with a variety of key stakeholders: HPTN research participants (n=42); HPTN study chairs, core staff, site investigators, and site staff (n=20); community representatives (n=11); representatives of the Division of AIDS at the National Institutes of Health (n=9); officials at institutions where HPTN research is conducted (n=6); and members of institutional review boards that review HPTN research (n=12). The data were analyzed using qualitative thematic analysis.

Results: Legal concerns were the most common barrier mentioned, followed by habit or reluctance to challenge the status quo, and then by a sense of duty to provide sufficient information. Stakeholders also described how multiple groups — institutions, agencies, and institutional review boards — must review, come to consensus on, and approve the language included in ICFs, while ensuring that their separate ICF template language remains intact. Several strategies were identified to reduce ICF length, such as reducing repetition, removing superfluous information, grouping study procedures by visits, simplifying the listing of risks, and placing reference-type information in appendices.

Conclusions: Multiple barriers limit the use of shorter ICFs in HIV prevention research. Identifying these barriers and building awareness of them among key stakeholders should facilitate dialogue on implementing the suggested strategies to reduce ICF length. In the next phase of the research, stakeholders will review findings from the initial in-depth interviews and reach consensus on recommendations for reducing ICF length through a series of online surveys. Findings from this research would be used to advance the use of shorter ICFs in HIV-related research.

Estimation of the size of HIV-infected and key populations

MOPEC494

Adjustment of HIV prevalence in men who have sex with men to account for changes in networking pattern following diagnosis

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Background: HIV prevalence of men who have sex with men (MSM) at community level is often determined by surveys conducted at specific venues. This approach is based on the assumption that MSM’s frequency of visiting social venues for sex-networking is independent of one’s HIV status. The validity of such assumption is questionable as sex-networking behaviours may change following HIV diagnosis. This study aims to assess the changes of sex-networking patterns among MSM following HIV diagnosis and assess its impact on estimating the HIV prevalence of MSM population.

Methods: A venue-based survey in 2011 gave an HIV prevalence of 4.08% among MSM in Hong Kong. Separately, data on the use of local bars, saunas and beaches for sex-networking among HIV-infected MSM were collected from a cross-sectional questionnaire survey, which was conducted at the largest HIV specialist clinic in Hong Kong between October and December 2014. The post-diagnosis sex-networking patterns were used to estimate the relative size of MSM populations in different social venues and adjust the result of the previous prevalence study.

Results: Out of 345 recruited MSM, 153 were diagnosed in or before 2010. Of these, 62.1%, 76.4% and 54.2% had visited local bars, saunas and beaches for sex-networking respectively before their HIV infection status was known, while the corresponding figures in 2011 were 64% (113/174), 83% (113/137) and 74% (106/143) respectively. Their HIV seroconversion was estimated to be 4.56% after accounting for the differential usage of social venues for sex-networking among HIV-infected MSM.

Conclusions: Since a proportion of MSM is likely to avoid social venues after their diagnosis of HIV infection, sampling bias might be introduced in venue-based subject recruitment for HIV prevalence studies. Thus, HIV prevalence derived from venue-based surveys have to be adjusted by the degree of venue attendance among HIV-infected MSM. The ever-changing sex-networking pattern among HIV-infected MSM also deserves monitoring for assessing its long-term impacts.

MOPEC495

Estimating the population size of injection and non-injection drug users along the coast and in other regions of Tanzania 2013/2014

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Background: People who use (PWUD) and inject (PWID) drugs are at higher risk for acquiring and transmitting HIV through sexual and injection behaviors. Injection and non-injection drug use is thought to be spreading in parts of sub-Saharan Africa; however, very little is known about the scope of drug use in regions of Tanzania outside Zanzibar and Dar es Salaam. From 2013-2014, we conducted a rapid assessment to identify drug-use hotspots and estimate the number of PWUD/PWID in 12 regions of Tanzania (Mwara, Dodoma, Morogoro, Pwani, Kilimanjaro, Arusha, Mtwara, Mbeya, Mwanza, Geita, Shinyanga, Kigoma).

Methods: To estimate the locations of drug use and the number of PWUD/PWID in each region, we triangulated data through:

(1) key informant interviews with PWUD, PWID community members, government officials, and health care providers;

(2) population size estimation using Wisdom of the Crowds, mapping enumeration, and modified Delphi;

(3) drug use hotspot location with GPS. Data collection and synthesis occurred successively within each region in a robust, iterative process.

Results: Of 436 key informants interviewed, 75% were PWUD/PWID, 9% police officers, 5% health care providers, and 11% community leaders and service providers overall. Illicit drug use occurred in all regions, with regional differences in the number of PWUD/PWID (table 1). Mwara had the smallest number of PWUD at 65 (35 - 105), with few PWID and no females. Mwanza had the largest number of PWUD and PWID, followed by Mwara and Arusha. Mwanza, Arusha, and Mwanza had the largest numbers of female PWID.

Conclusions: We found drug use in all twelve regions which highlights the need to develop substance use prevention and harm reduction services in a timely manner to protect these populations from adverse health outcomes including HIV. Our study serves as a foundation for understanding the nature of the drug use epidemic throughout a wide area of the nation. Data can inform geographic targeting of HIV prevention and care interventions and provide a sampling frame with points of access to the population’s future research.

 mopec496

Using GPS data to uncover a “hidden” HIV epidemic

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Background: Treatment-as-prevention (TasP) is being considered as a global policy to control the HIV pandemic. To implement the rollout of TasP in an efficient manner, it is essential to estimate the number of HIV-infected individuals and where they live. Here we show how to solve this problem by using geostatistical techniques and global positioning (GPS) data for Lesotho, which has one of the most severe HIV epidemics worldwide (prevalence 24%).

Methods: We used HIV prevalence data collected in the 2009-10 Lesotho Demographic and Health Survey (GPS data based on geographic cluster sampling) and geographic population data from WorldPop (raster image data based on settlement mapping and satellite imagery data) to estimate the number of HIV-infected individuals and where they live throughout Lesotho. We use geostatistical methods (e.g., adaptive bandwidth kernel density estimation and ordinary kriging) to map prevalence and the density of infection throughout the country.
MOPEC497
Unblocking the hurdles to key populations size estimations and effective service delivery among such groups: a study in response to effective planning for key populations in East Central Uganda

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Background: STAR-EC is a USAID supported program implemented by JSI and covering three million people in East-Central Ugandan region. About 20% of fisher-folk who are part of Key Populations (KPs) in the region are HIV positive - a far higher prevalence compared to 5.8% (regional average). KPs are therefore increasingly being targeted under the national HIV response. However, there is absence of national census data and limited strategic-information on key population size, locations and characteristics. In 2012, a study was conducted to fulfill the aforementioned and enhance realistic targeting, planning and response to needs of such groups that are the highest nexus of new HIV infections.

Methods: Quantitative methods were used through a descriptive-cross-sectional study. Methods and procedures varied according to the uniqueness of each target-population. They included: physical counts, register review, snowballing and individual survey enumeration matrices while geographical-coordinate systems were used to generate maps illustrating hotspots. Additionally, qualitative methods such as key-informant interviews, focus group discussions and observations were used in triangulation and enhancing validity of quantitative results. After estimating target groups, community service agents, peers and health-workers were used to implement tailored interventions that addressed their unique-needs.

Results: A total of 82,338 KPs (78.2%males, 21.8% females; and 10.4% HIV+) were estimated from predominately identified KP groups representing 3% of regional population. Among these were: 1,497 sex workers majority aged 15-40 years operating in urban areas; 63,640 highly mobile fishing community population with spouses at different landing sites (489 lodge based); 2,500 uniformed service personnel characterized with transactional nearby community sexual-contacts; different nationalities of truckers and their assistants (321 per night) formed the key customers of sex-workers at hotspots; 2,201 plantation-workers (mainly migrants) while 12,680 bodaboda motorcyclists mainly aged 15-35 years were identified among emerging groups. Within one year of implementation, 70,473 (86%) KPs were reached with different HIV prevention and care services.

Conclusions: Improved and successfully targeted interventions are achievable once population estimation and characteristics of such complex groups (KPs) is established. There’s a huge youthful-population of ‘bodaboda’ motorcyclists whose characteristics typify them as emerging-KPs and should be increasingly targeted with interventions. Some KP groups characterized with spatial-population distribution can be estimated and at lower costs.

MOPEC498
Estimating the size of the MSM population using multiple methods and data sources in Vancouver, British Columbia

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Background: Lack of a reliable population size estimate of men who have sex with men (MSM) impedes research and epidemiologic depictions of the HIV epidemic.

Methods: We estimated the Metro Vancouver MSM population size drawing on four data sources: Momentum Health Study cross-sectional questionnaire of MSM aged >15 years recruited from February 2012 - February 2014 using respondent-driven sampling, British Columbia Centre for Disease Control’s HIV testing data from February 2012 - February 2014 for three MSM-specific/popular sexual health clinics, the 2011-2012 Canadian Community Health Survey (CCHS) administered by Statistics Canada, and Facebook (social networking site). Estimates were calculated using the indirect method (Nv), where Nv is the population estimate, n is the number of MSM in the group (e.g., number of MSM-identified tests at a particular sexual health clinic, number of Facebook profiles indicating “men interested in men”) and p is the proportion of the Momentum Health Study participants self-reporting such membership (e.g., having tested at that clinic in the past 2 years, having a current Facebook profile). Estimates using HIV testing site data were adjusted by average number of tests in the past two years reported by Momentum respondents. ‘Wisdom of The Crows’ (WOTC) method was used to produce an additional point estimate based on Momentum participants’ estimates of the local MSM population.

Results:

<table>
<thead>
<tr>
<th>Data Source &amp; Method</th>
<th>Estimate</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOTC</td>
<td>45,800</td>
<td>To the best of your knowledge, how many men who have sex with men, whether they identify as gay or not, do you think live in the Greater Vancouver region?</td>
</tr>
<tr>
<td>Facebook</td>
<td>23,700</td>
<td>Data from Facebook required user profiles to include personal gender identity and preferred gender of partners</td>
</tr>
<tr>
<td>Sexual Health Clinic HIV Testing Data</td>
<td>44,300</td>
<td>Adjusted for the average number of tests Momentum participants reported on average in the past 2 years</td>
</tr>
<tr>
<td>Canadian Community Health Survey (CCHS) 2011-2012</td>
<td>22,100</td>
<td>Required disclosure of sexuality on government-sponsored, interviewer-administered questionnaire</td>
</tr>
</tbody>
</table>

Table 1. Population estimates by data source
Methodological challenges to scale up and optimization of services

MOPED681
Survey of healthcare professionals on the role of pharmacists in an outpatient HIV clinic setting

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Background: Pharmacists play a variety of roles in the interdisciplinary care of HIV-infected patients. The objective of this study was to describe how HIV healthcare professionals perceive the relative importance of pharmacist activities and compare pharmacist perception to the other disciplines.

Methods: A descriptive cross-sectional survey was developed and sent to Canadian HIV practitioners involved in interdisciplinary teams, including pharmacists, physicians, nurses, etc. Data was collected anonymously in Fluid SurveyTM, a secure online survey tool, using a snowball sampling technique.

Results: Of the estimated 335 emails requesting participation, 95 participants completed the survey (response rate of 28%). Of the 53 criteria, 19 (36%) were characterized as “very important” by more than 50% of respondents. There was a high level of agreement between pharmacists, physicians and nurses on the top 5 most important pharmacist activities requiring patient referral: evaluation of patients on complex treatments, counselling for initiation in ARV therapy, assessment of drug interactions, counselling for change in ARV therapy and patient assessment for recommendations to change ARV therapy; the latter was considered less important by physicians (ranked 8th), whereas assistance in securing drug coverage was rated higher (ranked 3rd). When examining important patient characteristics requiring pharmacists’ intervention, there was a high level of agreement between pharmacists and nurses who ranked the presence of multiple co-morbidities (ranked 4th), whereas nurses added the presence of peri-organ transplant, malignancies requiring therapy and pregnancy as the 5 most important criteria. Despite the fact that 53% responded that a screening tool would not help identify at risk patients, 75% of respondents agreed that a short and simple screening tool could be easily implemented into clinical practice.

Conclusions: A large variety of pharmacist activities were considered “very important” by the majority of participants. The different perceptions of the role of a pharmacist in the care of HIV patients warrants the development of a short, simple screening or referral tool to identify patients most likely to benefit from a pharmacist consult.

MOPED682
Perspectives of HIV-infected adolescents on disclosure of HIV status in Western Kenya

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Background: Best practices for HIV disclosure to infected adolescents are not defined, and there are few data on disclosure practices from the viewpoint of infected adolescents. We sought to better understand HIV-infected adolescents’ perspectives on disclosure in a large HIV care system in Kenya.

Methods: We conducted a qualitative study using focus group discussions (FGD) with HIV-infected adolescents who knew their HIV status and were receiving HIV care at 3 AMPATH clinics in western Kenya. A trained facilitator led the FGD in Kiswahili using a semi-structured interview guide that was based in grounded theory. FGD recordings were translated into English, transcribed, and analyzed using constant comparison, progressive coding, and triangulation to arrive at a contextualized understanding of HIV disclosure from the perspective of infected adolescents.

Results: Twenty-three HIV-infected adolescents participated in 3 FGD. Adolescents’ current average age was 13.5 years, and average self-reported age of disclosure was 10.9 years. Most denied knowing they were HIV-infected before explicitly being told. Per adolescents, clinicians most often conducted disclosure, followed by close relatives (e.g., mother, aunt). Adolescents suggested that disclosure should occur by someone close to the child and should be a process over time, rather than a single event. Adolescents suggested varying ages for disclosure, ranging from 6-18 years, but most agreed that physical and cognitive maturity should be considered prior to disclosure. Services provided by healthcare workers and clinics were described as helpful in the disclosure process, specifically the availability of post-disclosure peer support groups and educational videos. The self-perceived impact of disclosure was mixed, but largely positive; most adolescents saw knowing their status and managing their health (e.g. medication adherence and avoiding HIV transmission) as positive advances, while others reported disclosure did not affect them. Few negative emotional reactions (e.g. “shock” and “confusion”) from disclosure were described, although adolescents noted their caregivers expected more negative reactions.

Conclusions: Adolescents in western Kenya provided valuable insights (e.g. considering maturity level before disclosure and disclosing gradually over time) into preferred practices of disclosure timing and methods. Clinicians should explore how children’s beliefs, preferences, and needs can be incorporated into disclosure.

MOPED683
Criminal justice involvement and the continuum of HIV care among people who inject drugs or smoke crack cocaine in Oakland, CA, USA

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Background: HIV disproportionately affects people who inject drugs (PWID) or smoke crack cocaine (PWSC). Concurrently, PWID and PWSC are more likely than people who do not use illicit drugs to be involved in the criminal justice system, complicating access to coordinated HIV prevention, care and treatment services. We conducted a community-based study of PWID and PWSC to characterize and assess predictors of access to the continuum of HIV services.

Methods: This cross-sectional survey utilized targeted sampling methods to recruit PWID and PWSC in Oakland, California between 2011 and 2013 (N=2,094). Participants were surveyed using a computer-assisted personal interview and received rapid HIV antibody testing. Multivariable logistic regression models were built to assess for associations between predictors and access to the continuum of HIV care.

Results: In the past 6 months, 24% of respondents had been incarcerated and 46% had used illicit drugs to be involved in the criminal justice system, complicating access to coordinated HIV care system in Kenya. Eighty-five percent had ever and 22% had in the past 6 months tested for HIV. HIV antibody prevalence was 2.6% (95% confidence interval [95%CI]: 1.9-3.4%). Men who have sex with men (adjusted Odds Ratio [aOR]=13.41, 95%CI: 5.76-31.18), transgender people (aOR=27.37; 95%CI: 4.58-163.09) and having been in prison (aOR=1.96; 95%CI: 1.03-3.07) was associated with being HIV-positive. Figure 1 illustrates access to the continuum of HIV care, disaggregated by HIV status.

Figure 1. Continuum of HIV care for people who inject drugs or smoke crack cocaine
Participating in risky sexual or injection practices in the past 6 months did not increase the likelihood of having been HIV tested (p=0.183). People with a history of incarceration (aOR=1.54; 95%CI: 1.07-2.23), community supervision (aOR=1.50; 95%CI: 1.08-2.13) and drug treatment (aOR=1.60; 95%CI: 1.13-2.27) in the past 6 months were associated with an increased likelihood of HIV testing. Though high levels of linkage to HIV care and treatment were reported, only 20% remained HIV treatment adherent. Reasons for non-adherence included drug use (32%), adverse side effects (28%), and entry/release from incarceration (13%).

Conclusions: These findings highlight unrealized public health opportunities among this high-risk population. Interventions placed in correctional or community supervision settings, which increase routine HIV testing and ensure proper linkage and adherence support among PWID/PWID, are critical to maximize the prevention and treatment benefits of antiretroviral therapy and end the AIDS epidemic.

MOPED684
Lower ART retention by 2010 guideline revision in resource-limited settings, Zambia

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Background: The Zambian government has been scaling up Antiretroviral therapy (ART) to selected Rural Health Centres (RHCs) since 2007. The guidelines for ART in Zambia were revised in 2010 to follow the recommendation from WHO and revised again in 2014 to follow the new WHO guidelines. However, the impact of the revision in 2010 in RHCs was not evaluated enough.

Methods: The clinical files of all the adult patients (>14 years) who newly initiated ART from 2008 to 2012 at Llungobe RHC, Mumbwa district were reviewed. The number of new ART patients and their characteristics were compared by the year. The One year retention rate on 2011 and 2012. Cox regression analysis was used to evaluate independent factors associated with retention.

Results: Total 412 patients were enrolled in the study. There was no remarkable change in human resource in Llungobe RHC from 2008 to 2012. The number of patients who initiated ART before the guideline revision (2008 and 2009), in the year of the revision (2010), and after the revision (2011 and 2012). Cox regression analysis was used to evaluate independent factors associated with retention.

Results:

<table>
<thead>
<tr>
<th>Year</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age median (IQR)</td>
<td>37 (30-45)</td>
<td>36 (32-45)</td>
<td>36 (32-45)</td>
<td>37 (34-45)</td>
<td>38 (32-46)</td>
</tr>
<tr>
<td>Sex Male (%)</td>
<td>34 (45.3)</td>
<td>35 (46.1)</td>
<td>43 (40.6)</td>
<td>27 (39.1)</td>
<td>34 (40.0)</td>
</tr>
<tr>
<td>WHO stage III or IV (%)</td>
<td>30 (48.0)</td>
<td>54 (72.0)</td>
<td>64 (62.1)</td>
<td>50 (72.5)</td>
<td>47 (57.9)</td>
</tr>
<tr>
<td>CD4 count (Cell/mm³)</td>
<td>180 (105-206)</td>
<td>186 (104-209)</td>
<td>202 (181-225)</td>
<td>196 (170-224)</td>
<td>187 (158-216)</td>
</tr>
<tr>
<td>ART regimen d4T base (%)</td>
<td>61 (81.3)</td>
<td>18 (23.7)</td>
<td>4 (3.8)</td>
<td>3 (5.0)</td>
<td>6 (7.2)</td>
</tr>
<tr>
<td>ART regimen AZT (%)</td>
<td>10 (13.3)</td>
<td>49 (64.5)</td>
<td>27 (25.5)</td>
<td>26 (37.7)</td>
<td>20 (24.1)</td>
</tr>
<tr>
<td>ART regimen TDF (%)</td>
<td>4 (5.3)</td>
<td>9 (11.8)</td>
<td>75 (70.8)</td>
<td>39 (59.5)</td>
<td>57 (68.7)</td>
</tr>
<tr>
<td>1 year retention rate (%)</td>
<td>86.7% (78.7-94.5)</td>
<td>88.0% (80.5-90.5)</td>
<td>76.2% (67.8-84.7)</td>
<td>84.1% (75.2-92.9)</td>
<td>88.0% (80.8-91.9)</td>
</tr>
</tbody>
</table>

[Characteristics of new ART client (2008-2012)]

Compared to before the revision, initiating ART in 2010 were less likely to retain (Hazard ratio: 2.53; 95%CI: 1.25-5.09), while initiating after the revision did not affect significantly. (Hazard ratio: 1.15; 95%CI: 0.54-2.46)

Conclusions: The guideline revision may have affected temporarily the quality of ART services in rural area in Zambia because of rapid increase in patients' number and rapid shift of ART regimen. Considering the capacity of RHC, new guidelines should be introduced carefully to select Rural Health Centres since 2007. The guidelines for ART in Zambia were revised in 2010 to follow the recommendation from WHO and revised again in 2014 to follow the new WHO guidelines. However, the impact of the revision in 2010 in RHCs was not evaluated enough. Further investigation is required in other facilities and also focusing on the guideline revision in 2014.

MOPED685
Use of novel geographic information systems (GIS) improves planning, delivery, and tracking of voluntary medical male circumcision (VMMC) scale up in Tanzania

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Background: Supporting the Ministry of Health and Social Welfare, Jhpiego (funded by USAID through PEPFAR) has worked since 2009 in three regions of Tanzania with a goal of providing VMMC to 80% of uncircumcised males aged 10-34, per national and regional targets. These regions have 660+ health facilities/villages. By 2012, traditional methods of selecting, preparing and tracking outreach service delivery sites became inefficient. Program managers invested in GIS technology to create continuously updated online maps to inform better decision-making.

Methods: Routine VMMC de-identified client data is collected as part of the clinical services and entered into a database. Geocoded data on general facility and community information, access to electricity and water, population catchment size, road access, facility size, affiliation, and mobile phone network availability were collected at every facility and entered into a database, along with census data. This data was overlaid into Google Maps through OpenLayers software, giving program managers a web-based view of various parameters associated with VMMC service delivery for strategic campaign site selection and progress tracking.

Results: Campaign site selection was significantly more effective with the assistance of GIS technology. For example, during a six-week VMMC campaign in 2012 the program served 25,816 males in rural communities, compared with 14,476 over the same timeframe in the previous year. Program managers now conduct site selection activities without physically visiting the sites. Features such as the satellite layers on the maps allow program managers to view sites for demand creation activities. Using GIS's decision support capabilities, program managers also identify potential sites mobile VMMC services, plan campaign logistics, and analyze circumstances performed by age within specific communities.
Results: Between 2010 and 2014, the five sampled facilities experienced an average of 163% growth in HIV patient volumes, ARV costs increased by 60% as a result of the switch from ddI to TDF-based regimens; however, this was largely offset by reductions in service delivery costs. These include fixed costs that were spread across increased patient volumes, and lower personnel costs as a result of multi-month ARV prescriptions and task shifting. Lab costs remained low due to limited access to viral load and other tests nationwide. Overall, cost increased slightly from $134 PPPY in 2010 to $146 PPPY in 2014.

Conclusions: Initial results suggest that, to date, ART scale up may lead to even lower service delivery costs than previously observed, as fixed costs are spread over larger patient numbers and trends such as task shifting reduce HRH costs. In Malawi, these cost reductions were offset by increased ARV costs, but in countries that had previously switched to TDF-based regimens, total ART costs on a per-patient basis may be going down. This study will be repeated in Zambia in 2015 to provide an additional data point.

Methods: In 2010, MATCH collected comprehensive data on one year of ART costs in 30 facilities across Malawi, selected using stratified random sampling. In 2014, the same data points were examined at a diverse sample of five of the original facilities. The study evaluates costs including drugs, laboratory services, direct and indirect personnel, equipment and running costs.

Results: Among the 30 facilities, 14 had not fully implemented the new guidelines in 2014; however, it has led many to question the cost implications of such ambitious scale up. The 2010 ‘Multi-Country Analysis of Treatment Costs for HIV/AIDS (MATCH)’ study established that average facility-level treatment costs were $136 per patient per year (PPPY) in Malawi. Following on the MATCH analysis, this study costs ART service delivery at five of the MATCH facilities in Malawi, using the same methodology, to observe how costs have changed over time.

Impact evaluation of different models of service delivery

MOPE687
Text message reminder-recall to increase HPV immunization uptake in young HIV-1-infected patients

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Background: This quality improvement pilot project was conducted to evaluate the impact of text message immunization reminder-recall in young HIV-positive patients (pts) in a large urban academic HIV clinic.

Methods: All HIV pts age 16-26 who had not completed a 3-dose HPV vaccine series. We compared immunization uptake for pts who received reminders vs. those who did not. We used multivariate logistic regression to assess the impact of age, gender, race/ethnicity, and insurance status.

Results: A total of 255 HIV pts age16-26 were seen in our clinic from July 1 2013-June 30, 2014. Of the 28 pts who received text reminder-recall, compared to control, they were more likely to be black and uninsured compared to the 212 pts who received standard of care without any reminder-recall. 15 pts who died or moved were not included in the final analysis. At 6 month, significantly more pts in the intervention group received ≥ 1 HPV vaccination, 60% vs. 19.4% (41.5 percentage point difference, p < .001). All 3 HPV (13% vs. 4.7; 8 percentage-point difference, p < .001). At 12 months those with ≥1 HPV vaccination was 89.3% vs. 62.1% (27.7 percentage-point difference, p < .001). After controlling for age, gender, race/ethnicity, and insurance status text message reminders were still significantly associated with improved HPV vaccination uptake.

Conclusions: Text message reminder-recall improved HPV immunization uptake in a young HIV-1-infected, low-income urban population. As communication by texting is characteristic of teens and young adults in the general population, text and email reminder-recalls should be considered a viable option to improve vaccination rates among young HIV pts. As secure platforms for texting protected health information are developed, more clinics and caregivers that treat adolescents/young adults will adopt texting to communicate with patients.
MOPED689
Healthcare provision for truck drivers in sub-Saharan Africa: a systematic review of interventions, methods of evaluation and impact
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Background: Mobile populations can be at higher risk of acquisition and transmission of HIV and governments have prioritised these populations in their National Strategic Programmes. In particular, truck drivers, due to the nature of their occupation, can face important challenges accessing healthcare. Currently, the implementation of effective health interventions for truck drivers is hindered by the lack of knowledge of what is currently available and the impact of services on health outcomes. The aim of this review is:

(1) to describe health interventions implemented in sub-Saharan Africa and the methods used to evaluate them;
(2) to assess the impact these interventions have had on truck drivers’ health outcomes.

Methods: A broad strategy using both MeSH headings and free text, with no language limitations, was used to search PubMed/Medline, ISI Web of Knowledge, and online search engines. We included all publications (peer-reviewed or reports) describing a health intervention in sub-Saharan Africa and its evaluation where the main clients were truck drivers. Experts and organisations working with truck drivers were consulted for unpublished reports. We extracted data related to services provided, location, provider, evaluation method, and outcomes measured.

Results: After removing duplicates, we screened 6,479 reports. Of the 229 articles eligible, 21 documents were included. These described 16 interventions across 17 countries and mainly focused on HIV prevention and sexual health services. Evaluation methods varied from pre- and post-intervention surveys to the analysis of routinely collected data. Outcomes reported included individual-level (e.g. HIV knowledge, sexual behaviour) and programme-level (e.g. attendance, client satisfaction) outcomes. While changes in knowledge, attitudes, and behaviours have been attributed to the interventions; impact on health outcomes and its attribution to the interventions remains a challenge.

Conclusions: Transport companies have recognised that HIV/AIDS can drain productivity levels and are increasingly training of replacement workers. In recent years, the number of initiatives providing services tailored to truck driver’s needs across sub-Saharan Africa has increased. It is important for managers and funders to understand the impact on health outcomes of these initiatives. This review provides a starting point on how to build on past evaluations to answer this key question.

MOPED690
The cost-effectiveness of the mothers2mothers Mentor Mother Model as a psychosocial well-being intervention
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Background: mothers2mothers is a peer education and psychosocial support programme that enhances the effectiveness of PMTCT services. Aligned with a public health perspective and against the background of the positive influence of wellbeing on health and mortality, m2m aims to impact on the health of its clients by addressing the challenges facing HIV-positive pregnant women and mothers, thus improving their psychosocial wellbeing. m2m’s impact on psychosocial wellbeing was used in a cost-effectiveness analysis of the m2m Mentor Mother Model implemented under the STAR-EC Programme in Uganda in which one of the objectives was to investigate whether maternal psychosocial wellbeing and empowerment outcomes were associated with exposure to Mentor Mothers.

Methods: A quasi-experimental matched area comparison design was used. Seven hundred and ninety six (796) pregnant women and new mothers accessing PMTCT between June 2012 and March 2014 in 31 intervention facilities (where m2m Mentor Mothers provided peer education and psychosocial support) and 31 matched control facilities (where no peer education and psychosocial support were provided) participated in facility based Psychosocial Wellbeing surveys. A standardised questionnaire that was informed by the m2m Theory of Change was administered. Bivariate and multivariate inferential statistical analysis was done using STATA 12. Propensity Score Matching was used to investigate the net effect attributable to the m2m standard-of-care.

Results: Clients exposed to m2m support demonstrated better psychosocial wellbeing and empowerment outcomes compared to non m2m exposed clients. i.e. coping self-efficacy (66.6% vs 64.5%; p-value 0.001), and better coping behaviour (69.4% vs 56.9%; p-value 0.001).

Conclusions: Exposure of pregnant women and new mothers living with HIV to m2m’s psychosocial support positively impacts on their psychosocial wellbeing and empowerment compared to women not exposed to the mentor mother support services.
<table>
<thead>
<tr>
<th>Psychosocial wellbeing outcome indicators</th>
<th>Average effects among matched exposed subjects in m2m sites</th>
<th>Average effects among matched unexposed subjects in control sites</th>
<th>Net effect (Percentage points)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience of social support</td>
<td>80.10%</td>
<td>71.70%</td>
<td>8.4</td>
<td>0.003</td>
</tr>
<tr>
<td>Demonstrates HIV Disclosure and Safer Sex Self-Efficacy</td>
<td>71.70%</td>
<td>50.70%</td>
<td>21</td>
<td>0.001</td>
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<tr>
<td>Did not experience Depression</td>
<td>83.30%</td>
<td>78.10%</td>
<td>5.2</td>
<td>0.028</td>
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<tr>
<td>Experience of Good relationship with health worker</td>
<td>95.20%</td>
<td>86.00%</td>
<td>9.2</td>
<td>0.001</td>
</tr>
<tr>
<td>Experience of Good relationship with partner</td>
<td>72.20%</td>
<td>58.30%</td>
<td>13.9</td>
<td>0.001</td>
</tr>
<tr>
<td>Demonstrates coping with stigma</td>
<td>40.20%</td>
<td>31.20%</td>
<td>9</td>
<td>0.006</td>
</tr>
<tr>
<td>Demonstrates no experience of internalized stigma</td>
<td>99.50%</td>
<td>97.90%</td>
<td>1.6</td>
<td>0.025</td>
</tr>
<tr>
<td>Accurate HIV Knowledge</td>
<td>87.10%</td>
<td>81.80%</td>
<td>5.3</td>
<td>0.015</td>
</tr>
<tr>
<td>Positive Gender attitudes</td>
<td>44.70%</td>
<td>36.50%</td>
<td>8.2</td>
<td>0.01</td>
</tr>
</tbody>
</table>

**MOPED692**

Impact of harm reduction interventions under the community action on harm reduction “Hridaya” programme on safe injecting and sexual behaviours among people who inject drugs in India

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**Background:** Injecting drug use has emerged as an important route for HIV transmission in India. The government currently estimates that there are approximately 200,000 people who inject drugs (PWID) in India (NACO, 2011). Surveillance shows HIV prevalence among PWID at 7.14% (NACO, 2011). India HIV/AIDS Alliance implements the Hridaya programme in the Indian states of Bihar, Haryana, Uttarakhand, Jammu and Manipur as part of the five-country, Dutch government-funded Community Action on Harm Reduction initiative (CAHR). The programme strengthens harm reduction services for PWID and their close contacts within government-supported Targeted Interventions for HIV prevention.

**Methods:** A cross-sectional survey at the end of phase one of the programme (2012-14) was conducted as part of an impact assessment using the same methodology used for the baseline in 2012. A total of 600 semi-structured interviews and 50 case studies with PWID were conducted, along with twelve key informant interviews. PWID were selected for semi-structured interviews through systematic random sampling using client information from partner NGOs at selected sites.

**Results:** The majority of respondents were young (mean age: 31.7 years), had no education/primary education (51.4%), worked as unskilled workers (38.5%), were married (49.7%), and had a permanent partner and lived at home (94.3%). The mean duration of injection drug use was about seven years. The most common frequency of injections was daily (38.7%), and the most common frequency of injection on the injection day was one to three times (93.5%). Significant reduction in injecting with used equipment was observed (22% at baseline to 5% at endline, p < 0.001) as was an increase in condom use with commercial sex partners (22% at baseline to 90% at endline; p < 0.001). A large majority of respondents (91%, versus 74% at baseline) had not sold or lent their injecting equipment in the previous 30 days (p < 0.001).

**Conclusions:** Reductions in reuse and lending or sale of injecting equipment show a positive change in injecting behaviour. Hridaya programme components have contributed to safer injecting and sexual behaviours among PWID. Similar strategies can be scaled up in other states of India to strengthen harm reduction efforts for this vulnerable population.

**MOPED693**

Clinical outcomes of HIV care delivery models in the US: a systematic review

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**Background:** The US faces national challenges in HIV care delivery. These include decreasing HIV specialists, shortages of primary care physicians, an aging HIV-infected population, and policies across health care shifting chronic disease care from specialty to primary care providers. Alternative HIV care delivery models may address these needs. We systematically reviewed evidence on patient-level health outcomes of different HIV care delivery models in the US.

**Methods:** We identified randomized trials and observational studies in PubMed and ISI Web of Knowledge, March 1987–June 2014. Eligible studies examined a model, process, or system for providing outpatient HIV care delivery in the US and reported patient-level clinical outcomes. Two reviewers independently screened studies and extracted data using predefined criteria. We categorized care delivery models as: task shifting (redistributing HIV care to non-doctors), shared (co-managed HIV care by generalists and HIV experts), specialist (HIV care by HIV expert physicians only), and integrated (comprehensive team management of HIV and primary care).

**Results:** We identified 3102 studies, with 13 meeting eligibility criteria. Eight of 13 (61%) reported outcomes related to specialist care, 3 (23%) integrated care, 1 (8%) task shifting, and 1 (8%) shared and specialist care. Across all studies, the majority reported mortality and antiretroviral use, with specialist care at the provider or clinic level generally associated with improved HIV-related outcomes. We found limited outcomes for retention in care, HIV RNA suppression, and mental health, substance abuse, or hepatitis C screening. Descriptive synthesis summarized the evidence; we did not conduct a formal meta-analysis due to heterogeneity in reporting.

**Conclusions:** Evidence on the impact of alternative HIV care delivery models on clinical outcomes is extremely limited. Better understanding of these outcomes, especially in different patient populations and geographic locations, is urgently needed.
MOPED695
Patient satisfaction with methadone maintenance treatment in Vietnam: a comparison of standalone- and integrative- service delivery models
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Background: Methadone Maintenance Treatment (MMT) services have been rapidly scaled up in Vietnam, with the goal of covering 80,000 drug users by 2015. Identifying how effective delivery models is necessary, however, title is known about experience and preference of clients at different clinics. We assessed satisfaction of drug users taking MMT at standalone- versus integrative- clinics in two provinces of Vietnam.

Methods: A cross-sectional survey was conducted among 1016 patients enrolling 5 MMT sites in Hanoi and Nam Dinh in 2013. Patients’ satisfaction was measured using a 10-item interview scale. Construct validity of the measure was assessed using exploratory factor analysis. Censored linear regression was used to determine factors associated with satisfaction of patients.

Results: The mean score of satisfaction was high in all three domains of the measure, it was the highest in ‘Health workers’ competency’ (9.21/10, 95% CI:9.12-9.27), and the lowest in ‘Quality, counseling and guidelines’ (9.12/10, 95% CI:9.04-9.19), and ‘Services availability’ (9.12/10, 95% CI:9.03; 9.20). There was 36.5% and 34.9% reported completely satisfied with overall service quality and treatment outcomes, respectively. In multivariate analysis, patients taking MMT integrated with general health care services had significantly higher satisfaction than patients of MMT stand-alone model. Other factors related to higher satisfaction included younger age, higher education, and not have health problems in self-care and pain/depression.

Conclusions: Integrating MMT with general health care services is preferred and may improve the efficiency and quality of MMT in large drug using populations.

MOPED696
Using unique identifiers with key population HIV prevention programmes to measure coverage, prevalence and incidence: TB/HIV Care Association’s sex worker HIV prevention model and data from Durban, South Africa
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Background: HIV prevention programming often only reports numbers reached with HIV testing and counselling (HTC) as their primary indicator for reduction in HIV infections. However, in the absence of a standard programmatic or national service user unique identifier system, HIV prevention programmes tend to over-report HTC testing, are unable to determine proportion of a population reached against size estimates, and are unable to determine accurate prevalence and incidence figures to monitor outcomes and impact of HIV prevention programmes.

Methods: In October 2011, TB/HIV Care Association (THCA) was awarded a five year CDC/PEPFAR grant to develop a sex workers (SW) focused programme in five urban areas of South Africa. THCA provides a variety of HIV/AIDS/STI/TB (HAST) services using a simple anonymous unique identifier based on initials and date of birth. This identifier allows THCA to identify unique numbers of SWs reached, to identify more realistic HIV prevalence figures, and to capture incidence data from a longitudinal group of HIV negative SWs.

Results: From July 2012 to July 2014, THCA provided 3,276 health screens to 2,861 unique SWs, and 3,062 HIV screens (known and unknown status) to 2,756 unique SWs (778 known HIV positive and 1,978 unknown) in Durban, South Africa. The unique number of HIV+ SWs was 1,493 for an HIV prevalence of 54% (1,493/2,756). Ten seroconversions were documented within a cohort of 122 SWs who initially tested HIV negative and later seroconverted for an overall incidence of 8%. Year one identified 39 HIV negative SW with 4 seroconversion (10.25% incidence) and in year two 83 and 6 respectively (7.2% incidence). Additionally, using the South African National AIDS Council’s (SANAC) SW size estimation of 5,670 SW in THCA’s catchment area in the Durban area, THCA documented having had reached 50% of SWs (2,861/5,670) in two years.

Conclusions: Rigorous data collection using unique identifiers will help target key affected populations with effective programmes, and assist the government to allocate resources where they are needed most. Ultimately consistent and effective use of programmatic data will help drive the number of infections among KPs and the general population down.
function, and the patients in RHCs were less likely to be tested for Creatinine (p<0.04). The patients with renal dysfunction (Creatinine clearance < 30) were less likely to survive (HR:11.98, 95%CI:1.74-82.50) as well as low CD4 count (< 160) (HR:9.88, 95%CI:1.21-80.66).

**Conclusions:** The ART retention rates through more than 42 months observation were not different between RHCs and District hospital. However, some patients initiated TDF without monitoring their renal function especially in RHCs. Mobile HIV services may be an effective strategy to expand service coverage area but require more attention on how to support laboratory services in RHCs.

**MOPED698**

**Scaling up access to second line antiretroviral therapy in rural Zimbabwe: impact of routine viral load, model of care and re-suppression after switch**

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**Background:** In many resource-limited settings, access to second-line antiretroviral therapy (ART) is centralised and prescribed only by doctors. After implementing routine viral load (VL) monitoring in two rural districts in Zimbabwe in 2012, switching of patients to second-line ART and their follow-up was decentralised to all primary care clinics, and carried-out by a multidisciplinary team.

**Methods:** Information was extracted from patient and laboratory records and analysed to assess virological response to second-line ART. The analysis used data from 358 patients with confirmed virological failure, who switched to second-line ART between June 2008 and November 2014. Binary logistic regression was used to identify factors associated with a poor virological response.

**Results:** Second-line ART initiations increased from 13 in 2011 to 243 in 2014. Of the patients in the analysis 55.0% were female, with a median age of 33 years; a median time on first-line ART of 3.7 years; and a median follow-up after switching of 42.2 weeks. The median pre-switch VL was 30,940 copies/ml (IQR: 12,285 - 88,000), with 22.6% having a VL of >100,000 copies/ml. Of 196 patients retested 3 to 6 months after switching to second-line ART, 72.5% re-suppressed to < 1,000 copies/ml, and an additional 11% had a < 1.0 log drop in VL. At the most recent test, 72.9% had a VL < 1,000 copies/ml. Of those who initially re-suppressed and had a subsequent VL test, 17.7% had viral rebound. Patients were significantly less likely to re-suppress if they were < 15 years old (adjusted risk ratio [ARR]: 2.56; 95% CI: 2.00 - 3.28); female (ARR: 1.57; 95% CI: 1.23 - 2.01); had an initial VL ≥50,000 copies/ml versus < 10,000 copies/ml (ARR: 1.87; 95% CI: 1.10 - 2.54); or switched < 3 years versus 3 - 5 years after starting ART (ARR: 1.60; 95% CI: 1.25 - 2.13).

**Conclusions:** Although the majority of patients responded to second-line ART, a sizeable minority had an inadequate response. This illustrates the importance of ongoing VL monitoring and adherence counselling for patients on second-line ART. Children and adolescents are at particular risk of ongoing adherence challenges, resulting in a poor response to second-line ART.

**MOPED700**

**Effects of clinical flow and patient initiation mentorship on point-of-care CD4 testing**

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**Background:** Malawi has scaled-up Point-of-Care (POC) CD4 testing to 122 publicly operated health facilities covering 34% of the pre-ART cohort. Using a training-of-trainers approach over 500 health workers were trained in 2013. However, the patient flow and support systems to maintain a decentralized laboratory network are only now being developed through guidance on the health facility level best-practices and regular mentorship visits.

**Methods:** Biannual mentorship visits reached over 97% of facilities offering on-site POC CD4 in 2014. Trained laboratory technicians from the district health office travelled to health facilities for a day-long site visit, which included observation of sample collection and processing, a careful examination of documentation for patient initiation on ART, and corrective actions, as needed. The mentors used a five-page assessment tool to capture key data, including testing volumes, clinical integration, technical use of POC CD4 devices, and patient care. Data from the two rounds of POC CD4 mentorship were analyzed in Excel.

**Results:** Overall, 97% of patients with CD4 < 350 received a test result and were initiated on treatment. After the first round of mentorship there was a 19% reduction in the average days elapsed between CD4 result and ART initiation, demonstrating improved turn-around-time (TAT). The TAT dropped from 7.98 days to 6.49 days. For patients with CD4 > 350 only 79% of POC CD4 results were accurately documented in patient records, with the same proportion scheduled for a subsequent visit. However, this result may be indicative of POC CD4 sites acting as hubs for patients at nearby health facilities, who seek testing services, but then return to their nearest facility to receive HIV care and treatment.

**Conclusions:** POC CD4 testing offers significant benefits to patients through increased access to CD4 testing, however maximum benefits cannot be realized without careful consideration for patient flow at the health facility level and regular mentorship to ensure that all POC CD4 results are well documented, clinically relevant, and used to improve patient care. Any implementation of POC CD4 should make provisions for these factors, especially to achieve the 90-90-90 targets laid out in the Diagnostics Access Initiative (DAI).

**MOPED701**

**Effect of PIMA point of care instruments for CD4 counting on time to ART initiation in rural Botswana**

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**Background:** Point of care (POC) CD4 platforms have the potential to reduce delays in linkage to care and antiretroviral therapy (ART) initiation. We implemented the PIMA POC technology in Tumte, north of Botswana and determined the impact on time to ART initiation.

**Methods:** PIMA testing was introduced at 6 rural clinics in Tumte in August 2013 as part of a treatment optimization strategy to improve care for HIV-infected patients. Electronic data recording patients initiating ART at the clinics were reviewed to determine the impact of POC testing on time to ART initiation. Data on time to ART initiation were collected and compared between the periods prior to and following PIMA implementation.

**Results:** A total of 400 records were reviewed for patients initiating ART between January 2013 and February 2014. The proportion of patients initiating ART was higher in the post-PIMA period (57% vs. 43%; p=0.01). The median time from CD4 testing to ART initiation decreased from 24 days (IQR 12-41) to 20 days (IQR 10-35; p<0.05) in the pre- and post- PIMA periods respectively. The time to ART initiation was significantly reduced in newly diagnosed patients; 16 days (IQR 9-27) post-PIMA compared to 26 days (IQR 14-53; p<0.01) pre-PIMA. This was as a result of a significantly reduced time from HIV diagnosis to CD4 testing form 5 days (IQR 1-16) to 6 days (IQR 0.5-9; p<0.01).

**Conclusions:** Point of care CD4 testing significantly reduces the time to ART initiation for newly diagnosed patients. It therefore has the potential to improve retention of patients in ART programs.

**MOPED702**

**Is CD4 monitoring needed where there is routine viral load? A cohort analysis from Kibera, Kenya**

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**Background:** In 2013, WHO recommended viral load (VL) monitoring as the strategy of choice for patients on ART, and it has been suggested that CD4 monitoring may be stopped. There is, however, little data on the safety of this approach from resource-poor settings. In a retrospective cohort study we aimed to determine the safety of VL monitoring alone in an MSF ART programme in Kibera, Kenya.

**Methods:** Data was extracted from an electronic patient database. Adult patients >15 years initiated on ART between January 2011 and December 2012, with paired VL and CD4 data (interval 490 days) at months 12 and 24 were included in the analysis. Routine VL was performed yearly and CD4 6-monthly. VL was tested on plasma samples using the Roche platform.

**Results:** 754 (63%) and 194 (60%) of those remaining in care at months 12 and 24 received a paired CD4 and VL test; 70% were female. At baseline, median age was 32 years (IQR 27-40) and CD4 258 cells/mm³ (IQR 138-337), 265 (33%) had baseline CD4 < 200 cells/mm³. Of

**Scale up of viral load monitoring**
those with sequential VL < 1000 copies/mL, 601 (85%) and 169 (9%) maintained CD4 ≥200 cells/mm³ at months 12 and 24, respectively. Of those with baseline CD4 ≥200 cells/mm³ who remained suppressed < 1000 copies/mL, nine (2%) dropped below 200 cells/mm³ at month 12 (zero at month 24). Of these nine patients, three were retested at month 24 with a viral load < 1000 copies/mL and two returned to >200 cells/mm³. Of the 133 (50%) whose CD4 increased to >200 cells/mm³ at month 12, and remained virologically suppressed, 27/31 tested (87%) remained >200 cells/mm³ at month 24.

**Conclusions:** When virologically suppressed at <1000 copies/mL, most patients maintained CD4 ≥200 cells/mm³. As more patients are enrolled at higher CD4 counts this proportion is likely to increase. Of those with baseline CD4 >200 cells/mm³, only a very small proportion had a subsequent low CD4 count, in line with previous findings. Our results suggest it could be safe to stop routine CD4 in such settings where there is access to routine VL.

### MOPED0703

**Introduction of viral load in routine settings in Kenya: implications for programs**

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**Background:** Routine laboratory monitoring is part of the basic care package offered to people living with HIV. In line with WHO recommendations, Kenya has adopted the use of viral load tests to monitor patients on antiretroviral therapy (ART). This study describes viral suppression among patients on ART suspected to have had treatment failure in Eastern and Central Kenya, where the USAID-funded APHIAPlus Kamili project supports HIV services. Indications for viral load testing included clinical failure (new or recurrent WHO stage 3 or 4 disease) and immunological failure (CD4 fall by >30% from peak or failure of CD4 count to rise to >100 cells/mm³ after 12 months of ART).

**Methods:** A retrospective, cross sectional analysis of patient data collected between January 2015 and June 2014. The main outcome variable of interest was viral suppression, defined by the Kenya Ministry of Health as VL < 1000 copies/mL. Blood samples were collected as DBS (90%) or frozen plasma (10%). These were analysed by the Standard Roche COBAS® AmpliCor™ HIV-1 Monitor(®) Test and Abbott HIV-1 RealTime™ assay. Statistical analysis was conducted using the software SPSS v20 for Windows, with an alpha value of 0.05 used to indicate significance.

**Results:** Of the 27,418 patients on ART, 1,375 (aged between 2 and 80 years) were suspected to have treatment failure and were analysed for viral load. 597 (43%) patients had viral suppression. The median viral load was 3,317 (IQR 0-47,547). Patients aged below 40 years and those with ≤ 3 years on ARVs were associated with a high viral load (p < .001 and p = .01 respectively). Sex of the patient and ARV combination were not associated with the viral load.

**Conclusions:** Viral suppression in patients suspected to have had treatment failure is significant. This study brings out the discrepancy between clinical, immunological and viral load monitoring. In line with WHO recommendations, viral load test is important in patients on ART as it identifies genuine treatment failure, minimizes unnecessary switching leading to reduced costs and high quality care.

<table>
<thead>
<tr>
<th>Cost-effectiveness</th>
<th>ART regimen</th>
<th>Budget impact over 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discounted life expectancy (months)</td>
<td>Discounted lifetime cost (USD)</td>
<td>ICER (USD/YLS)</td>
</tr>
<tr>
<td>Annual CD4 with confirmatory viral load</td>
<td>186.6</td>
<td>11 320</td>
</tr>
<tr>
<td>Biannual CD4 with confirmatory viral load</td>
<td>191.9</td>
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<tr>
<td>Biannual CD4 (Standard of care - SOC)</td>
<td>187.2</td>
<td>11 980</td>
</tr>
<tr>
<td>Adaptive: biannual then annual viral load</td>
<td>196.5</td>
<td>12 680</td>
</tr>
<tr>
<td>Biannual CD4 and annual viral load</td>
<td>196.0</td>
<td>13 000</td>
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</table>

**Adaptive viral load monitoring for second-line ART in Côte d’Ivoire: cost-effectiveness and budget impact analysis**

E. N. Ouattara1,2, S. P. Eholié1,3, M. Robine4, R. L. MacLean4, R. Moh5,6, E. Losina4,6, D. Gabillard7, A. D. Patile,8, C. Daniel9, R. P. Valerany10, X. Anglaret11,12, K. A. Freedberg13,14, Programme PMC-CUARIS Research Site, CHU de Treichville, Abidjan, Côte d’Ivoire, 9-Centre Insitine BST, University of Bordeaux, Bordeau, France, 3-Centre Hospitalier Universitaire Hospital, Department of Infectious and Tropical Diseases, Abidjan, Côte d’Ivoire, 1-Centre Hospitalier Universitaire Hospital, Department of Infectious and Tropical Diseases, Abidjan, Côte d’Ivoire, 12-Massachusetts General Hospital, Harvard Medical School, Divisions of General Internal Medicine and Infectious Disease and Immunological Failure (CD4 fall by >30% from peak or failure of CD4 count to rise to >100 cells/mm³ after 12 months of ART).

**Background:** Routine HIV viral load monitoring is recommended by the WHO to optimize outcomes of second-line antiretroviral therapy (ART) in sub-Saharan Africa. We evaluated the cost-effectiveness and budget impact of new viral load monitoring strategies in Côte d’Ivoire.

**Methods:** We used the Cost-Effectiveness of Preventing AIDS Complications (CEPAC) International Model to compare clinical outcomes, costs, incremental cost-effectiveness ratios (ICERs), and 5-year budget impact of 11 laboratory monitoring strategies in patients on or initiating ART from 2013-2018. We varied viral load testing availability and frequency and considered “adaptive” strategies, where testing frequency decreased from bi-annual to annual in patients virologically suppressed after one year. We assumed that a 6-month adherence intervention was performed before switching any regimen if laboratory tests suggested ART failure. Mean age of the cohort was 40 years, viral load cost was $33, and annual first- and second-line ART costs were $123 and $391, respectively. The current standard of care (SOC: bi-annual CD4 testing) served as the basis of comparison. We used the 2013 per-person GDP in Côte d’Ivoire ($1,530) to define “cost-effective,” in sensitivity analyses, we evaluated parameter uncertainty.

**Results:** Projected discounted life expectancy for the SOC strategy was estimated at 187.2 months, mean time to observed first-line ART failure was 104.2 months (Table). Adding confirmatory viral load increased survival to 191.9 months, increased time to first-line failure to 124.8 months, and was cost-saving compared to SOC. Adaptive viral load monitoring alone increased survival to 196.5 months (ICER: $2.800/YLS) and increased the 5-year budget by $39 M (7.7%) compared to SOC. Adaptive monitoring with CD4 and viral load had an ICER of $4,600/YLS compared to viral load alone (Figure). In sensitivity analyses, the adaptive viral load strategy was budget neutral if viral load cost was reduced by 30% or if annual second-line ART cost was reduced by 10%.

**Conclusions:** Using viral load to confirm failure by CD4 criteria will be cost-saving in Côte d’Ivoire. Adaptive viral load monitoring, with or without CD4 testing, will be cost-effective by GDP criteria. With modest reductions in either viral load or second-line ART costs, routine adaptive viral load monitoring would improve outcomes without increasing costs.
MOPED705
Introduction of a routine viral load algorithm in rural Zimbabwe: programmatic strategies for implementation and impact on second line needs
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Background: In 2012, routine viral load (VL) monitoring was implemented among 14,000 patients on antiretroviral therapy (ART) in 26 clinics in Bulawayo district Zimbabwe, assisted by a mobile mentorship team. Dried blood spots were tested using the bioMérieux NucliSSENS assay. Patients with a VL >1,000 copies/mL received enhanced adherence counselling (EAC), including completion of a high viral load form and VL repeated after three months. Those with a persistently high VL were switched to second-line ART. Implementation of the algorithm was assessed in 2014.

Methods: Data were extracted from patient folders, electronic medical records, counselling registers and a laboratory database, and combined to assess adherence to the VL algorithm between March 2013 and September 2014. Virological outcomes were further assessed by patient age and time on ART.

Results: 4661 patients were included in the analysis. Coverage of routine annual VL testing was 92.0%. Of those tested in the previous year, 13.9% had a VL >1000 copies/mL. A VL >1000 copies/mL was more common in children <15 years (32.3%; 95% CI: 29-35%) than those aged ≥15 years (14.0%; 95% CI: 13-15%), but showed little variation by time on ART (13.6% at 3 months, 14.9% at 12 months, 15.3% at 24 months, and 12.3% at 36 months on ART). Of those eligible, 57.4% had documented evidence of EAC and 67.8% had a repeat VL test. Of those retested, 43.1% re-suppressed, and 36.9% (1.1% of all those tested) were switched to second-line ART.

Conclusions: Routine VL testing is feasible in resource-limited settings. Monitoring and evaluation of adherence to the VL algorithm is essential in order to ensure appropriate response to VL results. Essential components of implementation include patient education, clinician training on the VL algorithm, task-shifting of sample preparation, provision of EAC, and decentralisation of access to second-line ART.

MOPED706
HIV prevention research & development funding trends 2000-2014: investment priorities to fund innovation in an evolving global health and development landscape
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Background: Since 2004, the HIV Vaccines and Microbicides Resource Tracking Working Group has employed a comprehensive methodology to track trends in research and development (R&D) investments and expenditures for biomedical HIV prevention, including HIV vaccines, microbicides, PrEP, treatment as prevention and medical male circumcision.

Methods: Data were collected on annual disbursements by public, private and philanthropic funders for product development, clinical trials and trial preparation, community education and policy advocacy efforts to estimate annual investment and expenditure in HIV prevention R&D. Implementation of the algorithm was assessed and compared by year, prevention type, research phase, funder category and geographic location.

Results: The Working Group collated and analyzed 2014 data for all areas of HIV prevention R&D. In contrast to the broader context of slight year-to-year increases in funding for international development and health research, funding for HIV prevention R&D overall continued to decline, although this trend did not consistently apply to all funders, sectors or technologies. US investment in HIV R&D continued a flat trend, but European public sector funding increased slightly under the European Union’s recently launched Horizon 2020 initiative. Public sector research agencies increased support for HIV prevention R&D, with larger investments by several middle-income countries suggesting a potentially critical shift. Philanthropic support for HIV prevention R&D continued a decline that began several years ago. Commercial-sector funding saw a nominal increase.

Conclusions: Monitoring HIV prevention R&D investment trends permits identification of investment needs, prioritization of research areas and assessment of the impact of public policies that increase or decrease investment. Investment data also supports the fact base for advocacy around spending levels, resource allocations and messages around the value of sustained investments in the research required to build on the success of recent trials, bring novel HIV prevention candidates into the pipeline and support follow-on clinical trials to assure the safety, immunogenicity, efficacy and acceptability of new HIV prevention products. As United Nations negotiations toward updated global development goals proceed, articulating the value of HIV prevention research investments in the wider context of public, private and philanthropic funding priorities will be increasingly important to ensure continued support for the development of new prevention technologies.

Transitional financing
MOPED707
Planning for the transitioning of PEPFAR investments to Government in Nigeria: Kwara State experience
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Background: A range of clinical, systems strengthening and community services are supported by PEPFAR to ensure quality care and support for persons living with HIV (PLHIV). In its program review for Nigeria early 2014, PEPFAR indicated that it will transition clinical chemistry, hematology laboratory tests and maintain a cap on ART enrollments in states with lower than national prevalence rates. One of these states is Kwara with a HIV prevalence rate of 1.4% as against the National prevalence of 3.4% (NARH2012). USAID Nigeria, through Management Sciences for Health (MSH), supported Kwara State to implement a model for incremental transitioning of PEPFAR investments to governments at sub-national level.

Methods: Using an ART treatment and care transition capacity assessment tool, MSH assessed Kwara state’s readiness capacity across seven domains: leadership, policy, systems, quality of care, infrastructure and resources, fiscal management and partnership. MSH with stakeholders developed a costed transition strategic plan that highlights the current
Monitoring and evaluation of testing

MOPED709
Two-year performance of an early infant diagnosis program in rural north-central Nigeria

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Backgrounds: Prevention of mother-to-child transmission of HIV (PMTCT) in Nigeria has been challenging: only 3.9% of HIV-Exposed Infants (HEI) receive early infant diagnoses (EID), and >50,000 HEI acquire HIV annually, at an MTCT rate of ~30%. PMTCT scale-up is focusing on Primary Healthcare Centers (PHCs) in rural areas, where access, uptake and retention are especially low. This study was conducted to evaluate EID performance at PHCs in rural North-Central (NC) Nigeria.

Methods: This retrospective study examined a database of HEI receiving virologic HIV testing in a 2yr period (Oct. 2011 to Sept. 2013) at rural PHCs. These PHCs, located in 4 of the 7 NC states, had undergone integration of PMTCT services with antenatal care. HEI data (including testing age and results) from PHCs in Benue, Federal Capital Territory, Nasarawa, and Niger states were analyzed. “Population” EID coverage was calculated as no. HEI tested by age 2 months/all HEI (the true definition of EID coverage per the WHO). “Program” EID coverage was defined as no. HEI tested by age 2 months/all HEI who received testing.

Results: Data from 723 infants out of 2,543 expected HEI births at 127 PHCs were reviewed. Overall MTCT rate was 3.8%. MTCT rate in Yr 2 (3.0%) was lower than in Yr 1 (7.4%), p<0.02. Overall, “population” EID coverage was 19%; Yr 2 coverage (23.9%) was higher than Yr 1 (8.4%), p<0.001. Further results are displayed in Table 1.

| Two-Year EID Program Performance at PHCs in 4 North-Central Nigerian States |
|---------------------------------------------|-----------------|-----------------|
| Gender, Female                              | N evaluated | N [%]            |
| Male                                         | 322           | 375 (49.5%)     |
| Female                                       | 401           | 375 (49.5%)     |
| No. HEI receiving virologic testing          | 691           | 647 (99.6%)     |
| *Program* EID coverage: denominator – all-HIV-exposed infants who received virologic testing |
| Age at sample collection                     | 723           | Less than or equal to 2 months: 472 (65.5%) |
|                                            |               | Greater than 2 months: 251 (34.5%) |
| Median age of infants presenting at:         |               | Greater than 2 months: 5.5 months (3.6) (8.0) |
| No. HEI HIV-positive                         | 756           | 29 (3.8%)       |
| *Population* EID coverage: denominator – all-HIV-exposed infants expected |
| Age at sample collection                     | 2,543         | Less than or equal to 2 months: 179 (7.0%) |
|                                            |               | Greater than 2 months: 860 (33.9%) |

[EID Program Performance at PHCs in NC Nigeria]

Conclusions: MTCT rates in our rural EID program were lower than national, with a significant reduction from Yr1 to Yr2. Population EID coverage (19%) was higher than national, with a marked improvement between Yr1 and 2; however, this was far below the 80% national target. There was a large drop-off between numbers of expected and tested HEI; likely due to death, loss to follow-up or transfers of care. Program EID coverage (65.3%) was closer to national target, suggesting more focus on reducing early HEI dropout in PMTCT. Client education, community tracking and inter-facility linkage should be strengthened to improve retention and timely HEI testing.
MOPED710
The cost of providing rapid HIV testing for screening men who have sex with men in new community sites compares favorably with established clinics in Sydney, Australia

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Background: Rapid HIV testing (RHT) is well established in many countries, but is relatively new in Australia. We compared the cost of providing RHT with the Trinity Uni-Gold assay for screening men who have sex with men (MSM) in new community-based sites versus existing clinical sites in Sydney.

Methods: During the study period (October 2011–June 2014), RHT was delivered at five sites: two new community sites (fixed and temporary), two established public sexual health clinics (SHCs) and a gay-friendly general practice clinic (GPC). SHCs delivered RHT in both express and general clinical sessions (shorter screening consultations with enrolled nurses and longer consultation with doctors for symptomatic patients, respectively). RHT was delivered by peer workers and nurses at community sites and by doctors and nurses at the GPC. We calculated RHT cost per patient tested and cost per HIV-positive case diagnosed for each site/session type.

Results: RHT cost per patient tested was lowest in SHC express sessions and community fixed site sessions. Cost per positive case was lowest in SHC express sessions and community fixed site sessions. RHT delivery costs at community sites were comparable to or less than the weighted average community temporary site, followed by central SHC express, GPC and community fixed site sessions. RHT delivery costs at community sites were comparable or less than the weighted average for cost per patient and cost per positive case. Overall, costs were lower if nurses and peer workers delivered RHT during shorter consults.

Conclusions: RHT cost per patient tested was lowest in SHC express sessions and community sites. Due to their higher observed HIV positivity, community-based and GPC sites compared favorably to SHCs regarding cost per positive case. These findings should inform decision-making regarding RHT implementation in other locations and services.

<table>
<thead>
<tr>
<th>Site (session)</th>
<th>Staffing</th>
<th>HIV positivity</th>
<th>Cost per patient*</th>
<th>Cost per positive case*</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practice</td>
<td>Doctors/hnurse</td>
<td>1.57%</td>
<td>$198</td>
<td>$12589</td>
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<tr>
<td>Suburban SHC (general)</td>
<td>Doctors/hnurse</td>
<td>0.74%</td>
<td>$134</td>
<td>$18146</td>
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<tr>
<td>Central SHC (general)</td>
<td>Doctors/hnurse</td>
<td>0.94%</td>
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<td>Suburban SHC (express)</td>
<td>Nurse</td>
<td>0.74%</td>
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<tr>
<td>Central SHC (express)</td>
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<td>0.94%</td>
<td>$105</td>
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<tr>
<td>Weighted average</td>
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MOPED711
IAQ/UK NEQAS EQA participation and accuracy of patient monitoring in clinical trial networks

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Background: United Kingdom National External Quality Assessment Service for Leucocyte Immunophenotyping Immune Monitoring Program (UNNEQAS), an ISO 17043 accredited proficiency testing program, provides external quality assessment (EQA) to non-U.S. laboratories affiliated with the NIH Division of AIDS (DAIDS) clinical trials networks. Such laboratories are required to participate in UKNEQAS with oversight, performance monitoring and remediation undertaken by Immunology Quality Assessment (IAQ) staff, under DAIDS contract. Using data from November 2003 to September 2014, the first four years EAQ participation of each of the 1242 laboratories was examined. Up to 65,297 data points were analyzed to determine if longer EQA participation was associated with improved laboratory accuracy.

Methods: Laboratory accuracy, defined as residuals from respective trial sample medians, was measured on four outcomes: CD4 counts (cells/ul) and percentages plus CD8 counts (cells/ul) and percentages. Three laboratory categories were defined: IQA monitored (n=149), United Kingdom/DAIDS (n=137), and non-DAIDS/non-UK (n=1035). Four longitudinal mixed models were fitted with polynomials of program participation duration together with selected covariates. The fixed effects were used to generate trajectories for each of the four lymphocyte subset residuals in each laboratory category. For count outcomes, the groups were subdivided into single platform (SP) and dual platform (DP).

Results: Improvement in accuracy was found for all outcomes (p< 0.0001). IAQ monitored laboratories (particularly IAQ SP) had the most accurate counts (p< 0.0001) across the board. For percentage and DP count outcomes, British laboratories performed best at entry into the program (p< 0.05). For SP count outcomes there was no difference at entry by laboratory category. SP laboratories did better than DP laboratories for all four outcomes (p< 0.0001) overall for the four laboratories. Figure 1 shows increasing accuracy (decreasing CD4 count residuals) for all groups, but the IAQ DP group showed the greatest improvement (p< 0.0001).

Conclusions: EQA participation coupled with effective laboratory monitoring and remedial action is strongly associated with improved laboratory accuracy. Improvement in accuracy provides more reliable information to clinical trials facilitating better patient treatment decisions. UK laboratories (predominately SP) have high levels of accuracy at EQA program entry and therefore have limited room for improvement.

![Figure 1](image_url)
MOPED712

“I did not see a need to get tested before. Everything was going well with my health”: a qualitative study of HIV testing in KwaZulu-Natal, South Africa

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Background: KwaZulu-Natal has the highest prevalence of HIV in South Africa (SA) at nearly 40%. In 2010 the government launched a national HIV counseling and testing campaign (HCT), later raising the threshold for antiretroviral therapy (ART) initiation. Limited qualitative data exists on HIV testing in SA, including the impact of the HCT on decision-making. We describe barriers to and facilitators of HIV testing among participants in Pathways to Care, a cohort study of newly-diagnosed HIV+ adults in Durban, KwaZulu-Natal.

Methods: We conducted semi-structured interviews with 26 cohort participants (13 women, 13 men, median age 28 years), within one month of diagnosis, in 2012. Interview data were analyzed thematically and coded in NVivo. Coded text was compared across interviews to develop broader categories, and consensus was reached among the research team regarding the emerging explanatory framework.

Results: Less than half (n=12) of participants reported that they were aware of the HCT, and it was rarely cited as a major influence in decisions to test for HIV. Most participants (n=22) deferred testing until they had developed symptoms (many indicative of HIV), with only three directly seeking an HIV test when first developing symptoms. Instead, the majority of symptomatic participants consulted a variety of other medical professionals, local chemists, family members and traditional healers, which resulted in delayed HIV diagnoses. Of the eleven symptomatic participants who made contact with medical services, only three reported that a healthcare professional offered or recommended an HIV test. Fear of death and HIV-related stigma were identified as other key barriers to testing. However, ART emerged as a fundamentally important motivator to test, offering the hope of health and normalcy.

Conclusions: Despite the large-scale 2010-2011 national HCT and the raised threshold for starting ART, most participants deferred testing until they had some symptoms. Efforts to encourage local health systems (including non-medical) to direct clients towards HIV testing, and continued expansion of HIV testing in medical services, may reduce testing delays. Future testing campaigns will benefit from a focus on the importance of testing when asymptomatic and the health-benefits of early ART.

MOPED714

Increased counseling and testing visits are associated with remaining HIV uninfected

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Background: Voluntary counseling and testing (VCT) for HIV is provided for men who have sex with men (MSM) at the Siriraj Community Clinic @TroMed (SCC @TroMed) in Bangkok, Thailand. We assessed the number of MSM participating with remaining HIV uninfected over a nine-year period since the founding of the clinic.

Methods: At every HIV VCT visit at SCC @TroMed, MSM received a comprehensive counseling session, HIV transmission information, risk-reduction strategies, condoms and lubricants, and HIV and syphilis testing. Men had demographic information collected from self-registration and behavioral information collected by a counselor. We included MSM uninfected with HIV at baseline who received more than one HIV VCT from September 30, 2006 to August 30, 2014 in the analysis. Logistic regression was used to investigate factors associated with remaining HIV uninfected (having all HIV tests negative).

Results: There were 2,209 MSM for our analysis; the mean number of VCT visits was 3 (range 2-27 visits). Two-hundred-fifty-five men acquired HIV during the study period. In multivariable analysis, when adjusted for current residency, engagement in commercial sex work, and history of HIV testing, remaining HIV uninfected was associated with each additional VCT visit presenting with low CD4+ count increased after the HCT ended, whereas the proportion reporting previous HIV tests declined. This may indicate that the HCT led to uptake of HIV testing by healthier individuals, but that this pattern was not sustained after the campaign ended. Continued testing campaigns and interventions, especially targeting men, are needed to encourage regular testing and prevent late diagnoses.

Conclusions: Despite the implementation of more aggressive HIV prevention and control efforts in South Africa, over 50% of participants presented with CD4+ count ≤350 cells/µl.

MOPED713

Factors associated with low CD4+ count at diagnosis among patients enrolled in a prospective cohort study in KwaZulu-Natal, South Africa

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Background: At nearly 40%, KwaZulu-Natal has the highest HIV prevalence in South Africa (SA). Since the national government’s April 2010-June 2011 HIV counselling and testing (HCT) campaign and the raising of the CD4+ threshold for antiretroviral therapy (ART) initiation to ≤350 cells/µl, there has been limited information on timing of HIV diagnosis in SA.

Methods: We analyzed data from Pathways to Care, a prospective cohort of 459 newly-diagnosed HIV-positive adults recruited from three public-sector clinics and interviewed between November 2010-May 2012. We restricted analysis to 282 (61.4%) participants who had a CD4+ blood draw within 4 months of HIV diagnosis, and self-reported the value of their first CD4+ count. Low CD4+ count was defined as CD4+ ≤350 cells/µl.

Results: Three-fifths (n=205) of participants were female; the median age was 30 years (interquartile range [IQR]: 18-52). The majority of participants (80.9%, n=171) had not previously tested for HIV. Over 50% reported a CD4+ count ≤350 cells/µl at diagnosis; median CD4+ count was 318 cells/µl (IQR: 10-870). In multivariable analysis male sex and age ≥25 years were associated with late-stage diagnosis, whereas having ≥2 previous HIV tests was protective (Table 1).

Over the period of study enrolment, the proportion of participants presenting with low CD4+ count increased from 45.7% in the first 6 months (during the HCT) to nearly 70% in the last 6 months, after the HCT had ended (p=0.025). Over this same period, the proportion who had never previously tested for HIV increased from 51.6% to 73.7% (p=0.061).

Conclusions: Despite the implementation of more aggressive HIV prevention and control efforts in South Africa, over 50% of participants presented with CD4+ count ≤350 cells/µl.

Background: There were 2,209 MSM for our analysis; the mean number of VCT visits was 3 (range 2-27 visits). Two-hundred-fifty-five men acquired HIV during the study period. In multivariable analysis, when adjusted for current residency, engagement in commercial sex work, and history of HIV testing, remaining HIV uninfected was associated with each additional VCT visit (AOR 2.5, 95% CI 1.6-3.9).

Characteristics

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<thead>
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<th>Characteristic</th>
<th>Odds Ratio (95% CI)</th>
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<tr>
<td>Recruitment Period</td>
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<td>Jan 2012 - May 2012</td>
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<td>≥2</td>
<td>0.36 (0.18, 0.72)</td>
<td>0.78 (0.41, 1.50)</td>
</tr>
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</table>

Conclusions: Despite the implementation of more aggressive HIV prevention and control efforts in South Africa, over 50% of participants presented with CD4+ count ≤350 cells/µl.

Background: More than 40% of participants with low CD4+ count presented with low CD4+ count increased after the HCT ended, whereas the proportion reporting previous HIV tests declined. This may indicate that the HCT led to uptake of HIV testing by healthier individuals, but that this pattern was not sustained after the campaign ended. Continued testing campaigns and interventions, especially targeting men, are needed to encourage regular testing and prevent late diagnoses.

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Late Breaker Posters
Publication Only Abstracts
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MOPED715
Shaping care: a case study from Sierra Leone

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Background: The ‘vertical’ versus ‘horizontal’ debate to healthcare delivery and financing has been discussed globally, for decades. Over the past twenty years, research has detailed the negatives of a ‘vertical’ (i.e. disease-specific) approach, including program instability. Recently this delivery trajectory has shifted towards a ‘diagonal’ approach, which encourages gradual integration by strengthening the larger health system, while still working towards specific program goals. Current arguments suggest that ‘diagonal’ financing might be essential for maintaining HIV/AIDS treatment in low-income countries; however, donor conditionality can create space for negative characteristics (i.e. instability) of vertical programs, to manifest. This project critically analyzes donor expectations and conditionality through an ethnographic account of HIV/AIDS programs and practices in Sierra Leone, focusing on the Global Fund, which provides 97% of the country’s HIV/AIDS funding. The Global Fund has taken up Health Systems Strengthening (HSS) as a cross-cutting and diagonal element to their funding approach. This move towards HSS in the global health community has simultaneously provoked a largely technocratic shift for programming efforts, with increased funding from donors to strengthen disease surveillance, data collection and reporting mechanisms.

Methods: Drawing on three months of multi-sited ethnographic fieldwork in Sierra Leone, I demonstrate how the realities of this technocratic push and conditionality are challenging due to current infrastructural, increasing the administrative burden on HIV/AIDS program workers. From participant-observation in clinics, government agencies and multi-entity meetings, and semi-structured interviews with HIV/AIDS counselors and program officers, I show how donor expectations and stipulations have altered the perceptions and foci of many HIV/AIDS personnel, which can have detrimental outcomes.

Results: While recognizing the potential of a ‘diagonal’ service delivery, the resulting technocratic push has shifted in-country focus to producing reports and digitizing data, rather than providing services. I argue that funding stipulations and expectations have transformed HIV/AIDS programs and practices into business-like transactions, limiting autonomous decision-making in Sierra Leone.

Conclusions: I conclude that closer examination needs to be paid to the ‘friction’ created between donor conditionality and their implementation and influence on HIV/AIDS programs and practices using the particular Sierra Leonean context, encouraging more context-specific funding terms.

MOPED716
Trends in testing outside of traditional settings in England

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Background: In 2012, it was estimated ~22% of people living with HIV were undiagnosed and 48% of adults were diagnosed late. BHIVA and BASHH guidelines highlight the importance of increasing HIV testing outside of traditional services. The sentinel surveillance of blood borne viruses collects data irrespective of test result, providing information on the population undergoing HIV testing at 15 sentinel laboratories.

Methods: Demographic and testing data for people tested for HIV between 2008 and 2012 were extracted in yearly testing cohorts. Duplicate records, reference testing, under 16’s, and people tested via unknown locations were excluded. HIV positive individuals were excluded from analysis in subsequent years. GP services were linked to a dataset of all GP services across England to determine coverage.

Results: Overall 1,480,882 individuals were tested for HIV, of whom 0.9% tested positive. Half were tested in STI clinics (48.8%). Non-traditional settings accounted for a third of all testing (31.3%; n=463,827), with the number of individuals tested in NTS increasing 1.6-fold from 69,940 in 2008 to 112,033 in 2012, and the proportion positive declining from 1.1% to 0.8%. GP services accounted for one third (36.7%) of all NTS testing. Sentinel surveillance captures testing among 34% of all GP services, covering an estimated 20 million individuals. In 2008 48.8% of these GP services tested at least one individual for HIV, increasing to 54.6% in 2012. GP services tested 301 individuals per 100,000 population in 2008, increasing by two fifths to 425 by 2012. The greatest increase was in areas with a diagnosed prevalence of >2 per 1000 population, where testing rates increased by 49.4% (348 to 520 per 100,000 population) compared with 36.4% (288 to 393) in low prevalence areas, between 2008 and 2012. Despite an increase in testing among GPs, the proportion positive remained stable at between 0.5% and 0.6%.

Conclusions: Since 2008, there has been a 1.6-fold increase in HIV testing in NTS. Testing rates increased overall by one third across all GP services captured within the sentinel surveillance, mainly among those in high prevalence areas. These findings highlight the importance of HIV testing outside of traditional specialised sexual health services.

MOPED717
Impact of STOP HIV/AIDS program on HIV, hepatitis C and syphilis testing volumes in British Columbia

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Background: Diagnosing individuals living with HIV who are unaware of their HIV status provides an opportunity for health providers to engage clients into care, improving the outcomes for the client and reducing forward transmission. The STOP HIV/AIDS pilot was implemented in 2008, to increase population awareness of and testing for HIV. In 2013 the program was expanded province-wide. One of the indicators to assess the province’s progress has been HIV testing volumes. Because of shared risk factors, HIV testing was expected to affect syphilis and hepatitis C (HCV) testing as well. We examine the trend in HIV, HCV and syphilis testing from 2006 (pre-STOP pilot) through 2014 in relation to the STOP implementation.

Methods: HIV, HCV, and syphilis testing data from 2006 to 2014 conducted at the Public Health and Microbiology & Reference Laboratory (PHMRL) in BC were analyzed. PHMRL conducts over 95% of HIV and HCV screening tests and over 99% of screening syphilis tests in BC. The data include tests where the resulting laboratory was PHMRL. A preliminary total of 1,938,765 HIV, 1,508,551 syphilis, and 1,387,123 HCV screening tests were included in the analyses.

Piecewise regressions were used to evaluate the trend in testing volumes before and after STOP implementation with calendar year and month predicting number of tests for each screening test type. The change points were estimated through the model.

Results: A significant change in testing trends for syphilis, HCV and HIV occurred between 2011 and 2012 based on model predicted change points. Preliminary analyses show that HIV testing increased significantly after the change point (unstandardized β=0.61, p < .001). Furthermore, significant increases in trends for both syphilis (unstandardized β=2.01, p < .001) and HCV (unstandardized β =3.35, p < .001) testing were noted after the change point. Annual percent increase in testing will be calculated since the implementation of STOP.

Conclusions: Significant increases in HCV and syphilis testing corresponded with increases in HIV testing, suggesting a simultaneous increase in awareness and testing of related infections. Roughly a 2 year lag is noted between the implementation year and change point estimated. Testing volumes continue to increase in 2014.

MOPED718
Medication possession ratio as a tool for assessing the adherence of antiretroviral therapy among HIV-infected Malaysians: a cross-sectional study

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Background: Adherence to antiretroviral therapy (ART) is a predictor of virologic suppression, emergence of HIV drug resistance, disease progression and death. Monitoring of adherence is often necessary to identify patients at risk of poor clinical outcomes. One of the widely used measures to assess medication adherence is medication possession ratio (MPR). MPR is defined as the days of medications dispensed divided by the number of days between the first and last prescription refill. The aim of this study is to determine whether MPR can be a predictor of viral load outcome among patients who have failed first line ART.

Methods: A cross sectional study was carried out in Malaysia’s National Tertiary HIV/AIDS referral hospital using computerized prescribing system between January 2008 and January 2013. We included 76 adult patients who have failed first line ART requiring a switch to second
line ART and compared with 77 adult patients on ART whom are virologically suppressed since 2008. MPR was computed and compared between the two groups using SPSS Statistics ver19. Adherence levels were categorized as: optimal (>95%) and suboptimal (<95%).

**Results:** Mean duration of pre-treatment days was 182 days. Mean MPR of patients virologically suppressed on ART and failed ART were 86.05% and 75.29% respectively. A significant percentage of patients (88%) who failed ART had suboptimal MPR (<95%). Patients with suboptimal MPR had 3 fold odds of developing virological failure (VF) (p< 0.001, OR=3.944, 95% CI = 1.68 -6.5). We assessed the performance of two MPR threshold in predicting VF. When less than 90%, MPR threshold was used, the sensitivity was 69%, specificity 61%, positive predictive value (PPV) 63% and negative predictive value (NPV) 66%. When MPR threshold was less than 80%, sensitivity was 44%, specificity 82%, PPV 71% and NPV was 60%.

**Conclusions:** This study proved that a significant association between MPR and virologic outcome exist in patients on ART. However, the suboptimal sensitivity and specificity of the MPR limits its utility as a sole predictor of VF. 

**MOPED719**

Improving the provision of antiretroviral therapy (ART) using the community balance scorecard methodology in 8 districts of Malawi

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**Background:** Malawi, with funding from the Global fund, provides free Antiretroviral drugs to approximately 500,000 People living with HIV (PLHIV). Although this is the case, the provision of antiretroviral (ART) drugs has a lot of challenges including few trained ART technicians, stock outs and attitude of health care workers towards PLHIV.

**Methods:** Malawi and the Coalition of Women Living with HIV in Malawi implemented the monitoring of HIV and AIDS services project whose objectives were to:
- Empower 240 PLHIV to monitor quality and availability of HIV/ADS services using the balance scorecard 8 districts by 2014
- Increase participation of PLHIV in demanding quality services from service providers in 8 districts by 2014
- Increase national level engagement between representatives of PLHIV and policy makers by 2014.

**Results:** The one year project which was implemented in 8 districts in Malawi used the community balance scorecard which is a monitoring methodology where trained people living with HIV develop simple scoring tools to score, monitor provision of ART and engage the service providers to demand solutions on the challenges. 240 PLHIV were trained in the community balance scorecard methodology while another 240 were trained in advocacy. 40 health facilities were monitored by the PLHIV who also held 40 engagements with service providers on the identified challenges.

**Results:** 75% of the health facilities reported no antiretroviral drugs stock outs during the period of the monitoring, 28% of the facilities reported of changes in the attitude of health personnel, 59% of the facilities reported an increase in the number of trained personnel in the administration of ART.

**Conclusions:** Monitoring of HIV and AIDS services by PLHIV increases the efficiency and accessibility of these services. To increase the efficiency and accessibility of ART, PLHIV should be empowered to identify challenges in the provision of ART and be able to engage service providers on the identified challenges.

**MOPED720**

Alcohol and depression: link with adherence and viral suppression in patients on antiretroviral therapy in rural Lesotho, Southern Africa

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**Background:** Alcohol use disorder and depression have been shown to be associated with poor adherence to antiretroviral therapy (ART), but only limited data are available regarding a possible association with viral suppression.

**Methods:** Within the context of a registered prospective multi-center study in rural Lesotho (NCT02126696), adult patients on ART ≥6 months were screened with the Alcohol Use Disordering Test (AUDIT), using the thresholds recommended in the guidelines. Depressive symptoms were measured using the Patient Health Questionnaire (PHQ-9). Low adherence to ART was defined as ≥30copies/mL. Chi-square tests and logistic models were used to investigate the association between alcohol use, depression, adherence, and viral suppression.

**Results:** Of 1,198 patients, 1,388 (86.6%) had fully documented AUDIT and PHQ scores. Main data, stratified by sex, are summarised in Table 1.

**Conclusions:** Positive screening for depression (31.7% of women, 20.2% of men) showed a higher prevalence than the general population, while the contrary was observed for hazardous drinkers (4.4% of women, 10.7% of men).

**MOPED721**

Achieving viral suppression with antiretroviral treatment (cART) in an Eastern-European HIV population predominantly consisting of people who inject drugs (PWID)

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**Background:** Estonia, an Eastern European country, has experienced “new” concentrated HIV epidemic among PWIDs, with transition to general population and increasing number of subjects receiving cART. As there is little data on treatment effectiveness in Eastern Europe, we aimed to define the proportion of subjects and factors associated with achieving viral suppression.

**Methods:** Data were extracted from nationwide Estonian HIV Cohort Study (E-HIV) database. Subjects diagnosed HIV positive between 01.01.2000-31.12.2013, were included. All subjects ever received cART and at least two follow-up HIV-RNA plasma viral load (VL) measurements were eligible for analysis. VS was defined as two consecutive VL measurements of
Background: Surveillance of transmitted HIV drug resistance (TDR) amongst individuals accessing voluntary counselling and testing (VCT) services was conducted from May 2013 to April 2014 in two geographic regions of Papua New Guinea: Port Moresby, National Capital District and Mt Hagen, Western Highland Province.

Methods: Dried blood spots (DBS) were collected from HIV infected, ARV-naive VCT attendees age <30 years, if female, nulligravid or primigravid. Genotyping was performed using previously described methods[1]. TDR was defined using the 2009 WHO Surveillance Drug Resistance Mutations List[2]. SLEAC classification[3] with floor and ceiling decision rules modelled to return probabilities of classification similar to those described for the original WHO TDR survey method[4].

Results: Of the 3764 patients in E-HIV diagnosed in 2000-2013, 3080 had ever received cART. Of these, 1702 were lost to follow-up. Of the remaining 1378, 322 (59%) self-identified as Aboriginal. Overall, HIV-RNA VL <75 copies/ml (significant VS) or <1000 copies/ml (acceptable VS) within 360 and 720 days, respectively; p=0.061). We also observed declines in HIV-related mortality for Aboriginal and non-Aboriginals for all-cause mortality (6% vs 2%, p=0.027; 2.50 vs 0.89 per 100 PYRs, p=0.063, respectively). Over time, from 2007-09 to 2013-2014, annual mortality rates were 5.10 vs 4.57 per 100 PYRs, p=0.087, respectively.

Conclusions: Mortality declined for HIV-positive Aboriginal patients after the initiation of quality improvements in chronic disease management of HIV at the clinic. This highlights the effectiveness of both the chronic care model approach and the culturally-informed primary care at the clinic.

MOPED725
Analysis of ART clinical outcomes

Background: This study aimed to describe loss to follow-up, treatment adherence and antiretroviral treatment (ART), viral load suppression and increase in CD4 counts data from adult patients on the ART programme between 2004/05 and 2013/14.

Methods: ART data was collected routinely through the TIER.Net database and exported to District Health Information System. Data was retrieved from the standardized clinical stationery and recorded into either TIER.Net in public health facilities providing ART.

Results: Data presented summarised clinical outcomes from 1,823 facilities and a total of 1,386,290 adult patients who started ART from April 2004 to March 2014. This represents 54% of total patient population.

The proportion of patients starting ART with CD4 count between 200-350 cells/µl increased from 6.9% of all patients starting ART in 2004/05 to 33.0% in 2013/14 while the proportion of patients with CD4 count below 100 decreased from 33.5% of all patients started in 2004/2005 to 18.5 % in 2012/13. Retention of patients on treatment at 12 months was 87.5% for patients who started ART at any point in 2004/05 and 2005/06, while about 78.8% of patients started in 2011/12 were retained on ART at 12 months.

Data further demonstrates that at 12 months, 44.5% of adult patients had a viral load done and 79.7% of these results were <400 copies/µl, the proxy for viral load suppression. The 2004/05 cohort had 3.7% of adult patients lost to follow-up at 3 months whereas the 2012/13 cohort shows 10.2% lost to follow-up for the same period.

Conclusions: Adult patients who formed part of the 2004/05 cohort had superior retention prospects compared to all later cohorts. Loss to follow-up was higher in clients who were part of the later cohorts when compared with the 2004/05 cohort. Innovative interventions to improve patient retention are required.

MOPED727
Rate of ART initiation and time to ART initiation among HIV-infected participants in the Bangkok MSM cohort study, 2006-2014
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Background: To achieve the UNAIDS goal of zero deaths from HIV/AIDS, HIV-infected persons should be retained in care and antiretroviral treatment (ART). We report the rate of follow-up with CD4+ cell count monitoring, ART initiation, and time to ART initiation of HIV-infected participants in the Bangkok Men who Have Sex with Men Cohort Study (BMCS).

Methods: Between 2006-2010, we enrolled participants into the BMCS and followed them every 4 months for 3-5 years. For HIV-infected participants, we provided post-test and antiretroviral therapy (ART) counseling, follow-up with CD4+ cell count monitoring every 4 months, and referral to ART services.

ART initiation was reported during follow-up visits. We conducted descriptive analysis of the data from follow-ups, including CD4+ cell count and ART initiation.

Results: We enrolled 1,744 men into the BMCS. As of 16 December 2014, 614 (35%) had been diagnosed with HIV infection. Of HIV-infected men, 482 (79%) had follow-up with CD4+ cell count.

At HIV diagnosis, the median CD4+ cell count was 438 cells/mm3 and 141/482 (29%) were eligible for ART based on the 2011 Thailand HIV Guidelines – having CD4+ cell count <350 cells/mm3 and/or an AIDS-defining illness. During follow-up, 271/482 (56%) initiated ART. Among these, ART initiation occurred for 144 (53%) when their CD4+ cell counts were <200 cells/mm3 and for 119 (44%) when their CD4+ cell counts were between 200-349 cells/mm3.

The mean duration from HIV diagnosis to ART initiation was 2 years (IQR: 0.8-3.0 years).

The median annual CD4+ cell count of those who initiated ART (423 cells/mm3, IQR: 334-518) was lower than that of those for whom ART was deferred (463 cells/mm3, IQR: 404-644) (p<0.001). In total, 186 (68%) of the 271 who reported initiating ART had an AZT- or d4T-based regimen.

Conclusions: In a sizeable fraction of HIV-infected BMCS participants, ART initiation was deferred despite low CD4+ cell counts and eligibility under 2011 guidelines. Efforts may be needed to ensure that HIV care providers incorporate updated information from the new Thai guidelines released in 2014 which allow for ART initiation at any CD4+ cell count and include a preference for non-AZT/d4T-based regimen.

MOPED727
12-month costs of care of HIV-infected children initiating early antiretroviral therapy before the age of 2 years in Abidjan, Cote d'Ivoire, 2011-2014. The MONOD ANRS 12206 project
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1Université Bordeaux, Institute de Santé Public, d’Épidémiologie et de Développement, Bordeaux, France, 2Programme RAPCI - Site ANRS, Projet Monod, Abidjan, Cote d’Ivoire, 3CHU de Cocody, Service de Pédiatrie, Abidjan, Cote d’Ivoire, 4CHU de Yopougon, Service de Pédiatrie, Abidjan, Cote d’Ivoire, 5Centre Pédiafract et de Prise en Charge, de Recherche et de Formation, Abidjan, Cote d’Ivoire

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Background: To determine the healthcare resource use and costs attributable to the care of HIV-infected infants on early antiretroviral therapy (EART) initiated < 2 years old.

Methods: We assessed the direct costs of care for all HIV-1-infected children ≤2 years old, whose parents agreed to participate, without tuberculosis, included in an initial prospective cohort to receive an EART based on LPV/r in Abidjan. During the first 12-month, we documented all severe morbidity events (SME), leading to death or hospitalization and recorded drug prescriptions, ART and cotrimoxazole prophylaxis delivery, medical exams and consultations with specialists, hospital admissions and routine biological follow-up.

Results: We included 99 children, at a median age of 13.5 months (IQR: 6.8 - 18.6); 45% had reached WHO stage 3 or 4 at enrolment. Of these children, 5 (5%) died and 3 (3%) were lost to follow-up. During the first 12 months, 27 children presented 35 SME, the incidence rate was 36.77 per 100 child-years (IC95%: [35.55 - 37.96]). The mean cost of care per child-month reached 67.24 USD per child-month (IQR: 61.47 USD per child-month, 95% CI: 36.77 per 100 child-years). The mean cost of care per child-month was 36.77 per 100 child-years (IC95%: [35.55 - 37.96]). The mean cost of care per child-month reached 67.24 USD per child-month (IQR: 61.47 USD per child-month, 95% CI: [36.77 per 100 child-years].

The mean cost of care per child-month of a SME was estimated 14.03 USD (IC95%: 9.45-18.60) in children who deceased and 8.03 USD in children who survived.

Table 1. Mean cost of care per child-month during the first 12 months of the MONOD trial

<table>
<thead>
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<th>Table 1. Mean cost of care per child-month during the first 12 months of the MONOD trial</th>
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<tr>
<td><strong>Type of Cost</strong></td>
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<tr>
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<tr>
<td>Medical exams</td>
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<td>Hospital admissions</td>
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<td>Routine biological follow-up</td>
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</table>

Conclusions: The cost of care per child-month during the first 12 months of the MONOD trial was 67.24 USD per child-month, 36.77 per 100 child-years (IC95%: 35.55 - 37.96). The cost of care per child-month was 14.03 USD (IC95%: 9.45-18.60) in children who deceased and 8.03 USD in children who survived.
### MOPED728

**Third-line antiretroviral treatment: the Brazilian experience**

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**Abstract**

Background: Approximately 718 thousand people are infected with HIV in Brazil, among which 313,175 were in treatment in 2012. Third line antiretroviral drugs are indicated for the treatment of multi-resistant HIV/AIDS patients with virological treatment failure. Brazilian program distributes six third-line drugs: Darunavir (introduced in 2007), enfuvirtide (2005), étravirine (2010), raltegravir (2008), tipranavir (2010), maraviroc (2013), all patented and imported at very high prices.

Our aim is to examine the Brazilian’s situation regarding the supply of 3rd line antiretrovirals: are there affordable? Is the price comparable to other countries?

**Methods:**

The methodology for the study was based on a statistical work on Brazilian databases. We analyzed drug prices from 2010 to 2013 and calculated the price / patient / year, which is relevant to compare to other countries.

**Results:**

Brazil regularly gets good discounts because of the annual and central purchase. Table 1 shows the annual values (price / patient / year) in dollars and the quantity purchased separately by year and by product. As we can compare, in 2012 according to data from MSF (2013), for raltegravir, Brazil paid less than Armenia (US$ 13,213), Georgia (US$ 13,225) and Paraguay (US$ 7,008). For étaravine, Brazil paid also less than Jamaica (US$ 5,758), Paraguay (US$ 7,752) and Ukraine (US$ 6,679).

<table>
<thead>
<tr>
<th>Drug</th>
<th>Price/patient/year (US$)</th>
<th>Purchased Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raltegravir 400 mg tablet</td>
<td>2011: $6,394.80</td>
<td>512,000</td>
</tr>
<tr>
<td></td>
<td>2012: $5,245.70</td>
<td>14,920,000</td>
</tr>
<tr>
<td>Étravirine 100 mg tablet</td>
<td>2010: $6,671.80</td>
<td>602,160</td>
</tr>
<tr>
<td></td>
<td>2011: $5,659.40</td>
<td>1,768,000</td>
</tr>
<tr>
<td></td>
<td>2013: $4,761.57</td>
<td>3,870,240</td>
</tr>
</tbody>
</table>

Table 1: Monitoring of EWIs, Thailand, 2010-2014

### MOPED730

**Integrating HIVDR early warning indicators with quality improvement to minimize HIVDR occurrence, Thailand**

C. Lertpiriyasuwat1, A. Teeraratkul2, S. Bhakeechee3, N. Chatharojwong4, K. Phoksawad5, P. Yukaran6, N. Pattapanayon7, O. Sum1, S. Thanprasertkasak1, T. Rodgul8,9

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**Abstract**

Background: Managing optimal antiretroviral treatment (ART) is essential for program quality and to minimize occurrence of HIV drug resistance (HIVDR). Preliminary results from Thailand’s experiences on implementing HIVDR “Early Warning Indicator (EWI)” which are ART site factors associated with emergence of HIVDR as a quality improvement (QI) tool are described.

**Methods:**

Trends for five Thai EWIs (T-EWI) were monitored during 2010-2014 including 1) viral load (VL) coverage (T-EWI1a), 2) VL suppression (T-EWI1b), 3) inappropriate ARV prescription (T-EWI2), 4) loss-to-follow-up to T-EWI3, and 5) on-time drug pick-up to T-EWI4 (Table 1). Data were collected through an electronic, web-based information system, linked with the National Death Registry. Medical records of adults receiving ART under the national Universal Coverage Program have been used to quarterly generate standard reports for hospital, provincial and national levels. Weighted averages for hospital performances of T-EWIs of hospital performance were calculated. HIVDR-QI was first implemented in 2013 and hospital providers and regional and provincial coaching teams were trained. Individual scores for each of the five T-EWIs (0 for poor, 1 for fair and 2 for desirable) and median composite scores (with a maximum score of 10) were calculated to identify site-based QI priorities.

<table>
<thead>
<tr>
<th>T-EWIs</th>
<th>Desirable target</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>P value (Wilcoxon for trend)</th>
</tr>
</thead>
<tbody>
<tr>
<td># ART sites</td>
<td>-</td>
<td>902</td>
<td>907</td>
<td>892</td>
<td>889</td>
<td>905</td>
<td></td>
</tr>
<tr>
<td># Adults receiving ART</td>
<td>-</td>
<td>128,894</td>
<td>140,949</td>
<td>160,126</td>
<td>174,256</td>
<td>185,437</td>
<td></td>
</tr>
<tr>
<td># Adults newly started ART</td>
<td>-</td>
<td>20,415</td>
<td>19,780</td>
<td>20,166</td>
<td>18,114</td>
<td>18,922</td>
<td></td>
</tr>
<tr>
<td>T-EWI1a: VL coverage</td>
<td>&gt;90</td>
<td>54.8</td>
<td>65.5</td>
<td>70.3</td>
<td>77.3</td>
<td>80.4</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>T-EWI1b: VL suppression</td>
<td>&gt;90</td>
<td>93.5</td>
<td>93.0</td>
<td>92.8</td>
<td>92.7</td>
<td>92.8</td>
<td>0.848</td>
</tr>
<tr>
<td>T-EWI2: ARV prescription</td>
<td>0%</td>
<td>0.3 (0.1-0.7)</td>
<td>0.2 (0.0-0.7)</td>
<td>0.1 (0.0-0.5)</td>
<td>0.0 (0.0-0.5)</td>
<td>0.0 (0.0-0.0)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>T-EWI3: Mono/ Dual ARV</td>
<td>0%</td>
<td>7.5 (7.1-7.7)</td>
<td>7.2 (7.0-7.4)</td>
<td>7.4 (7.1-7.4)</td>
<td>8.9 (7.6-8.1)</td>
<td>8.1 (7.2-8.1)</td>
<td>7.9 (7.1-7.7)</td>
</tr>
<tr>
<td>T-EWI4: Lost-to-FU</td>
<td>&lt;5</td>
<td>19.7</td>
<td>17.2</td>
<td>17.4</td>
<td>19.2</td>
<td>21.9</td>
<td></td>
</tr>
<tr>
<td>T-EWI5: On-time pick-up</td>
<td>&gt;90</td>
<td>91.9</td>
<td>91.9</td>
<td>94.2</td>
<td>94.2</td>
<td>94.2</td>
<td>0.270</td>
</tr>
</tbody>
</table>

1) T-EWI1: % patients initiating with ARV who had VL test at least once during 12-month (12-32 months) after initiation; 2) T-EWI1b: % patients whose VL at 12 month after infection was <1000 copies/mL; 3) T-EWI2: % patients receiving ART were being prescribed mono- or dual-regimen; 4) T-EWI3: % patients initiating with ART who lost to follow-up (missed appointment > 90 days) during 12 months after ART; and 5) T-EWI4: % patients receiving ART who returned for ARV pill pick up < 2 days after the ran-out date.

Table 1: Monitoring of EWIs, Thailand, 2010-2014

Conclusions: Most HCP believe there are health benefits of starting ART in PHI as opposed to deferring to CD4<350. The majority, however, would not recommend ART for asymptomatic patients with CD4<350. Clinicians with more PHI experience were more likely to recommend at CD4≥350.
Results: By September 2014, 185,437 persons were receiving ART at 905 hospitals. The 5-year trend for the individual EWIs median percentages are shown in Table 1; Figure 1 shows the median composite score and the trends in hospital EWI performance. Key findings include significant improvement in T-EWI1a, though only 42% of hospitals met the desirable target, and T-EWIV and stayed >80%. The overall median composite score increased from 6.2 (IQR: 5.8-6.6) in 2010 to 7.1 (3.0-9.6) in 2014 (p < 0.001).

Conclusions: EWIIs have been used as a QI monitoring tool in Thailand. The results indicated areas for improvement and identified targeted site-based interventions for QI coaching. Priorities for hospitals to reach desirable performance are:
1) Increase VL screening,
2) Reassess VL suppression, and
3) Minimize lost-to-follow-up.

MOPED732
Acceptability of internet and cell-phone messages to promote linkage to HIV care

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Presenting author email: rcebello@via libre.org.pe

Background: The Peruvian government has been providing free highly active antiretrovi-

ral therapy (HAART) since 2004. As of December 2013, Peru had an estimated 22,157 people on HAART, which represents 51% of those eligible. To improve linkage and retention to HAART, innovative and effective approaches are needed. The objective of this study was to assess the acceptability of receiving information about the National HAART Program via the internet and/or cell phones to promote linkage to care.

Methods: Between November and December 2014 we conducted a cross sectional survey at VIA LIBRE an HIV clinic that provides free HAART in Lima, Peru. During these months all participants who attended the clinic were invited to participate by completing self-administered online questionnaires using tablets.

Results: 920 patients were eligible to participate in the survey; 41 declined and 30 did not complete the survey. Of the 549 surveyed, 513 were people living with HIV (453 male and 60 female) completed the questionnaire. The mean age was 37.9 (IQR 28-53), 14% had finished high school and 84.8% were studying at the university or have completed a degree. Both males and females (252/63.5% males and 387/77.6% females) (p=0.42) reported as important or very important (4 and 5 respectively on a scale of 1=not important and 5=very important) to receive information through SMS, 200/50.4% males and 34/69.4% females (p=0.11) preferred cell-phone voice messages and 177/44.6% males and 23/46.9% females (p=0.23) favorred social networks. Additionally, 243/61.2% males and 29/59.2% females (p=0.11) believed that it was important or very important to receive information through emails, 207/56.2% males and 24/66.1% females (p=0.23) preferred webpages, 195/49.1% males and 26/53.1% females (p=0.21) favored instant-messaging and 176/44.3% males and 21/42.9% females (p=0.06) using a blog. We did not find any significant difference in the acceptability of receiving messages through SMS, cell-phone voice messages, social network, chat, email, blog and websites by gender.

Conclusions: The internet and/or cell phones were recognized as important ways to deliver information about the HAART Program in our study sample. SMS messages, followed by email, and cell-phone voice messages had the highest acceptability. These forms of ICT should be used to improve linkage to care among people living with HIV in Peru.

MOPED733
The effectiveness of compulsory addiction treatment: a systematic review

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Background: Drug addiction is a major source of HIV transmission. In many settings, compulsory treatment, wherein drug dependent individuals are mandated to receive addiction treatment, has been adopted as a strategy to address HIV transmission among this population. However, research on the effectiveness of this approach has yet to be systematically evaluated. We sought to conduct a systematic review of the effectiveness of compulsory addiction treatment.

Methods: We systematically reviewed and extracted findings from studies examining the outcomes of compulsory treatment. The primary outcome of interest was post-treatment drug use. The secondary outcome of interest was post-treatment recidivism. Two authors searched eight English-language databases (PubMed, PNAS International, Proquest, PsychINFO, Web of Science, Scopus Abstracts, JSTOR, EBSCO/Academic Search Complete), one Spanish-language database (REDALYC), one Portuguese-language database (SciELO Brazil), the Internet (Google, Google Scholar), and article reference lists, from database inception to December 1st, 2014.

Results: Of an initial 430 potential studies identified, nine quantitative studies met the inclu-
sion criteria. Studies evaluated compulsory treatment options including drug detention facilities, short (i.e. 21-day) and long-term (i.e., 6 months) inpatient treatment, community-based treatment, group-based outpatient treatment, and prison-based treatment. Three studies (33%) reported no significant impacts of compulsory treatment compared with control interventions. Two studies (22%) found equivocal results but did not compare against a control condition. Two studies (22%) observed negative impacts of compulsory treatment on recidivism. Two studies (22%) observed minor impacts of compulsory inpatient treatment on recidivism and this literature does not suggest benefits of this treatment modality on drug use or recidivism. Given the known benefits of a range of voluntary approaches to treatment, such programs should be prioritized by policymakers seeking to reduce drug-related health and social harms.
Monitoring and evaluation of HIV cascade

MOPED735
Early retention in care at an HIV outpatient clinic in Rio de Janeiro, 2000-2013

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1University of California, Los Angeles, United States, 2Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz, Rio de Janeiro, Brazil

Backgrounds: In high-income settings, retention of people living with HIV (PLHIV) in early HIV care has been associated with improved survival and virologic outcomes. This study aims to characterize individual-level factors associated with early retention at an outpatient HIV clinic in Rio de Janeiro, Brazil.

Methods: We assessed early retention after initial linkage to HIV care among antiretroviral therapy (ART) naive PLHIV ≥ 18 years old who presented to the outpatient HIV clinic at Instituto Nacional de Infectologia Evandro Chagas, Fundação Oswaldo Cruz (INI) between 2000-2011. Linkage within six months of cohort entry was defined by date of the first CD4+ T-lymphocyte count (CD4 count) or HIV viral load (VL), or ART start date, which ever occurred first. Early retention in the two years following linkage was defined by the proportion of six-month intervals with a one CD4 count of VL measurement in the possible categories being 100%, 75%, 50%, 25%, 0%. Logistic regression quantified the association of socio-demographic and clinical factors with good retention (≥ 75%).

Results: The 1251 participants were 70% male, 48% non-white, median age was 35.02 years (IQR, 28.34-42.42), and 80% met criteria for good retention. Early retention improved over time (Figure 1). Compared to individuals < 30 years of age, older individuals were more likely to have good retention (30-40 years adjusted odds ratio (aOR)=1.58 [95% confidence interval, 1.12-2.24]; 40-50 years aOR=2.87 [1.85-4.54]; >50 years aOR=2.48 [1.35-4.78]). Having >6 years of education (aOR=1.93 [1.40-2.67]) and starting ART >3 months after linkage (aOR=4.17 [2.69-6.38]) increased the odds of good retention. Unknown HIV transmission route and among those aware, less likely to report ART use (54% vs 69%, p=0.05). Both age groups reported high 100% ART adherence (63% vs 88%). However, only 62% of SW <25 were less likely to have tested in the last 6 months (75% vs 68%, p=0.08). Among HIV+ SW those <25 were moderately more likely to have tested in the last 6 months (75% vs 68%, p=0.09). However among HIV+ SW those <25 were less likely to know their status (39% vs 69%, p=0.01) and among those aware, less likely to report ART use (54% vs 69%, p=0.05). Both age groups reported high 100% ART adherence (63% vs 88%). However, only 62% of SW <25 reporting ART use had VL<1000 copies/mL, compared with 78% in SW ≥25 (p=0.06). Of all HIV+ SW <25 only 13% were on ART and had a VL<1000, compared with 37% in SW ≥25 (p=0.01; Figure 1). In both groups 16% reporting no ART use had VL<1000.

Conclusions: Retention in early HIV care in this urban Brazilian cohort is comparable to high-income settings. Increasing ART availability may partially account for improved early retention over time. Approximately 20% of persons linked to care have poor retention, and efforts to improve early retention should target younger and less educated patients. Further research may elucidate possible psychosocial and structural barriers to early retention in this population.

MOPED736
Engagement in HIV care among young female sex workers in Zimbabwe

S. Napiela Navedenzago1, E. Fearon1, J. Hargreaves3, P. MUSHALI, T. Chiyakai2, G. Mugurungi2, D. Hanisch1, K. Hatzold1, A. Phillips1, F. Cowan4

Background: Young sex workers (SW) are highly vulnerable to HIV, with data from Zimbabwe estimating HIV incidence at 10.8% among SW ≤25 years. The extent of young SW engagement with HIV services is unknown. In the baseline survey for a community-randomized trial of antiretrovirals for HIV prevention and treatment among SW in Zimbabwe (the SAPPH-Re trial), we compared engagement in services and estimated the HIV care cascade among SW aged <25 compared with those ≥25 years.

Methods: We conducted the survey among 2722 SW recruited using respondent-driven sampling (RDS) in 14 sites. Eligible participants were ≥18 years and working as SW. A questionnaire was administered collecting data on demographics, sexual behaviour, sex work, HIV testing history and serostatus, uptake of HIV services and ART use. We collected dried blood spots for HIV testing, and if positive measured viral load (VL). Analysis used RDS-2 estimation pooling data across sites.

Results: Mean age was 31 years (range 18-65); 27% were <25 years. HIV prevalence was 56% overall, and was lower among those <25 (33% vs 64%, p<0.01). Among HIV+ SW those <25 were moderately more likely to have tested in the last 6 months (75% vs 68%, p=0.08). However among HIV+ SW those <25 were less likely to know their status (39% vs 69%, p=0.01) and among those aware, less likely to report ART use (54% vs 69%, p=0.05). Both age groups reported high 100% ART adherence (63% vs 88%). However, only 62% of SW <25 reporting ART use had VL<1000 copies/mL, compared with 78% in SW ≥25 (p=0.06). Of all HIV+ SW <25 only 13% were on ART and had a VL<1000, compared with 37% in SW ≥25 (p=0.01; Figure 1). In both groups 16% reporting no ART use had VL<1000.

Conclusions: HIV prevalence was lower and recent testing common among SW <25, yet young HIV+ SW were less likely to know their serostatus. Fewer reported taking ART, perhaps reflecting more recent infection, and/or slower HIV progression. Despite high reported adherence, overall just 13% of young HIV+ SW on ART had VL<1000. Services need to be tailored to address the unique needs of young SW.

MOPED737
Evaluating the HIV cascade of care: model design, evaluation and results after implementation in one center for 2 consecutive years

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1University of Chile, School of Medicine, Santiago, Chile, 2San Borja Arriaran Hospital, Fundacion Amarian, Santiago, Chile

Background: The Cascade of Care (CoC) of the HIV epidemic implies many components, from a larger undiagnosed infected population to a minority successfully treated. The expanding access to antiretroviral therapy (ART) worldwide requires evaluating the whole process and its components; no standard method for that exists. Initial steps depend mainly in public health policies, the later ones in clinical performance at sites.

Objectives: To validate, in a large AIDS care site, a proposed model for evaluating the CoC in the initial and advanced phases of the process, using simple, easily available parameters.

Methods: The 3 main model components are: Proportion of patients initiating ART with baseline CD4 cell count (CD4) > 200 cells/mm³ in one calendar year (A1); proportion of patients retained in care (by drug pick up or medical visit) (B1) and proportion of active patients with viral load (VL) < 200 copies/mL (C1) both at one year + 3 months. Secondary components of non-compliance in each main category were classified in: lower baseline CD4 (A2) and non data available (ND) (A3); abandonment (LTFU) (B2) and transfer (B3) and death (B4) during year 1; VL < 200 copies/mL (C2) and undetectable VL (C3).

Results: In this cohort, the proportion of HIV+ patients initiating ART within the first year was 90% (95% CI 88-92), which was maintained at 6 months (90% 95% CI 89-92). The proportion of patients retained in care at 12 months was 87% (95% CI 85-89), which was maintained at 15 months (90% 95% CI 88-92). Of all HIV+ patients, 95% (95% CI 93-97) had a VL < 200 copies/mL at 6 months (95% CI 94-97). Of the patients with detectable VL, 99% (95% CI 97-100) had a VL < 200 copies/mL at 15 months (95% CI 97-100).

Conclusions: This model is feasible, reliable and valid in routine implementation, simplifying complex CoC evaluation.

Figure 1. Proportion of patients remaining in care at each ART link: retained >75%

Proportion of patients remaining in care at each ART link: retained ≥ 75%

Year 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010
Proportion A 80% 84% 85% 87% 87% 89% 92% 92% 92% 92% 92%
Proportion B 90% 90% 90% 90% 90% 90% 90% 90% 90% 90% 90%
Proportion C 90% 90% 90% 90% 90% 90% 90% 90% 90% 90% 90%

[Figure 1. Retention in early care of patients entering the HIV outpatient clinic at INI, 2000-2010]

Conclusions: Retention in early HIV care in this urban Brazilian cohort is comparable to high-income settings. Increasing ART availability may partially account for improved early retention over time. Approximately 20% of persons linked to care have poor retention, and efforts to improve early retention should target younger and less educated patients. Further research may elucidate possible psychosocial and structural barriers to early retention in this population.
**MOPED738**

**Loss of HIV-positive patients in rural primary health care facilities in North West province, South Africa: a retrospective register audit**


**Background:** Retention of patients in HIV care is a challenge among ART programs in South Africa. Clinic-based registers may provide a mechanism for tracing clients and assessing outcomes throughout the HIV care cascade, though typically clients are not identified and linked across registers.

**Methods:** As part of an overall health systems strengthening program in a rural area of North West Province, South Africa, a retrospective government register audit was conducted. Three members of HIV counseling & testing (HCT) and antenatal registers, and six months of Pre-ART and ART registers, were reviewed in twelve clinics. HIV-positive clients in HCT registers were traced to Pre-ART and ART registers. Documented CD4 counts, retention in care, initiation of ART, and referrals were assessed. Among HIV-positive clients identified in antenatal registers, proportions of clients with a documented CD4 result and initiating ART or PMTCT were calculated. Client charts were also accessed, but teams could not link the charts to register entries.

**Results:** Overall, 7,522 patients were identified accessing HCT services over three months; 653 (8.7%) patients were documented HIV-positive. Patients accessing HCT services were more frequently female (66.0%), adults (66.8%), and referred by health providers (55.9%). Four-hundred and twenty patients (64.3%) were successfully traced to Pre-ART or ART regis-

**Conclusions:** The model was easily implemented; gaps preventing optimal endpoints at initial and advanced steps of the CareCo were defined. Tailored planning for improving outcomes can be made and standards for performance established. We propose that the model is helpful for evaluating the CareCo and can be applied elsewhere.

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**MOPED739**

**Treatment as prevention in Brazil: speeding up the pace to reach the 90-90-90 targets**

A.R. Pascom, C. Habckost, F. Mesquita

**Background:** The HIV cascade of care framework allows efficient and effective monitoring of the fundamental needs of people living with HIV/AIDS (PLWHA). In 2014, WHO, UNAIDS, Latin America and Caribbean HIV Technical Cooperation Working Group (GCTH) and regional non-governmental organizations in Latin America established treatment targets to be reached by 2020, that were later incorporated by UNAIDS as global targets, the 90-90-90 targets. This study aims to present 2013 HIV continuum of care cascade and to foresee what Brazil still needs to do in order to achieve these targets.

**Methods:** Information was extracted from National HIV/AIDS databases. We defined four steps in the cascade framework: HIV infected (estimated from a statistical model based on the CD4 count at diagnosis); HIV diagnosed; on ARV treatment (ART); and virologically suppressed (VL ≤ 100 copies/mL). Based on this cascade, the 90-90-90 targets were estimated to Brazil. In our analysis we considered the number of PLWHA that were incorporated during 2014 to estimate the number of people we have to include by 2020 to reach the 90-90-90 targets.

**Results:** Nearly 734,000 Brazilian residents were infected with HIV/AIDS in 2013. Of them, 80% (589,000) were already diagnosed. Around 355,000 (48%) PLWHA were on ART and 293,000 (40%) had viral suppression. In 2014, we included 49,000 PLWHA on ART (excluding deaths and abandonment), meaning Brazil achieved 68% of its treatment target. Furthermore, we already achieved 63% of 90-90-90 targets related to the viral load suppression.

**Conclusions:** This study showed that in one year Brazil has achieved more than one fifth of its treatment and viral load suppression 90-90-90 targets. The adoption of treatment as prevention strategy in December 2013 appears to have accelerated the progress towards achieving these treatment targets. Brazil seems to be on the right track to reach the 90-90-90 targets, if it maintains the same rhythm observed in 2014.
families to care. We describe the results of the national PMTCT program implementation in all public hospitals using the national PMTCT intervention monitoring system (PHIMS).

**Methods:** Aggregate data from ANC, delivery logbooks, counseling records, laboratory reports, and hospital data sources were summarized by hospital staff from ANC units, labor rooms, post-partum wards, and pediatric clinics. Data were compiled into a monthly report form and entered in the web-based PHIMS program. Standard national PMTCT reports were generated and used for analysis.

**Results:** From October 2013 to September 2014, 3,628 (79.0%) of 10,920 expected reports were received from 784 (96.2%) of 810 public hospitals in all 77 provinces. Among 513,631 women giving birth, 505,158 (98.4%) received ANC, 512,728 (99.9%) had HIV testing results, and 133,930 (26.1%) had received CHTC. Of women who gave birth and had HIV test results available, 3,164 (0.62%) were HIV positive, of whom 2,675 (84.6%) received CD4 count testing and 2,675 (84.6%) received triple ARV, 358 (11.3%) other ARV regimens, and 131 (4.1%) received no ARV. There were 3,152 infants born to HIV-infected mothers including 31 (0.97%) stillbirths, 599 (18.8%) low birth weight ( 2500 grams), and 355 (11.2%) preterm (<37 weeks) infants. Among 2,689 HIV-exposed infants who received two HIV PCR tests during the reporting period, 60 (2.2%) were HIV infected and 49 (18.7%) of these infants were linked to HIV care.

**Conclusions:** We found high levels of ANC and HIV testing among pregnant women. Eighty-five per cent of HIV-infected expectant mothers received triple ARV and the mother-to-child HIV transmission rate was below 3%. Public health officials and providers should work to increase CHTC and linkage of HIV-infected infants to care.

**MOPED741**

**Completeness and accuracy of data in Zimbabwe’s national PMTCT program health facility registers: findings from a patient level data quality audit**

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1Elizabeth Glaser Pediatric AIDS Foundation, Technical Department, Harare, Zimbabwe, 2Elizabeth Glaser Pediatric AIDS Foundation, Social Research and Information Evaluation, Washington DC, United States, 3Elizabeth Glaser Pediatric AIDS Foundation, Technical Department, Washington DC, United States

**Background:** Prevention of mother-to-child transmission of HIV (PMTCT) remains a priority in Zimbabwe. Complete and accurate data are required to reliably monitor PMTCT targets. In 2014, the Elizabeth Glaser Pediatric AIDS Foundation (EGFAP) conducted a patient level data quality audit (DQA) of the national PMTCT program to measure completeness and accuracy of data in facility registers, which are used to measure PMTCT program performance.

**Methods:** A descriptive cross-sectional study was conducted in 43 randomly selected health facilities. Patient level data for pregnant and lactating women and infants aged six weeks to six months were abstracted from patient-held medical cards and facility registers. In addition, exit interview findings with antenatal (ANC) and postnatal (PNC) women were compared with data on patient held cards. A data element for example age was complete if patient held card and facility register were documented, and accurate if documentation on the two sources were the same. Reasons for discordance were explored through interviews with healthcare workers (%)

**Results:** Records for 292 ANC and 266 PNC women were reviewed. Table 1 summarizes average completeness and accuracy of data in facility registers by facility type. Overall completeness was 83% for ANC and 71% for PNC; overall accuracy was 75% for ANC and 66% for PNC. Completeness and accuracy of ANC data for clinics and rural hospitals were higher than referral hospitals (mission, district and provincial hospitals). Completeness and accuracy were largely a result of health workers documenting on patient held cards only and not updating facility registers; largely due to multiple registers and high workload. Figure 1 summarizes contribution of documentation practices to incompleteness. Completeness based on data from patients’ interviews and patients held cards was 100% for all data elements; accuracy was above 80%.

**Conclusions:** The variation in completeness and accuracy by facility type calls for targeted on-site mentoring and coaching of facility level health workers. Health worker documentation in patient held cards without updating facility registers was the major determinant of incompleteness and inaccuracy. There is need to ensure that health workers document in facility registers in order to accurately measure PMTCT service uptake.

<table>
<thead>
<tr>
<th>Health Facility Type</th>
<th>Completeness of ANC data elements</th>
<th>Completeness of PNC data elements</th>
<th>Accuracy of ANC data elements</th>
<th>Accuracy of PNC data elements</th>
</tr>
</thead>
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<tr>
<td>Clinic</td>
<td>91%</td>
<td>69%</td>
<td>78%</td>
<td>63%</td>
</tr>
<tr>
<td>Rural Hospital</td>
<td>94%</td>
<td>65%</td>
<td>89%</td>
<td>60%</td>
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<td>Mission Hospital</td>
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<td>76%</td>
<td>76%</td>
<td>72%</td>
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<tr>
<td>District Hospital</td>
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<td>74%</td>
<td>54%</td>
<td>66%</td>
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<tr>
<td>Provincial/Central Hospital</td>
<td>75%</td>
<td>70%</td>
<td>70%</td>
<td>67%</td>
</tr>
<tr>
<td>Average</td>
<td>83%</td>
<td>71%</td>
<td>75%</td>
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</table>

[Completeness and Accuracy of data by facility type]

**MOPED742**

Are HIV-positive individuals more likely to engage with HIV care if someone else in the household is HIV-positive and in care?

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**Background:** Our understanding of how household-level factors can influence engagement in HIV care is limited. We examined whether people living with HIV identified through home-based HIV testing (HBCT) were more likely to engage with care if there was already someone living with HIV and in care in the household.

**Methods:** The Academic Model Providing Access to Healthcare (AMPATH) program is one of Africa’s largest HIV care providers and initiated HBCT in 2007. Electronic data from the care program (through June 2014) were merged with data from HBCT of 2009-2011 for one sub-county using probabilistic matching. We used adjusted prevalence ratios estimated from log-linear models with robust standard errors and Cox regression to measure the association between engagement in care (at least one visit with an HIV care provider) and having other HIV-positive household members in care for those previously known HIV-positive and the newly diagnosed, respectively. Models were adjusted for the number of HIV-positive members in the household, the total household size, and individual socio-demographic characteristics (i.e., age, sex, marital status, employment, income, education).

**Results:** A total of 2,355 individuals from 1,796 households were identified during HBCT as previously known HIV-positive, of whom 72%, 23%, and 5% had 1, 2, or ≥3 HIV-positive members in the household respectively. Compared with living in a household with no one engaged in care, having one (adjusted prevalence ratio (APR) = 1.63, 95% confidence interval (CI): 1.43, 1.85) or more (APR = 2.49, 95% CI: 1.96, 3.16) other household members engaged in care was associated with individual engagement in HIV care. Among 1,433 newly identified HIV-positive individuals from 1218 households, 70%, 26%, and 4% had 1, 2, or ≥3 HIV-positive members in the household, respectively. There was no association between household members’ engagement in care and prospective linkage to HIV care among the newly diagnosed.

**Conclusions:** Including family members in intervention strategies may promote individual engagement in HIV care. Additional research is needed to understand the mechanism by which living in a household with at least one other person engaged in HIV care influences individual engagement in care.
Predictors of viral suppression and rebound among HIV-positive gay, bisexual, and other men who have sex with men in a large multi-site Canadian cohort

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Background: Gay, bisexual, and other men who have sex with men (MSM) represent the largest HIV transmission category in Canada. However, there are limited pan-provincial data regarding HIV treatment outcomes after initiation of antiretroviral therapy (ART). We sought to identify socio-demographic and clinical correlates of viral suppression and rebound among MSM to inform treatment and retention strategies.

Methods: Our analysis included MSM participants in the Canadian Observational Cohort (CANOC), a multi-site cohort of HIV-positive adults from Canada’s three most populous provinces, which initiated ART naïvely between 2000-2011. Accelerated failure time models analyzed time to viral suppression (≤ 2 consecutive measures < 50 copies/mL, ≥30 days apart within 1 year following treatment initiation) and rebound (≥2 consecutive measures > 200 copies/mL, ≥30 days apart after achieving suppression), identifying key socio-demographic and clinical correlates.

Results: Within CANOC, 3180 participants were identified as MSM, of which 259 (8%) reported a history of injection drug use (IDU). At pre-ART baseline, the median age and CD4 count were 40 years (IQR=33-46) and 257 cells/μL (IQR=130-340), respectively. Viral suppression within 1 year of ART initiation was achieved by 2916 MSM (92.3%) in a median time of 5 months. Adjusted hazard ratios (HRs) of significant variables (p < 0.05) from the multivariate models are presented in Table 1. Independent predictors of viral suppression include more recent era of ART initiation, higher viral load testing rate, no IDU history, older age at baseline, lower baseline viral load, and prescription of a non-nucleoside reverse-transcriptase inhibitor (NNRTI) versus boosted protease inhibitor (PI) and unboosted PI. Independent predictors of subsequent viral rebound, experienced by 298 participants (11.4%) in a median time of 22 months, included less recent era of ART initiation, higher viral load testing rate, IDU history, younger baseline age, higher baseline CD4 count, and living in British Columbia versus Quebec or Ontario.

Conclusions: Identifying predictors of suboptimal treatment outcomes is an important step towards improving HIV treatment and retention programs for MSM across Canada. Priority target groups include younger MSM with a history of IDU, who demonstrated a greater likelihood of treatment failure in our analysis.

Cost-effectiveness analysis alongside the cascade of HIV care: to seek, test, treat or retain? That is the question

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Background: Interventions to improve the cascade of HIV care at its various stages may vary substantially in their ability to deliver good value for money. There is an urgent need to maximize the value of health spending by prioritizing cost-effective interventions and more broadly, identifying an optimal mix of interventions given available resources. We consider hypothetical scenarios of increased uptake of HIV testing and treatment, and improved treatment retention to identify the most cost-effective public health strategy.

Methods: We used a previously-validated dynamic compartmental HIV transmission model to project the costs, benefits and epidemiological outcomes of the HIV/AIDS epidemic in BC from 2015 to 2035 under six hypothetical scenarios: (1) current practice, characterized using available population-level epidemiologic and economic data; (2) a 10% increase in the HIV testing rate; (3) a 10% increase in treatment uptake; (4) a 25% decrease in the rate of treatment discontinuation; (5) interventions in scenarios (2)+(3); and (6) interventions in scenarios (2)+(3)+(4). Total HIV incidence, mortality, present-valued costs (in 2015$CDN) and quality-adjusted life years (QALYs) were estimated for each scenario, while incremental cost-effectiveness ratios (ICERs) were calculated against scenario (1), as well as the next-most resource intensive strategy in the interest of identifying the most efficient strategy. Analyses were executed from a third party payer (TPP) perspective.

Results: Scenarios (2) - (6) were all highly cost effective (< 1x GDP per capita) compared to actual practice. Strategies (3) and (4) were dominated by strategies (5) and (6) respectively. We found strategies (5) remained cost-effective compared to strategy (3), with an ICER of $30,351 per QALY gained. At an additional cost of $110M over the study timeframe (5.5M/year), jointly increasing HIV testing and treatment access and improving HAART retention resulted in 531 averted HIV cases, 115 averted deaths and an overall gain of 6,469 QALYs.

Conclusions: Despite significant investment and advances in HIV care in BC, we found interventions to further improve HIV testing and care were highly cost-effective. Further research is required to aid resource allocation decisions on the margin, and in real-time, using the observed effectiveness of such interventions as delivered within the province.
Results: We identified 2646 HIV positive women among a population of 18 005 attending ANC in 44 facilities (14.8%); 35.5% (n=930) had documented uptake of EID within three months (95%CI: 31.1%-39.9%). Average EID completion varied across ANC site volume (p< 0.01), but variability within groupings by site size was large and varied by more than 2-fold.

Conclusions: We observed low documented uptake for timely EID among a population-based sample of HIV positive women in ANC. While facility size had a strong influence on the probability of EID completion, dramatic variability within groupings by size indicate need for additional studies to understand facility characteristics related to size as well as local operational factors unrelated to size for effective service delivery. Future research should seek to trace and document true outcomes among mother-baby pairs with no documented uptake of timely EID.

MOPED748
Understanding gaps in service delivery through the HIV diagnosis-to-treatment cascade: findings from health facility surveys in six sub-Saharan countries

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Variable ANC Volume Risk Ratio p-value 95% CI
High: 1001-1500 (referent) 1 - -
Med-High: 501-1000 1.23 0.05 (1.00, 1.52)
Low: 201-500 1.78 > 0.0001 (1.45, 2.19)
Low: 0-200 1.85 > 0.0001 (1.44, 2.38)

Poisson regression showing association of site ANC volume on the probability of documented EID completion. Association is adjusted for gestational age at presentation and calendar time.

[Documented EID completion]

Conclusions: We observed low documented uptake for timely EID among a population-based sample of HIV positive women in ANC. While facility size had a strong influence on the probability of EID completion, dramatic variability within groupings by size indicate need for additional studies to understand facility characteristics related to size as well as local operational factors unrelated to size for effective service delivery. Future research should seek to trace and document true outcomes among mother-baby pairs with no documented uptake of timely EID.

MOPED746
Linkage to care among HIV-infected infants in Botswana

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Background: HIV prevalence among pregnant women in Botswana is 30.4% with mother to child transmission estimated at ≤ 4%. HIV-exposed infants are DNA PCR tested in the national Early Infant Diagnosis (EID) program. We assessed linkage of HIV-infected infants in the EID program to the ART program.

Methods: We de-duplicated the national EID database and the HIV care database. Demographic and clinical data for HIV exposed infants were collected on lab requisition forms and sent with dried blood spot specimens for DNA PCR testing at referral laboratories in Botswana. Infant data and HIV results were captured in the EID database. Using deterministic matching we linked matched infants who tested HIV-positive from 2008 to 2012 to infants registered for ART using name, date of birth and gender for the same time period. We assessed median days to linkage and report on demographic and clinical characteristics of these infants.

Results: A total of 54,343 infants were PCR tested from 2008 to 2012 and 1,389 (2.6%) were identified as being positive for HIV. The HIV care database contained 228,189 unique individuals who were registered to receive HIV care from 2008 to 2012. Only 218 (15.7%) HIV-positive infant names were found in the HIV care database and were considered linked. Median time to linkage was 64 days and 52.3% of the infants were female. Of those linked to care, 31.2% were infants born by 8 weeks of age compared to 6.7% of infants tested at more than 12 months of age. Of the matched infants, 67.0% were linked to care within six months of being diagnosed. The percentage linked to care within 6 months was 70.0% in 2008, 70.9% in 2009, 68.9% in 2010, 63.9% in 2011 and 63.8% in 2012 (test for trend p=0.19).

Conclusions: Early infant diagnosis is intended to promptly identify and link HIV-positive infants to link to treatment and care for reduced morbidity and mortality. Our results indicate that less than 20% of HIV-positive infants were linked to care, with two-thirds linked within 6 months of being diagnosed. This most likely represents the worst-case scenario of linkage to care success.

MOPED747
A population-based estimate of documented completion of early infant diagnosis in Mashonaland East Province, Zimbabwe

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Background: In Zimbabwe, information on health services received by HIV positive pregnant women and their exposed-infants across the PMTCT cascade is documented in multiple, paper-based registers at health sites. Summarizing individual completeness of service uptake can only be achieved by manual review and therefore the proportion of mother-baby pairs who uptake timely EID is not routinely reported. We conducted a population based survey in which individual HIV infected mother-baby pairs were followed through registers to better understand probability and determinants of completing EID.

Methods: We selected 45 of 193 health facilities in Mashonaland East Province using a probabilistic sampling technique to ensure facilities of different types were included in survey. We assessed median days to linkage and report on demographic and clinical characteristics of these infants.

Results: A total of 54,343 infants were PCR tested from 2008 to 2012 and 1,389 (2.6%) were identified as being positive for HIV. The HIV care database contained 228,189 unique individuals who were registered to receive HIV care from 2008 to 2012. Only 218 (15.7%) HIV-positive infant names were found in the HIV care database and were considered linked. Median time to linkage was 64 days and 52.3% of the infants were female. Of those linked to care, 31.2% were infants born by 8 weeks of age compared to 6.7% of infants tested at more than 12 months of age. Of the matched infants, 67.0% were linked to care within six months of being diagnosed. The percentage linked to care within 6 months was 70.0% in 2008, 70.9% in 2009, 68.9% in 2010, 63.9% in 2011 and 63.8% in 2012 (test for trend p=0.19).

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**Methods:** Health facilities serving the population were purposively sampled in nine HDSS sites in Uganda, Tanzania, South Africa, Zimbabwe, Malawi and Kenya. Between October 2013 and May 2014, structured questionnaires were administered to the in-charge staff at each facility covering provision of HTC, prevention of mother-to-child transmission (PMTCT) and ART services. Data were entered at a centralised location and descriptive statistics were produced using Stata12.

**Results:** 139 facilities were surveyed ranging from 6 in Malawi to 36 in Zimbabwe. 65% of facilities were government-run, 27% were lower-level facilities (eg/dispensaries) and 10% were referral hospitals. HTC was available in some form at all facilities, though provider-initiated testing and counselling was not systematically provided in any site, even for attendees at antenatal care or family planning clinics. The availability of mobile HTC services ranged from 13% of 8 facilities in Kisese (Tanzania) to 93% of 14 facilities in Rakai (Uganda). Over 60% of facilities in all sites provided PMTCT-related services, while the proportion initiating patients on ART ranged from 39% to 100%. Task-shifting was common with over 50% of facilities in all sites allowing nurses to distribute ART refills. Stock-outs of HIV test kits and antiretroviral drugs in the past year occurred in facilities in all sites except South Africa. Between 6% and 40% of facilities per site reported senior staff member departures over the past year.

**Conclusions:** HTC and PMTCT service coverage was high across all sites, but there was variability in ART availability, decentralisation and task-shifting. Key challenges for all sites include staff turnover and supply issues demonstrating that poor service quality represents an important barrier to effective ART delivery. Future analyses comparing these findings with the mortality distribution of HIV-infected persons in each site will help explain the impact of programme differences on survival.

**MOPED750**

**The care and treatment cascade and 2020 “90-90-90” targets in Latin America and the Caribbean: baseline 2013 estimates**

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**Background:** In 2011, Latin America and Caribbean (LAC) countries reaffirmed their commitment to Universal Access to antiretroviral treatment (ART) (i.e. 80% ART coverage of people in need) by 2015. In 2014, new regional targets for 2020 were presented and endorsed at the Regional HIV Care and Treatment Forum held in Mexico City in May 2014 (90% diagnosed with HIV, 90% ART coverage of those in need, 90% viral suppression on ART, <10% late diagnosis with < 200 CD4+), based on the framework of the HIV care and treatment cascade.

**Methods:** We estimated a 2013 baseline for the 2020 targets and the care and treatment cascade for LAC, based on analysis of secondary data from UNAIDS estimates of people living with HIV, 2014 Global AIDS Response Progress Reporting (GAPR) data, reports from PAHO technical cooperation missions and other published secondary sources.

**Results:** For 2013, the baseline regional situation for the 2020 targets showed that 71% of all estimated persons with HIV were aware of their status (data from 13 countries representing 73% of all persons with HIV). 56% of persons eligible for treatment were on ART (based on GAPR data for LAC), and 77% of persons on ART had a viral load <200 copies/ml (data from 21 countries representing 76% of all persons with HIV). In addition, 35% of new diagnosis were detected late with <200 CD4+ (data from 21 countries representing 76% of all persons with HIV). Based on 2013 data, the regional cascade of the continuum of care shows that 71% of people living with HIV were diagnosed (data from 13 countries), 44% were on ART (GAPR data) and 34% achieved viral load suppression (data from 21 countries).

**Conclusions:** In order for LAC to achieve the 90-90-90 targets by 2020, countries should increase efforts to expand HIV testing strategies for timely diagnosis prioritizing key populations based on epidemiological data. Strengthening linkage and retention in care key to achieve ART coverage and viral suppression targets. The 90-90-90 targets are ambitious, but this analysis demonstrates they can be adequately monitored with available data to assess progress and challenges.

**MOPED749**

**Linkage to TB treatment in Botswana among Tebelopele clients who screened positive for TB, 2008 - 2012**

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**Background:** The HIV prevalence in Botswana is 17.6%, while the tuberculosis (TB) case notification rate is 331 cases/100,000 population. The TB-HIV co-infection rate is estimated to be 65% (range 60-86%). In 2008, Tebelopele Voluntary Counseling and Testing (TVCT) began providing clients who screen positive for TB are evaluated and treated if diagnosed with active disease.

**Results:** Among the 425,157 TVCT clients, 28,542 (6.7%) screened positive for TB and of those, 63.4% were HIV negative. There were 25,958 individuals who received treatment in the BTNTP. Among TVCT clients who screened positive for TB, 521 (1.8%) were linked to TB treatment in a median of 74 days. Among those linked, 84.8% were HIV-positive, 39.9% were females and 62.0% were linked within 6 months of TB screening. HIV-negative clients were more likely to be linked to treatment within 6 months than HIV-positive clients (75.9% vs. 59.5%, p=0.010). Linkage to TB treatment within 6 months increased from 48.0% in 2008 to 95.8% in 2012 (p-value=0.02).

**Conclusions:** Results indicate that <2% of individuals who screen positive for TB in VCT are diagnosed with TB and linked to treatment. With HIV-associated deaths accounting for 25% of all TB deaths globally, early identification and linkage to treatment among co-infected patients is crucial in reducing morbidity and mortality. More efforts are required to ensure that clients who screen positive for TB are evaluated and treated if diagnosed with active disease.
MOPED752
Improving engagement in care and viral suppression through health systems linkages and intensive case management: preliminary findings from a multi-city implementation project

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Background: To optimize antiretroviral treatment effectiveness, health systems must respond to diverse medical and social service needs of persons living with HIV/AIDS. The aim of this study was to evaluate the effect of an intensive case management program administered across multiple agencies by the Wisconsin AIDS/HIV Program. The program was designed to provide clients with the knowledge and skills necessary to maintain care engagement and achieve sustained viral suppression, and specifically targeted 3 groups: (1) those newly-diagnosed with HIV, (2) individuals being released from prison, and (3) patients known to have HIV who have not consistently engaged in care.

Methods: This retrospective analysis compared clients enrolled in a time-limited, intensive case management intervention and propensity-matched controls selected from the Wisconsin HIV surveillance database. The study sample included 235 clients enrolled in intervention between 6/30/2013 - 6/26/2014 and a 1:1 matched control group. Engagement in care was defined as the presence of at least one HIV-specific laboratory test every 6 months since enrollment. Viral suppression was defined as a viral load ≤200 copies/mL at the time of the latest laboratory test during the follow-up period. Chi-square tests were used to assess differences between intervention and control groups.

Results: The intervention and control groups were similar with respect to median age (34 years, 28-48 years), and self-reported race/ethnic group (17.5% Black, 87.5% Latino, 3.4% Other). Compared to matched controls, a significantly higher proportion of intervention clients were engaged in care (73.5% vs. 48.3%, p<0.0001) and achieved viral suppression (76.2% vs. 35.7%, p<0.0001). A subgroup analysis comparing only newly-diagnosed clients suggested there was no significant difference in care engagement between the intervention and control groups (78.7% and 74.5%, p<0.049), however, the proportion of newly-diagnosed patients achieving viral suppression was significantly higher for intervention clients (74.5% vs. 58.5%, p<0.049).

Conclusions: Intensive case management appears to be an effective strategy for improving care engagement and viral suppression among individuals with substantial barriers to HIV care. Future studies should investigate long-term treatment outcomes after discharge from the intervention in order to assess the sustained impact of the intervention among this patient population.

MOPED754
The cost-effectiveness of population-level HAART expansion in British Columbia

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Background: The cost-effectiveness of widespread HIV screening and facilitated access to antiretroviral treatment was first illustrated using mathematical models and since validated in a clinical trial setting. However, coordination and execution of a population-level response to HIV/AIDS is resource-intensive. Few examples of extensive evaluations of the public health and economic value of extant systemic responses are available. We capitalized on comprehensive data infrastructure to determine the cost-effectiveness of highly active antiretroviral therapy (HAART) scale-up witnessed in BC. Canada from 1997 to 2010 compared to hypothetical scenarios characterized by constrained treatment access.

Methods: Using linked population-level data, we populated a dynamic compartmental HIV transmission model to simulate the HIV/AIDS epidemic in BC from 1997 to 2010. HIV screening, transmission, risk behaviours, costs (in 2010$CAD) and quality-adjusted life years (QALYs) were estimated as a function of HIV risk group and disease progression. Incremental cost-effectiveness ratios (ICERs) were calculated from societal and third party payer (TPP) perspectives to compare actual practice (the true number of individuals accessing HAART) to scenarios of constrained expansion. Structural and parameter uncertainty was investigated in sensitivity analysis.

Results: We estimated that actual practice resulted in 263 averted incident cases compared to the 75% HAART access scenario, and 624 averted cases compared to the 50% access scenario. Within the study timeframe and using a TPP perspective, actual practice was costlier than scenarios of reduced treatment expansion, but led to substantially greater QALY gains. Resulting in ICERs of $10,283/QALY compared to 75% expansion, and $11,153/QALY compared to 50% expansion. From a societal perspective, actual practice was cost-saving over the study horizon. Extending the time horizon to 2035 indicated that actual practice should lead to a (discounted) savings of $24.8M in total cumulative costs compared to the 75% access scenario, and a savings of $65.8M compared to the 50% access scenario.

Conclusions: The expansion of HAART in BC has resulted in substantial decreases in morbidity and mortality as well as a reduction in new HIV diagnoses. Resulting ICERs, derived within a limited timeframe, were well within the range of societal willingness to pay for an incremental QALY gain, and were cost-saving from a societal perspective.

MOPED755
Using the community score card approach to assess the quality of HIV/AIDS service delivery in public health facilities in Uganda

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Background: The Community Score Card is a participatory community based monitoring and evaluation tool that enables citizens to assess the quality of public services including health. It is used to inform the citizens about the services they are entitled to, empowers them to monitor the quality, accessibility, availability and engage duty bearers to address concerns and gaps that may exist.

Methods: The Community Score Card approach used a phased methodology; in put tracking that involved physical observations, assessments and awarding marks using Focus Group Discussions and Key Informant Interviews, interface meetings with all stakeholders to jointly agree on marks given. The study was conducted in 12 health facilities in districts of Kikyusa, Serere and Kalangala at Health Centre III and IV levels with a total of 472 (221 Male, 251 Female) respondents.

Results: The assessment was based on the thematic areas of the National HIV/AIDS Strategic Plan HIV of Prevention, Care&Treatment, Social Support and Systems Strengthening. The key areas for assessment was quality of service delivery in terms of EMCT, HIV Counseling&Testing, Male Circumcision, blood transfusion, family planning, condom supply, ART&TB services, palliative care, nutritional services, home visits, paediatric and adolescent

Conclusions: Metrics to monitor HAART churn should be prioritized for HIV surveillance. There is an urgent need to develop clinical strategies and public health policies to improve HAART persistence, particularly among those at earlier stages of disease progression, the young, and PWID.

Monitoring and evaluation of health systems

MOPED752
Improving engagement in care and viral suppression through health systems linkages and intensive case management: preliminary findings from a multi-city implementation project

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Background: To optimize antiretroviral treatment effectiveness, health systems must respond to diverse medical and social service needs of persons living with HIV/AIDS. The aim of this study was to evaluate the effect of an intensive case management program administered across multiple agencies by the Wisconsin AIDS/HIV Program. The program was designed to provide clients with the knowledge and skills necessary to maintain care engagement and achieve sustained viral suppression, and specifically targeted 3 groups: (1) those newly-diagnosed with HIV, (2) individuals being released from prison, and (3) patients known to have HIV who have not consistently engaged in care.

Methods: This retrospective analysis compared clients enrolled in a time-limited, intensive case management intervention and propensity-matched controls selected from the Wisconsin HIV surveillance database. The study sample included 235 clients enrolled in intervention between 6/30/2013 - 6/26/2014 and a 1:1 matched control group. Engagement in care was defined as the presence of at least one HIV-specific laboratory test every 6 months since enrollment. Viral suppression was defined as a viral load ≤200 copies/mL at the time of the latest laboratory test during the follow-up period. Chi-square tests were used to assess differences between intervention and control groups.

Results: The intervention and control groups were similar with respect to median age (34 years, 28-48 years), and self-reported race/ethnic group (17.5% Black, 87.5% Latino, 3.4% Other). Compared to matched controls, a significantly higher proportion of intervention clients were engaged in care (73.5% vs. 48.3%, p<0.0001) and achieved viral suppression (76.2% vs. 35.7%, p<0.0001). A subgroup analysis comparing only newly-diagnosed clients suggested there was no significant difference in care engagement between the intervention and control groups (78.7% and 74.5%, p<0.049), however, the proportion of newly-diagnosed patients achieving viral suppression was significantly higher for intervention clients (74.5% vs. 58.5%, p<0.049).

Conclusions: Intensive case management appears to be an effective strategy for improving care engagement and viral suppression among individuals with substantial barriers to HIV care. Future studies should investigate long-term treatment outcomes after discharge from the intervention in order to assess the sustained impact of the intervention among this patient population.
HIV care. Provision of IEC materials, capacity building, rights awareness and psychosocial support services, staffing, equipment and infrastructure were assessed. Gaps revealed were drug and other supply stock outs, low staffing levels, lack of transport, absence of CTD machines, limited knowledge on patients rights, staff absenteeism, fewer consultation rooms, fewer staff houses, poor patient-health worker relationship, low uptake of family planning services and negative attitudes towards female condom use. Despite the gaps, the facilities were doing their best to serve the masses.

Conclusions: The health facilities serve the populace amidst several gaps. There is an urgent need to recruit more health workers to fill up the staffing gaps and reduce on the waiting time that patients take to see health workers and to ensure constant supplies of drugs, equipments and reagents including testing kits and condoms to reduce on frequent stock outs. Community sensitisation sessions on the national patient’s charter as well as legal and human rights should be undertaken to empower citizens.

MOPED756
Assessment of data and service quality of the national PMTCT and ART programs in Cameroon

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Background: High quality prevention of mother-to-child HIV transmission (PMTCT) and antiretroviral treatment (ART) programs are necessary for HIV epidemic control. Program data and service quality must be monitored and strengthened to ensure that programs are optimized. The U.S. Centers for Disease Control and Prevention (CDC) provided technical assistance to the Cameroonian government to conduct a data quality and service quality assessment (DQA-SQA) in a sample of facilities in the Northwest and Southwest regions of Cameroon. The purpose was to measure data and service quality and to identify areas that need quality improvement. While the CDC through the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) currently only provides support to the PMTCT program, the activity served as a baseline for the newly-supported ART program.

Methods: Eighteen sites were selected based on a high volume of HIV-positive women receiving ARVs for PMTCT. 10 sites provided ART services; and 9 sites participated in an Option B+ pilot. A site assessment tool was developed in line with national guidelines to score facilities using a standardized scale to indicate site capacity. Assessment team members were trained to use the tool, and conducted the assessment through discussions with facility staff, review of national tools, and recreation of program indicators. Immediate written feedback was provided to facility staff and PEPFAR-funded partners to highlight strengths and challenges, provide recommendations, and facilitate remediation.

Results: DQA challenges included varying indicator calculation methods, incomplete national tools, and lack of data use for program management. The SQA identified gaps in patient care and management; where over 50% of sites needed improvement or urgent remediation. Although not a representative national sample, results demonstrate data and service quality are not always concordant by program area. While the PMTCT program data and service quality correlated, the data quality and quality of services at high-volume ART sites did not. (Figure)

Conclusions: High quality data may not imply high quality services. Poor clinical documentation may impede patient care despite high quality program data. DQA-SQA methods can be used to inform strategic planning and program improvement. Synthesis of results provides context and understanding of the interaction between data and service quality.

MOPED757
M&E priority interventions: an assessment of M&E interventions that promote data quality in HIV care and treatment setting

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Background: With the global scale-up of treatment and care services, interventions to enhance data quality are inevitable. We implemented interventions to promote data quality in health facilities in Eastern Uganda including data validation, training, mentorship, financing, staff time, data quality assessment and supervision. This paper presents a before and after evaluation of these M&E strategic interventions.

Methods: STUDY DESIGN: Before-and-after evaluation of the intervention.

POPULATION: 26 study sites were randomly selected from 78 ART sites in Eastern Uganda. STUDY PERIOD: Records of 2010 (before intervention) and 2014 (after the intervention) were evaluated.

DATA COLLECTION: A standard RDQA tool was used to collect data on accuracy, completeness and timeliness of reports and other Monitoring and Evaluation (M&E) system dimensions such as structure, functions & responsibilities; use of appropriate tools; availability of data SOPs and reporting through a national system.

ANALYSIS: A report was considered accurate if the variance between the actual and reported data was less than 5%; complete if all fields filled and timely if submitted before 7th day. The M&E system dimensions was assessed using binary responses (YES/NO). A logistic regression model was fitted using SAS 9.2.

Results: Sixty percent of monthly reports were submitted by the study sites before compared to 91% after the intervention. The proportion of reports reviewed by supervisors was 51% before compared to 94% after the intervention. Compared to the period before, the odds were higher after intervention by 4.4 times (95%CI: 2.3-8.6) for an accurate report, 7.3 times (95%CI: 5.7-9.6) for a complete report and 7.3 times (95%CI: 5.7-9.6) for a timely report. Regarding the M&E dimensions, 92%(24) of sites had a well-established M&E system with defined roles and responsibilities and capable staff after intervention than before(42%). There was an increase in the proportion of sites using appropriate tools (from 60% to 89%), with SOPs (from 31% to 76%) and reporting through national system (from 61% to 100%).

Conclusions: Results in this study reveal strong evidence of strategic M&E interventions that yielded good quality data. Service providers and implementing partners need to prioritize and integrate them in HIV care and treatment services.

MOPED758
Who accesses health services earlier than the other? Early lessons from an mHealth referral system in one of the 63 districts of Zimbabwe

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Background: The mobile health (mHealth) system can be used to track and trace clients in hard-to-reach communities. Although referral systems have been in use in some resource-constrained settings[1], limited data are available on the number of days taken from date of referral to date of accessing health service. Our primary outcome of interest was number of days taken from date of referral to date of accessing services.

Methods: Three community referral facilitators, each based at a clinic, and 36 village health workers based in the community were each provided with a mobile phone to facilitate communication and data collection. Mobile phones were installed with secure templates to collect client details. Data were collected prospectively between 12 October 2014 and 8 January 2015 and analysed descriptively.

Results: Of the 56 clients, 14 (25%) were male and 42 (75%) were female. Modal age was 24 years. About. Female clients mostly accessed HIV testing (n=15), TB screening (n=10), ANC booking (n=8) and baby clinic (n=5). About 36% of male clients above 15 years (n=7) accessed TB screening only. Number of days taken to access a health service ranged from 0 to 33 days with a modal of 2 days. Clients referred for ANC or TB screening tended to delay by between 3 to 7 days. When outliers were removed from analysis (Figure 1), mean number of days was 1.25 (95% confidence interval [CI], 0.84-1.68) for male and 2.44 (95%CI, 1.69-3.20) for female.

Conclusions: Analysis of mHealth data helped to identify number of days clients take to access services. Reasons why women take relatively longer number of days than men following a referral needs to be investigated. Providing outreach services for ANC services and TB screening is recommended.
MOPED759  
Leveraging mobile technology to send high quality ARV and HIV test kit consumption reports  
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**Background:** Avoiding stock outs of ARVs and HIV rapid test kits (RTK) are a pillar of any HIV care and treatment program. In Mozambique, health facility (HF) supply chain systems often rely on hand delivery and public transport to submit consumption reports from HF, then to the district, before reaching the provincial medications depot (PMD). To strengthen this logistics reporting system, the USAID-funded Clinical HIV/AIDS Services Strengthening (CHASS-SMT) project, in collaboration with the Mozambican MOH, began using mobile phones to send reports from HF to the PMD in order to improve access to quality consumption reports submitted in a timely fashion.  

**Methods:** CHASS-SMT, in collaboration with MOH, delivered 115 mobile phones to 115 HFs with ART services. Training on how to complete consumption reports using the CommCare data management technology was provided to pharmacy technicians and the phones were programmed with data verification capabilities and sufficient network coverage to send the information to the provincial system.  

**Results:** Following the implementation of this mHealth intervention, the number of days it took for the consumables report to reach the PMD was reduced from an average of 15 to 2 days. While this represents a successful reduction in reporting timeliness, a key lesson learned was the need for IT support to provide troubleshooting for technical problems. Despite training and potential effectiveness of the program, many staff in remote areas did not have the necessary background to respond to network connection problems.  

**Conclusions:** Using simple technologies, such as mobile phones in rural areas, can be a reliable technology to strengthen supply chain reporting in resource constrained environments; however, the rollout of such programs needs to ensure sufficient maintenance, oversight and supervision. With proper support, mobile technology ensures timely reporting to help reduce ARV and RTK stock-outs by improving the process of communication between health facilities and health authorities. In addition to looking at completeness and timely reporting, continued research is necessary to measure the potential improvements this intervention had on data consistency as the CommCare reporting tool also incorporated simple validations to help users identify and correct inconsistencies.

MOPED760  
The impact of social health insurance on HIV prevention and treatment: evidence from Kenya  
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**Background:** Health systems in developing countries continue to face dwindling tax revenues, increasing healthcare costs, decreasing donor funding, and burdensome out-of-pocket payments especially for the poor. This situation is compounded by incidence and prevalence of HIV/AIDS with women disproportionately affected. Moreover, the HIV+ women continue to desire children, become pregnant, and give birth after knowing their HIV+ status. In such an environment, HIV+ women without access to effective and appropriate healthcare are likely to have lower economic productivity, experience negative health outcomes, and risk being caught in the cycle of poverty. As such Social Health Insurance (SHI) has been identified as a mechanism to enhance and diversify health financing, and provide access to healthcare. This paper adds to the literature by empirically analyzing the impact of the Kenya National Hospital Insurance Fund (NHIF) on the health outcomes of HIV+ pregnant women in Kenya.  

**Methods:** We use electronic medical records (EMS) from the Academic Model Providing Access to Healthcare (AMPATH). We estimate patient level linear and logistic regressions with institutional delivery (Yes/No) and assisted by skilled birth attendant (Yes/No) as dependent variables for 16,000 HIV+ women. To make causal estimations, we implement propensity score methods including matching and inverse probability weighting. The models include a set of controls consisting of demographic, health, and economic variables.  

**Results:** The causal estimates from matching indicate that NHIF members are 15% more likely to deliver at an institution and 14% more likely to have a skilled birth attendant at delivery. The IVW estimates also show that those with NHIF membership are 14% more likely to deliver at an institution and 20% more likely to have a skilled birth attendant at birth.  

**Conclusions:** The findings show that Kenya’s NHIF does have positive and significant effects on the health outcomes of HIV+ pregnant women enrolled in the insurance scheme. This is important for at-risk populations like HIV+ pregnant women that need access to healthcare. NHIF’s promise as it undergoes reforms is shown and the findings are informative to countries similar to Kenya that are exploring localized and sustainable mechanisms of financing HIV care that include SHI.
TUA01 Survival of the Fittest: HIV Evolution and Adaptation

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Background: Treatment of HIV infection with antiretrovirals reduces individuals’ plasma viral loads to undetectable levels and in turn decreases the risk of transmission. Despite epidemiological evidence supporting the efficacy of ‘Treatment as Prevention’, quantifying this success remains a significant challenge. Phylogenetic analysis of viral sequence data can yield crucial insights into epidemic processes, including transmission dynamics. We sought to evaluate the impact of treatment on HIV transmission rates in British Columbia (BC), Canada using phylogenetic methods.

Methods: We recovered 27,296 anonymized HIV protease and RT sequences from 7,747 HIV patients in BC from the BC Centre for Excellence in HIV/AIDS database. Sequences were annotated with: sample collection date, treatment status at sample collection, date of first antiretroviral treatment, and risk factor (intravenous drug use (IDU), men having sex with men (MSM), heterosexual (HET)). Codons associated with known drug resistance were censored from the alignment prior to tree inference. We inferred a set of 1,000 maximum likelihood phylogenetic trees. We calculated a lineage level phylogenetic branching rate for each HIV lineage in the trees, which provides an approximate measure of transmission rates. We stratified branching rates by treatment experience and risk factor. To assess the impact of treatment on onward transmission of HIV, we compared the mean HIV branching rate between treatment-experienced and treatment-naïve lineages across the BC epidemic as a whole and among risk factors.

Results: Phylogenetic branching rates were significantly lower among treatment-experienced HIV lineages relative to treatment-naïve lineages (p < 0.001), implying reduced rates of both across different risk exposure categories and different treatment regimens.

Conclusions: Our results provide independent evidence that antiretroviral HIV treatment has limited the onward transmission of HIV to new hosts. These results are based on a lineage level measure, are measured phylogenetically rather than epidemiologically, and are replicated both across different risk exposure categories and different treatment regimens.

TUA0101 Phylogenetically estimated HIV diversification rates reveal prevention of HIV-1 by antiretroviral therapy

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Conclusions: Our results provide independent evidence that antiretroviral HIV treatment has limited the onward transmission of HIV to new hosts. These results are based on a lineage level measure, are measured phylogenetically rather than epidemiologically, and are replicated both across different risk exposure categories and different treatment regimens.

TUA0102 Phenotypic properties influencing HIV-1 transmission fitness

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Background: Sexual HIV-1 infection requires penetration of the virus across a mucosal barrier and the establishment of infection in target cells. It is widely accepted that only one or a small number of HIV-1 clones is successfully transmitted from the donor to the recipient. However, little is known about the phenotypic properties of the transmitted virus and the influence the phenotype plays in the genetic bottleneck selection process. Here we evaluated possible phenotypic differences between acute and chronic HIV-1 that may effect transmission fitness.

Methods: We compared the genetic diversity of HIV-1 isolates from the female genital tract with isolates from the blood of the same donor by 454 pyrosequencing of the env region. Furthermore, we generated chimeric viruses from acute and chronic envelope genes using a yeast-based cloning strategy. The chimeric clones were then evaluated for host cell entry and receptor efficiency, sensitivity to entry inhibitors and for replication fitness in PBMCs, T cells and macrophages. Additionally we evaluated the transmission fitness across mucosal tissues by multi-virus competitions.

Results: Both, acute and chronic HIV-1 clones showed similar cell entry and receptor efficiency, sensitivity to inhibitors and replication fitness. Sequence analysis revealed that primary infection in the cervix resulted in a highly genetically diverse HIV-1 population, while only one or a few HIV-1 clones are in matched blood. Analysis of mixed competitions of acute and chronic HIV-1 env-clones in ex vivo tissue models revealed higher transmission fitness of acute isolates than chronic. We observed that higher transmission fitness was related to a reduced number of conserved N-linked glycans on the envelope of acute viruses.

Conclusions: Chronic HIV-1 isolates appear to stay and replicate in the mucosal tissue, while acute isolates are preferentially bound by tissue residing DCs/LCs and are subsequently transmitted to T cells. High levels of mannose binding proteins in tissue and lectins on epithelial cells may be responsible for a passive selection process of HIV-1 with fewer glycans for transmission due to reduced lectin binding.

TUA0103 Population-level spread of immune-driven mutations in HIV-1 polymerase during the North American epidemic

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Background: HLA-driven HIV-1 immune escape mutations that persist following transmission could gradually spread in the viral population, compromising host antiviral immunity over time. We investigate the extent and correlates of escape mutation accumulation in HIV-1 Polymerase (Pol) sequences in North America from 1979-present.

Methods: HIV-1 RNA Pol and HLA class I genotyping was performed on 338 Historic (1979-1989) and 278 Modern (2001-2011) specimens from Boston, New York, San Francisco and Vancouver. HLA-associated polymorphisms were defined according to published lists. Historic and Modern datasets were also investigated for the presence of novel HLA-associated mutations using phylogenetically-informed methods. Ancestral reconstruction of the HIV-1 epidemic founder sequence was performed using BEAST and HyPhy.

Results: The estimated HIV-1 epidemic founder sequence dated to 1969 and was near-identical to the modern subtype B consensus, suggesting no historic selective sweeps have occurred to shift the population consensus. No HLA-associated polymorphisms unique to the historic dataset were identified. Nevertheless, pairwise sequence diversity of modern HIV-1 sequences was +2.9% greater than historic sequences, with diversification predominating at HLA-associated sites (p<0.0002). N=20 published HLA-associated polymorphisms were investigated for spread over time. Overall, their median ‘background’ frequencies (in individuals lacking the restricting HLA) were 6.6% vs 16.8% in historic and modern eras respectively (p<0.0004); polymorphism frequencies in reconstructed pre-1979 ancestral sequences were also consistent with gradual spread (p<0.01). No correlation was observed between HLA allele frequency and relative spread of its associated polymorphisms (r=-0.13, p=0.8); rather, polymorphisms restricted by protective HLA alleles exhibited greater relative spread than those restricted by non-protective alleles (r=0.83, p=0.0047). Despite these overall increases, the frequency of many polymorphisms (eg: B*51-associated RT-I135T) remained consistent throughout the era. Moreover, at the whole-sequence level, the median extent of adaptation of the typical circulating modern HIV-1 Pol sequence to the average North American host remains 0%, indicating a low overall risk of acquiring HIV-1 harboring adaptations to one’s HLA profile.

Conclusions: Immune escape mutations in HIV-1 Pol have spread significantly in the population since the genesis of the North American epidemic, however these changes are unlikely to herald immediate consequences for host antiviral immunity on this continent.
TUA00104
Primary resistance against dolutegravir decreases HIV integration

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Background: Dolutegravir is an integrase inhibitor that has shown a high genetic barrier against the emergence of resistant strains. No resistance substitution has been observed in treatment-naïve individuals treated with this drug. In tissue culture experiments, we have identified the R263K resistance substitution as a signature substitution for HIV resistance against dolutegravir, an observation that was later confirmed in highly treatment-experienced individuals. Given the importance of DNA integration in the establishment of HIV persistence, we tested the ability of dolutegravir-resistant HIV strains to integrate within human DNA.

Methods: We used an Alu-mediated quantitative PCR to measure levels of integration of dolutegravir-resistant variants in primary human PBMCs. Levels of integration were normalized using the β-actin gene. These experiments were performed using subtype B and C viruses.

Results: Our results show that dolutegravir-resistant variants are impaired in their ability to integrate within human DNA. The integration levels of subtype B and C R263K variants were decreased by 30% and 40% compared to WT viruses, respectively. More importantly, the addition of several secondary substitutions failed to restore integration to a level comparable to WT and, in some cases, further lowered integration to only 20% of WT.

Conclusions: The relative inability of dolutegravir-resistant variants to integrate within human DNA may contribute to a progressive decrease in the viral reservoir of individuals who develop these substitutions.

TUA00105
HIV-1 integrase variants retarget proviral integration and are associated with disease progression

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Background: Distinct integration patterns of different retroviruses, including HIV-1, have puzzled virologists for over 20 years. A tetramer of the viral integrase (IN) assembles on the two background:

Methods: We used an Alu-mediated quantitative PCR to measure levels of integration of dolutegravir-resistant variants in primary human PBMCs. Levels of integration were normalized using the β-actin gene. These experiments were performed using subtype B and C viruses.

Results: Our results show that dolutegravir-resistant variants are impaired in their ability to integrate within human DNA. The integration levels of subtype B and C R263K variants were decreased by 30% and 40% compared to WT viruses, respectively. More importantly, the addition of several secondary substitutions failed to restore integration to a level comparable to WT and, in some cases, further lowered integration to only 20% of WT.

Conclusions: The relative inability of dolutegravir-resistant variants to integrate within human DNA may contribute to a progressive decrease in the viral reservoir of individuals who develop these substitutions.

TUA00106LB
HIV-1 specific IgG antibody levels correlate with presence of a specific HLA class II allele to impact acquisition and vaccine efficacy

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Background: The RV144 trial had a vaccine efficacy of 31% and IgG antibodies to HIV-1 Envelope (Env) amino acid positions 120-204 were identified as a predictor of decreased risk of infection. The IgG responses were binding to scaffolded Env antigen comprising the variable loops 1 and 2, flanked by partial regions of the first and second conserved domains. Since HLA class II molecules are expressed on antigen presenting cells and modulate CD4 T cell stimulation of antibody production by B cells, we tested whether HLA alleles influenced vaccine response and efficacy.

Methods: HLA-DRB1, DQB1, and DPB1 were genotyped in 760 individuals. Direct associations of 31 HLA class II alleles on Env (120-204)-specific IgG were compared using linear regression models. Interaction of HLA with IgG response to Env (120-204) was tested for an effect on acquisition by logistic regression.

Results: Higher levels of Env (120-204) IgG antibody directly correlated with the presence of DPB1*13 (P<0.002, q<0.05). Env (120-204)-specific IgG allele levels also associated with decreased risk of HIV-1 infection only in the presence of DPB1*13 (OR=0.29 per 1-SD increase, P=0.006). Both of these findings were replicated with Env antigens across multiple viral subtypes. Vaccine efficacy increased to 71% among individuals that were DPB1*13+ and had higher levels of Env (120-204)-specific IgG levels relative to the placebo. To delineate the anti-Env antibody responses in DPB1*13+ individuals, we screened overlapping peptides to Env (120-204). Frequency and magnitude of IgG response specifically to Env peptide positions 119-133, which are involved in Env binding to CD4, associated with both presence of DPB1*13 and protection from HIV-1 acquisition among individuals with a DPB1*13 allele. Further evidence that immune responses induced by vaccination in individuals carrying DPB1*13 are different from those without DPB1*13, was apparent in significant viral sequence differences specifically in infected vaccine recipients with DPB1*13.

Conclusions: DPB1*13-associated immune responses to vaccination associate with decreased risk of HIV-1 acquisition. The specific differences in vaccine-induced responses elicited by individuals with HLA-DRB1*13 should be examined to determine the mechanism of protection of the vaccine. Understanding this HLA class II restricted mechanism will enable improved HIV vaccine design.

TUA00204
Hammer and Tickle: Targeting the Virus

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Background: Nuclease-mediated gene editing in hematopoietic stem cells (HSCs) holds great promise in the cure of HIV infection, but little information is available regarding the feasibility of this approach in large animal models. To better evaluate the function of HSCs following gene editing, we have engineered cells with disrupted CCR5 alleles and assessed engraftment following autologous transplant in the pigtailed macaque, M. nemestrina. Disrupted CCR5 alleles in this model should directly protect against infection with simian/human immunodeficiency virus (SHIV). We are evaluating the extent to which CRISPR/Cas9 mediated gene editing in HSCs is capable of imparting function in macaque models. Since these primate cells, and stem cell-derived lymphoid and myeloid cells, are measured ex vivo and in vivo. Animals are challenged with SHIV
Methods: T-lymphocytes, macrophages, and brain microglia, with no adverse impact on the host cells. 

Results: CRISPR targeting experiments yield up to 60% gene disruption in CD4+ cells ex vivo, translating to approximately 5% steady state bulk disruption in vivo. Gene-disrupted cells demonstrate long-term, multilineage engrafment in macaques, including comparable levels of disruption in CD40, CD207, and granulocyte subsets. We also observe bacillicis disruption of CRIS in colony forming assays. Importantly, this approach is equally feasible in SHIV-naive and in SHIV-infected, -RTD-suppressed animals. During robust SHIV replication, our preliminary data suggest that CCR5-deleted cells undergo positive selection in vivo.

Conclusions: This is the first demonstration of successful long-term multilineage engrafment of 274-infected, CRISPR-deleted HSCs in a NHP transplantation model. Our strategy results in robust levels of target gene disruption in vivo, yet does not impair HSC engrafment or differentiation. CCR5-deleted cells can undergo positive selection following challenge with SHIV. Our model enables the evaluation of novel therapeutic approaches not only in the context of acute HIV exposure, but also in the clinically relevant setting of pre-existing latent HIV infection.

TUA0203
Crispr/Cas9 gene editing eradicates latent and protects cells against new HIV-1 infection

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Background: A sterilizing cure for HIV/AIDS requires a strategy that eliminates all or at least some critical regions of the HIV-1 genome including the promoter positioned within the 5’ LTR of the viral genome from cells serving as a stable reservoir for HIV-1, i.e. resting CD4+ T cells. This is the first demonstration of successful long-term multilineage engrafment of 274-infected, CRISPR-deleted HSCs in a NHP transplantation model. Our strategy results in robust levels of target gene disruption in vivo, yet does not impair HSC engrafment or differentiation. CCR5-deleted cells can undergo positive selection following challenge with SHIV. Our model enables the evaluation of novel therapeutic approaches not only in the context of acute HIV exposure, but also in the clinically relevant setting of pre-existing latent HIV infection.

Methods: We have tailored CRISPR/Cas9 gene editing by bioinformatic screening, Surveyor assay, whole genome sequencing, and successfully developed a series of guide RNAs (gRNAs) that, in complex with Cas9 nuclease, effectively and safely eliminate integrated proviral DNA from chromosome 16.

Results: We demonstrated inactivation of HIV-1 gene expression and repulsion in latently infected T-lymphocytes and promonocytic human cell lines as well as microglial cells upon excising the proviral DNA fragment corresponding to the entire coding sequence of HIV-1 spanning the 5’ to 3’ LTRs from the host chromosome by the CRISPR/Cas9 approach. Further, we demonstrate that the presence of LTR-specific multiplex of guide RNAs in cells expressing Cas9 acts as an efficient inhibitor blocking new HIV-1 infection.

Conclusions: Our findings suggest that the strategy involving the newly developed CRISPR/Cas9 serves as a promising platform that can be advanced for eradication of HIV-1 and a cure for AIDS.

TUA0204LB
Investigating the role of the immune checkpoint receptor TIGIT in T cells during HIV disease progression and as a target for immune restoration

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Background: HIV infection induces a series of phenotypic and functional changes to T cells that eventually results in a state of T cell exhaustion and failure to control viral replication. T-cell-Ilg- and ITM-domain (TIGIT) is a recently described negative checkpoint receptor expanded on CD8+ T cells during LCMV infection in mice and inhibits anti-viral effector CD8+ T cell activity. We hypothesized that during progressive HIV infection, TIGIT surface expression will mark an expanded population of dysfunctional T cells, and that novel monoclonal antibodies targeting TIGIT would restore anti-HIV-specific T cell responses.

Methods: Surface expression of TIGIT and PD-1 on T cells were measured by flow cytometry from 103 HIV-infected participants [non-controllers (n=20), elite controllers (n=20), antiretroviral (ART) suppressed (n=39), acutely infected (n=24)] and 20 age and gender matched HIV-1 uninfected controls. Quantified cell associated HIV (CA-HIV) DNA and RNA from purified CD4+ T cells. Functional characterization of TIGIT+ T cells was performed and ex vivo HIV-specific cytolytic and proliferative responses were assessed in the presence of mononuclear antibodies (mAbs) targeting TIGIT and/or PD-1 pathways (anti-TIGIT mAb and anti-PD-L1 mAb).

Results: In controls a median of 28.95% of CD8+ T cells were TIGIT+ (IQR 24.43,39.15). In comparison, we found a significant expansion of TIGIT+CD8+ T cells during chronic (median 57.1%, IQR 42.6,63.45; p< 0.0001) and a non-significant trend in acute HIV infection (40.40%, 28.3,47.8; p=0.08). TIGIT expression remained elevated despite viral suppression and associated with CD4+ CD8+ HIV DNA. TIGIT and PD-L1+ T cells inversely correlated with CD4 count (p=0.0016, r=-0.658; p=0.0024, r=-0.385 respectively). TIGIT was expressed on >50% CD4+ HIV specific CA-HIV+ T cells, however TIGIT+ T cells failed to produce cytokines in response to HIV antigens. Single blockade of TIGIT led to a significant increase of interferon γ response to HIV Gag compared to no blockade (p=0.027). Co-blockade of TIGIT and PD-L1 lead to greater restoration of HIV-specific CD8+ T cell proliferative responses (4.10%, IQR 1.46,22.28) than single blockade of TIGIT (3.47, IQR 1.11,10.08; p=0.0078) or PD-L1 (3.945%, IQR 1.15,17.53; p=0.039).

Conclusions: These findings identify TIGIT as a novel marker of dysfunctional HIV-specific T cells and suggest TIGIT along with other checkpoint receptors may be novel curative HIV targets.

TUA0205LB
Estrogen blocks HIV re-emergence from latency and points to gender-specific differences in HIV reservoirs

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Background: Unbiased shRNA library screens have been used to identify novel genes and pathways that are required to maintain HIV latency and play an essential role in HIV transcription. One of the most prominent and robust “hits” was the estrogen receptor type 1 (ESR-1).

Methods: The activities of ESR-1 agonists, antagonists and estrogen on proproliferation were studied in transformed and primary cell models of latency and in patient cells.

Results: Specific antagonists of ESR-1, such as Tamoxifen and Fulvestrant, are weak pro- viral activators but sensitise latency infected cells to very low doses of the proactivators TNFα/IFN-β (IFN-β inducer) and SAHA (HDAC inhibitor). By contrast, a selective ESR-1 agonist, propylpyrazoletriol (PPT) and the broader spectrum ESR-1 agonist diethylstilbestrol, strongly suppress both TNF-α and SAHA reactivation. In contrast to the ESR-1 antagonists, ESR-2 antagonists were not effective inducers of HIV expression in cell models. Co-activator 3 (SRC-3) is a downstream mediator of ESR-1, which also was identified as a hit in the shRNA screen. Blockade of SRC-3 by its inhibitor Gossypol also induces latent proviruses. Consistent with these results, specific knock-down of ESR-1 in Jurkat 2D10 cells with shRNA constitutively re-activates the latent provirus. In the HAART-treated patient samples there was a modest increase of spiked HIV env RNA when resting memory cells were treated with the ESR antagonists Fulvestrant or Tamoxifen alone. Provoidation reactivation by ESR antagonists was synergistically increased by SAHA. By contrast, β-Estradiol at concentrations in the physiological range led to dramatic reductions in proviral reactivation efficiencies. This is consistent with earlier observations that high levels of β-Estradiol can block HIV replication.
TUAB01 ART: New Drugs, New Strategies

**TUAB0101**

Atazanavir/ritonavir 200/100 mg is non-inferior to atazanavir/ritonavir 300/100 mg in virologic suppressed HIV-infected Thai adults: a multicentre, randomized, open-label trial - LASA

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S. Banchongkit5, V. Khinboonayen5, S. Mekwattananawat1, S. Nimivite5, S. Jirajivay5, W. Prasitsakkit6, W. Munakul5, S. Bhaveecheep5, S. Chalvotch5, P. Phunruphaik5

D.A. Cooper5, T. Ampompang5, S.J. Keri6, K. Eamer5, K. Ruxurungham5, LASA Study Group

**Background:** Asian HIV-infected patients generally experience higher systemic exposure to HIV protease inhibitors (PIs). We compared the efficacy and safety of switching to lower vs standard dose of atazanavir/ritonavir (ATV/r) in virologically suppressed second-line patients.

**Methods:** Patients with plasma HIV-1 RNA(<50copies/ml, ALT<200 IUL, and creatinine clearance (CrCl) <60mL/min while using PI-based regimens were randomized to ATV/r 200/100mg (A200) vs ATV/r 300/100mg (A300) once daily with 2NRTIs at 14 sites in Thailand. Patients were followed every 12 weeks until week 48. Virological failure was defined as confirmed vPVL >200copies/ml. Patients in ATV200 with VF resumed standard dose PI-based regimens. Treatment groups were regarded as non-inferior if the lower limit of the 95% confidence interval (95%CI) for the difference in VF was above -10% in an intention-to-treat (ITT) analysis at 48 weeks.

**Results:** 559 patients were randomized (ATV200; N=279 vs ATV300; N=280). At baseline, 85% used lopinavir/ritonavir, mean age was 42 years, body weight was 59 kg, CD4 was 539 cells/mm^3, and total bilirubin was 0.85 mg/dL. At week 48, by ITT, the proportion of patients in ATV200 vs ATV300 with pVL<200copies/mL were 98.5% vs 99.2% [-0.72, -2.6 to 1.16]. Only one ATV200 recipient developed major resistance (I50L) to ATV.

**Conclusions:** Despite a favorable efficacy and safety profile, TDF-based regimens may be associated with renal toxicity and reduced bone mineral density (BMD). TAF is a novel tenofovir prodrug in which TFV plasma levels are 90% lower than seen with TDF, thereby reducing off-target side effects. Week 48 data in patients switching to a once-daily fixed dose combination regimen containing elvitegravir 85mg, coformycin 150mg, emtricitabine 200mg, and TAF 10mg (E/C/TAF) are described.

**Methods:** Virologically suppressed adults (HIV-1 RNA < 50 copies/ml) with normal renal function taking one of 4 different TDF-based regimens for at least 45 weeks were randomized 2:1 to receive E/C/TAF/ or to retain their prior TDF-based regimen. Following randomization, all treatments were open-label.

**Results:** Of 1196 patients completing at least 48 weeks of treatment, 799 received E/C/ TAF and 397 received their prior TDF regimen: E/C/TDF, 31.9%; EFV/FTC/TDF, 26.1%; ATV/RTV + FTC/TDF, 26.8%; ATV/COBI + FTC/TDF, 15.0%. Virologic success <50 copies/ml occurred in 96.0% on E/C/TAF and 92.9% on FTC/TDF + 3rd Agent (weighted difference: 2.7% CI: -0.3% to +5.6%), with virologic failure in 1.1% and 1.3% of patients, respectively. General safety was similar between the arms. The mean percent change (SD) in hip BMD was +1.95% (3.0) for E/C/TAF and -0.14% (3.0) for FTC/TDF + 3rd Agent (p<0.001); the mean percent change (SD) in spine bone BMD was +1.86% (3.1) for E/C/TAF and -0.11% (3.7) for FTC/TDF + 3rd Agent (p<0.001). There were no cases of Fanconi Syndrome on E/C/TAF and one case on FTC/TDF + 3rd Agent. For patients on either a COBI or RTV boosted regimen prior to randomization, the estimated GFR increased 1.8 mL/min for E/C/TAF and decreased 3.7 mL/min for FTC/TDF + 3rd Agent (p<0.001). As shown in the table, multiple measures of quantitative proteinuria, including tubular proteinuria, had statistically significant improvements for patients switching to E/C/TAF as compared with those retaining their prior TDF-based regimen.

**TUAB0102**

Switching from a tenofovir disopiroxyl fumurate (TDF)-based regimen to a tenofovir alafenamide (TAF)-based regimen: data in virologically suppressed adults through 48 weeks of treatment


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**Background:** Despite a favorable efficacy and safety profile, TDF-based regimens may be associated with renal toxicity and reduced bone mineral density (BMD). TAF is a novel tenofovir prodrug in which TFV plasma levels are 90% lower than seen with TDF, thereby reducing off-target side effects. Week 48 data in patients switching to a once-daily fixed dose combination regimen containing elvitegravir 85mg, coformycin 150mg, emtricitabine 200mg, and TAF 10mg (E/C/TAF) are described.

**Methods:** Virologically suppressed adults (HIV-1 RNA < 50 copies/ml) with normal renal function taking one of 4 different TDF-based regimens for at least 45 weeks were randomized 2:1 to receive E/C/TAF/ or to retain their prior TDF-based regimen. Following randomization, all treatments were open-label.

**Results:** Of 1196 patients completing at least 48 weeks of treatment, 799 received E/C/TAF and 397 received their prior TDF regimen: E/C/TDF, 31.9%; EFV/FTC/TDF, 26.1%; ATV/RTV + FTC/TDF, 26.8%; ATV/COBI + FTC/TDF, 15.0%. Virologic success <50 copies/ml occurred in 96.0% on E/C/TAF and 92.9% on FTC/TDF + 3rd Agent (weighted difference: 2.7% CI: -0.3% to +5.6%), with virologic failure in 1.1% and 1.3% of patients, respectively. General safety was similar between the arms. The mean percent change (SD) in hip BMD was +1.95% (3.0) for E/C/TAF and -0.14% (3.0) for FTC/TDF + 3rd Agent (p<0.001); the mean percent change (SD) in spine bone BMD was +1.86% (3.1) for E/C/TAF and -0.11% (3.7) for FTC/TDF + 3rd Agent (p<0.001). There were no cases of Fanconi Syndrome on E/C/TAF and one case on FTC/TDF + 3rd Agent. For patients on either a COBI or RTV boosted regimen prior to randomization, the estimated GFR increased 1.8 mL/min for E/C/TAF and decreased 3.7 mL/min for FTC/TDF + 3rd Agent (p<0.001). As shown in the table, multiple measures of quantitative proteinuria, including tubular proteinuria, had statistically significant improvements for patients switching to E/C/TAF as compared with those retaining their prior TDF-based regimen.

<table>
<thead>
<tr>
<th>Median % Change from Baseline to Week 48</th>
<th>E/C/TAF</th>
<th>FTC/TDF + 3rd Agent</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine Protein: Creatinine (UPCR)</td>
<td>-18.5%</td>
<td>+9.4%</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Urine Albumin: Creatinine (UCR)</td>
<td>-18.4%</td>
<td>+5.3%</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Retinol Binding Protein: Creatinine (RBP-CR)</td>
<td>-32.9%</td>
<td>+15.7%</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>Beta-2-Microglobulin: Creatinine (B2MG/CR)</td>
<td>-49.2%</td>
<td>+14.4%</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

**Conclusions:** These 48 week data demonstrate that patients who switch from a TDF-based regimen to E/C/TAF maintain high efficacy, have statistically significant increases in BMD and have statistically significant improvements in multiple tests of renal function, as compared with patients remaining on their prior TDF-based regimen.
**TUAB0103**

**Subjects with renal impairment switching from tenofovir disoproxil fumarate to tenofovir alafenamide have improved renal and bone safety through 48 weeks**


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**Background:** Tenofovir (TFV) is renally eliminated, and the produg, tenofovir disoproxil fumarate (TDF) has been associated with renal toxicity and reduced bone mineral density (BMD). Tenofovir alafenamide (TAF) is a novel produg of tenofovir (TFV) that results in 90% lower plasma TFV levels as compared to TDF. The safety and efficacy of a once-daily tablet regimen of efavirenz, cobicistat, emtricitabine, and TAF (E/C/F/TAF) was assessed in HIV-1 infected patients with mild to moderate renal impairment.

**Methods:** Virologically suppressed adults with stable renal impairment (eGFR, 30 to 69 mL/min) had their treatment switched from both TDF- and non-TDF-containing regimens to open-label E/C/F/TAF. Week 48 safety data by pre-switch TDF use are presented.

**Results:** Of 242 subjects switched to E/C/F/TAF [mean age 58 years (range: 24 - 82)], 18% Black, 39% HTN, and 14% DM] 158 subjects (65%) were taking TDF-containing regimens prior to switch. At Week 48, the median (Q1, Q3) change from baseline for eGFR was +0.2 (-5.8, 6.3) mL/min ([p=0.81] and for eGFR-cystatin C was +2.7 (-6.2, 14.1) mL/min.[73m:0.003]. The following measures of renal tubular function improved significantly (p<0.001 for all) for subjects switching from TDF-containing regimens to E/C/F/TAF: quantified proteinuria (UPCR, median [Q1, Q3] % change; -55 [-70, -28], albuminuria (UACR, median [Q1, Q3] % change; -61 [-81, -27], retinol binding protein (RBP-Cr, median [Q1, Q3] % change; -82 [-96, -55]), and beta-2-microglobulin (β-2-Mg:Cr, median [Q1, Q3] % change; -89 [-97, -41]). 10% of patients demonstrated a clinically significant increase in proteinuria (UACR > 20 mg/g) and albuminuria (UACR ≥ 30 mg/g) decreased from 45% to 13% and from 56% to 22%, respectively. Significant increase in mean % change in hip (+1.29%) and spine (+2.60%) BMD were observed at 48 weeks (p<0.001 for both). Subjects taking non-TDF based regimens pre-switch (n=84) had no significant changes from baseline of renal function or BMD.

**Conclusions:** Subjects with mild and moderate renal impairment (eGFR 30 to 69 mL/min) who switched from TDF-containing regimens to once daily single-tablet E/C/F/TAF experienced improvements in multiple assessments of renal and bone safety through 48 weeks. These data support the safety of E/C/F/TAF in patients with impaired renal function.

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**TUAB0104**

**Efficacy and safety of doravirine 100mg QD vs efavirenz 600mg QD with TDF/FTC in ART-naive HIV-infected patients: week 24 results**


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**Background:** Doravirine (DOR), an investigational NNRTI with a novel resistance profile, was compared with efavirenz (EFV) in a double-blind, randomized, 2-part study in ART-naive HIV-infected patients who also received tenofovir/emtricitabine (TDF/FTC). In Part 1 (dose selection) DOR at 25, 50, 100 and 200 mg QD showed rates of virologic suppression similar to EFV 600mg QD. DOR 100mg was selected for ongoing evaluation. Part 2 enrolled additional patients to receive DOR 100mg or EFV. Using data from Parts 1+2 combined, DOR 100mg showed significantly fewer CNS AEs than EFV at week 8.

**Methods:** Week 24 efficacy and safety results were analyzed for all patients who received DOR 100mg or EFV (Part 1 [n=44 per group] and Part 2 [n=66 per group] combined). Patients were stratified at randomization by screening RNA ≤ or >100,000 copies/mL. Primary endpoints were the proportion of patients with HIV RNA < 40 c/mL (efficacy) and the proportion of patients with pre-specified CNS events (safety).

**Results:** Of the 108 patients randomized and treated per group, mean baseline RNA was 4.6 log10 c/mL, in both the DOR and EFV groups, and mean CD4 counts were 432 and 448 cells/mm3, respectively. Discontinuations in the DOR and EFV groups, respectively, were 4.6% and 12.0%.

**Conclusions:** DOR was well tolerated and superior to EFV at week 24, in particular for treatment-naive patients with mild to moderate renal impairment.

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**TUAB0105**

**Raltegravir for prevention of mother-to-child transmission of HIV**

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**Background:** Raltegravir (RAL), though currently category C in pregnancy, and not recommended for use in newborns, has been used in exceptional cases for prevention of mother-to-child-transmission (PMTCT). We report on the outcomes of 14 infants exposed in utero to RAL, and the first newborn to be treated with RAL for 6 weeks for PMTCT.

**Methods:** Infants born to mothers treated with RAL during pregnancy from the Centre Maternel et Infantile sur le Sida (CMS) mother-child cohort between 2010 and 2014 were included in the study. RAL levels were tested in the first available stored plasma sample after birth, and in the treated newborn, therapeutic drug monitoring was done at weekly intervals.

**Results:** In RAL-exposed infants, RAL was given to mothers at standard dosing of 400 mg BID, started at a mean GA of 30 weeks (range pre-conception-37.5 weeks). Indications for RAL included drug resistance and/or detectable viral load in the third trimester. Mean GA was 38.5 weeks (± 1.76), and mean birthweight was 2020 (± 540). There were no clinical adverse events noted among RAL-exposed infants (mean follow-up time 119 weeks, range 48-144), and all were confirmed HIV negative. RAL levels tested in two exposed newborns at 16 and 30 hours of life were detectable at 0.9345 mg/L and 0.0381 mg/L, respectively and un detectable in 6 other infants at days 4-14. RAL granules for suspension (Merck, special access) were obtained for prophylaxis of a term newborn (39 weeks GA) from a mother with multidrug-resistant virus, and started at 1.5 mg/kg BID, along with zidovudine and lamivudine at standard doses. RAL levels were consistently above the target trough for treatment (0.02 mg/L) (Table 1) for the duration of therapy. RAL was well tolerated and at follow-up, the infant was confirmed HIV negative.
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IUAB0106LB
Second-generation HIV-1 maturation inhibitor BMS-955176: antiviral activity and safety with atazanavir +/- ritonavir

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Backgrounds: BMS-955176 is a second-generation HIV-1 maturation inhibitor that targets the HIV Gag protein, inhibiting the last protease cleavage event between capsid protein p24 and spacer peptide 1, resulting in the release of immature, non-infectious virions. Ten days of BMS-955176 monotherapy resulted in maximum median declines in HIV-1 RNA that plateaued at ~1.84 log10 c/mL at doses between 40mg and 120mg once daily (QD). Two drug combination studies in vitro demonstrated that BMS-955176 + atazanavir (ATV) had an additive effect. Due to the proximity of their sites of inhibition in the virus life cycle and the potential for synergy, we assessed the antiviral activity and safety of BMS-955176 with ATV+ritonavir (RTV) for 28 days in HIV-1-infected subjects.

In addition, this combination is being further evaluated to potentially serve as a part of a booster-sparing and nucleoside/sparing strategy.

Methods: AI468002 (NCT01803074) was a Phase 2a, randomized, open-label, multiple-dose, 4-arm, flexible design study in HIV-1-infected subjects. Subjects were randomly assigned in a 2:2:2:1 ratio to four treatment groups: BMS-955176 40mg+ATV 400mg; BMS-955176 40mg+ATV 300mg+RTV 100mg; BMS-955176 80mg+ATV 400mg; and a standard-of-care (SOC) control of tenofovir disoproxil fumarate 300mg+emtricitabine 200mg+ritonavir 400mg (fixed-dose combination)+ATV 300mg+RTV 100mg.

Results: Median change in HIV-1 RNA at Day 29 was -1.66, -1.19, -2.18, and -2.22 log10 c/mL, for BMS-955176 40mg+ATV 400mg; BMS-955176 40mg+ATV 300mg+RTV 100mg; BMS-955176 80mg+ATV 400mg; and a standard-of-care (SOC) control of tenofovir disoproxil fumarate 300mg+emtricitabine 200mg (fixed-dose combination)+ATV 300mg+RTV 100mg, respectively (Table, Figure). There were no deaths, serious adverse events (SAEs), or AEs leading to discontinuation. Furthermore, the median bilirubin level was below the upper limit of normal for subjects receiving unboosted ATV with BMS-955176, in contrast to the level observed for subjects receiving BMS-955176 40mg+ATV+RTV or SOC.

Conclusions: In this study, BMS-955176 80mg+ATV and 40mg+ATV+RTV had similar maximum median declines in HIV-1 RNA compared with the SOC control. BMS-955176 with ATV+RTV was generally well tolerated. A Phase 2b study investigating BMS-955176 in a booster-sparing and nucleoside/sparing regimen in treatment-experienced patients will begin in Q2 2015.

TUAB02 HCV: The Good News Continues

TUAB0201
A longitudinal analysis of liver fibrosis progression among NNRTI and PI users in the Canadian coinfection cohort study

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Background: Both protease inhibitors (PI) and non-nucleoside reverse transcriptase inhibitors (NNRTI) have been associated with acute hepatotoxicity, but their long-term effect on liver fibrosis remains uncertain. We explored rates of change in liver fibrosis as measured by the aspartate-to-platelet ratio index (APRI) among HIV/hepatitis C (HCV) co-infected users of modern PI- or NNRTI-based regimens.

Methods: Data from a Canadian prospective multicentre cohort were analysed for 397 HCV PCR+ persons who initiated antiretroviral therapy in or after 2000, with regimens at cohort entry comprised of a backbone of either Tenofovir/Emtricitabine or Adefovir/Lamivudine with a PI or NNRTI as the anchor agent. The natural logarithm of the APRI score was the outcome of interest. Three multivariate linear regression analyses with generalized estimating equations were performed: Analysis 1 (intention-to-treat) used baseline exposure to PI or NNRTI; analysis 2 (per protocol) was restricted to persons with a viral load under 1000 copies/ml and censored when the class of anchor agent was changed; analysis 3 (as treated) allowed for changes in the class of anchor agent during follow-up.

Results: At cohort entry, 74% of participants were male, the median age was 44 years and 56% had used alcohol in the past six months. Therapy was started a median of 1.9 years before cohort entry (IQR: 0.3, 5.0), 70% used a PI and 69% were on a backbone of Tenofovir/Emtricitabine. PI use was associated with a median increase in APRI per 5 years of 16% (95% CI: 3%, 30%) in Analysis 1, 16% (95% CI: 0%, 32%) in Analysis 2 and 13% (95% CI: -1%, 27%) in Analysis 3. NNRTI use was not significantly associated with change in APRI in any of the three analyses, as shown in the table.

<table>
<thead>
<tr>
<th>Analysis</th>
<th>APRI score at cohort entry, Median (IQR)</th>
<th>PI users (APRI units/5 years), Exp(β) (95% CI)</th>
<th>NNRTI users (APRI units/5 years), Exp(β) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Intention-to-treat</td>
<td>0.63 (0.39-1.03)</td>
<td>1.09 (1.03, 1.13)</td>
<td>1.07 (0.89, 1.24)</td>
</tr>
<tr>
<td>2. Per protocol</td>
<td>0.60 (0.39-1.22)</td>
<td>1.13 (1.00, 1.32)</td>
<td>1.09 (0.93, 1.25)</td>
</tr>
<tr>
<td>3. As treated</td>
<td>0.63 (0.39-1.03)</td>
<td>1.13 (0.99, 1.27)</td>
<td>1.09 (0.93, 1.25)</td>
</tr>
</tbody>
</table>

*Multiple median change in APRI per 5 years*

Conclusions: PI use seems to be associated with a faster progression of liver fibrosis, as measured by the median change in APRI score over five years. The consistency of estimates across the three analyses suggests that this is not the result of the type of patients using PI-based regimens, although we could not account for all patient characteristics influencing the choice of an anchor agent.
TUAB0202
Ledipasvir/sofosbuvir for 12 weeks in patients co-infected with HCV and HIV-1

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Background: Highly HIV co-infection was considered a negative predictor of HCV response to treatment with interferon-based regimens (IFN/RBV). For sofosbuvir-based regimens, HIV patients may benefit from treatment with Ledipasvir/sofosbuvir (LDV/SOF) in HCV genotype 1 or 4 patients co-infected with HIV-1 in the Phase 3/ION-4 study.

Methods: HCV treatment naive and experienced HIV co-infected patients on stable, approved antiretroviral (ARV) regimens were enrolled and received LDV/SOF (90mg/400mg) once daily for 12 weeks. Patients with compensated cirrhosis were eligible. Permitted concomitant ARVs included tenofovir and entecavir (TDF/FTC) with ritonavir-boosted (PTV/r) elvitegravir (EVI) or ritonavir-boosted ritonavir (RPV). Safety evaluations included adverse event (AE) and standard laboratory parameter monitoring in addition to enhanced renal toxicity monitoring, CD4 count and HIV-1 RNA levels. The primary efficacy endpoint was SVR12.

Results: 353 patients with GT1a (75%), GT1b (23%) and GT2 (4%) were enrolled; 82% were male, 61% were white, mean age was 52 years (range 26-72), mean baseline HCV RNA was 6.7 log10 IU/mL (range 4.1-7.8), median baseline CD4 count was 962 cells/µL (Q1 = 469, Q3 = 1833), 20% had cirrhosis, 24% were IL28B CC genotype and 55% did not respond to prior HCV treatment. Patients were taking EVI (45%) or RPV (44%) or both (9%). The table shows SVR12 by ARV regimen. Overall, the SVR12 rate was 96% (320/335); 2 patients had treatment virologic failure likely due to non-compliance and 1 had virologic relapse after discontinuing treatment. SVR12 was similar among naïve (94%) and experienced (97%) patients. No patient had treatment failure of hepatitis C. No significant lab abnormalities were observed.

Conclusions: The IFN-free, RBV-free, single tablet regimen of LDV/SOF administered once daily for 12 weeks is highly effective and well tolerated in treatment-naive and experienced, genotype 1 or 4 HCV-infected patients with HIV-1 co-infection, including those with cirrhosis.

TUAB0203
High SVR rates in HCV/HIV-1 co-infected patients regardless of baseline characteristics

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Methods: The ledipasvir/sofosbuvir (LDV/SOF) regimen of ombitasvir (OBV), paritaprevir (PTV) and ritonavir-boosted ritonavir (RPV) with dasabuvir (DSV) achieved high rates of SVR12 regardless of baseline host, viral and disease characteristics whether treated with 12 or 24 weeks of therapy.

Results: SVR12 rates. The regimen was well tolerated with no discontinuation due to adverse event or protocol violation.

Conclusions: SVR12 rates by baseline characteristic, n/N (%)

TUAB0204
Liver fibrosis regression after anti HCV therapy and the rate of death, liver-related death, liver-related complications, and hospital admissions in HIV/HCV co-infected patients with cirrhosis

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Background: There are few data about the clinical outcome of hepatitis C (HCV)/HIV coinfected patients with liver cirrhosis after therapy, considering the possibility of fibrosis regression (FR) and plasma HIV-1 RNA suppression while receiving a stable atazanavir- or rifampin-inclusive antiretroviral (ART) regimen.

Methods: Study-three patients were enrolled, of whom 92% were male, 24% black race, 15% with compensated cirrhosis, and 16% with a prior null response to pegIFN/RBV treatment. Two patients in the 12-week treatment group (1 withdrawn consent, 1 HIV relapse), and 3 in the 24-week treatment group (1 on-treatment virologic breakthrough, 2 post-treatment HCV re-infections) did not achieve SVR12. The patients with on-treatment breakthrough and relapse were both genotype 1a-infected with prior null response to pegIFN/RBV and had F4 fibrosis (cirrhosis). High SVR12 rates were achieved in patients with historically difficult-to-cure characteristics including those with IL28B non-CC genotype, high viral load, prior treatment failure, and advanced liver disease (Table). Lower baseline CD4+ T-cell counts did not negatively affect SVR12 rates. The regimen was well tolerated with no discontinuation due to adverse event or protocol violation.

Conclusions: In HCV genotype 1 patients co-infected with HIV-1, OBV/PTV/r + DSV + RBV achieved high rates of SVR12 regardless of baseline host, viral, and disease characteristics whether treated with 12 or 24 weeks of therapy.
Background: Worldwide approximately 7 million people are co-infected with HIV/hepatitis C (HCV). The most common risk factor for co-infection is injection drug use. HCV treatments have evolved at an unprecedented speed; Sofosburvir (SOF) and Simpeprevir (SIM) are among the latest DAAs approved for use. However clinical trials conducted with these agents have not been generalizable to the HIV-HCV patients in Canada and caution should be used when translating trial results in the real world. C-EDGE Co-infection is an on-going phase-III study evaluating GZR/EBR among treatment-naïve, HIV/HCV co-infected patients with GT 1, 4, or 6.

Methods: Enrolled patients were on a stable antiretroviral (ARV) regimen (tenofovir or abacavir, and lamivudine or emtricitabine; and either raltegravir, dolutegravir or rilpivirine) with a CD4 >200 cells/mm³ at last visit; 899 (66%) infected with HCV genotype 1 and 887 (84%) were infected with HCV (RNA+) at last visit; 699 (66%) infected with HCV genotype 1 and 887 (84%) participants in the Canadian Co-Infection Cohort (CCC), a prospective cohort following 1383 co-infected patients with compensated cirrhosis who achieve SVR, and it is associated with the highest reduction of death of any cause, liver-related mortality, liver-related complications, and hospital admissions.

Conclusion: Fibrosis regression is frequent after ant-hCV therapy in HCV co-infected patients with compensated cirrhosis who achieve SVR, and it is associated with the highest reduction of death of any cause, liver-related mortality, liver-related complications, and hospital admissions.

**Conclusions:** Limited population level data makes it difficult to examine external validity of clinical trials. However using data from the CCC we have illustrated that results obtained from clinical trials are not generalizable to the HIV-HCV patients in Canada and caution should be used when translating trial results in the real world.

**TUAB0206L**

**High efficacy of grazoprevir/elbasvir in HCV genotype 1, 4, and 6-infected patients with HIV coinfection: the phase 3 C-EDGE co-infection study**


**Background:** The fixed-dose combination of grazoprevir (GZR, MK-5172, 100mg, an NS3/4 protease inhibitor/elbasvir (EBR, MK-8742, 50mg, an NS5A inhibitor), an interferon-free, ribavirin-free, once-daily tablet has shown robust efficacy and safety in diverse populations. C-EDGE Co-infection is an on-going phase-III study evaluating GZR/EBR among treatment-naïve, HIV/HCV co-infected patients with GT 1, 4, or 6.

**Methods:** 218 patients were enrolled; 211 had suppressed HIV viremia, 7 were ARV-naïve. In the Full Analysis Set population, SVR12 was achieved by 207/218 (95%) patients, including 35/35 (100%) patients with cirrhosis (Figure 1). Of the 11 non-SVR12 patients, 4 failed for reasons other than virologic failure and 7 patients met criteria for virologic failure. Phylogenetic analysis was performed to distinguish relapse from reinfection.

**Conclusions:** A 12-week regimen of GZR/EBR FDC was highly effective among HIV/HCV co-infected patients with GT1, 4 or 6 infection, with a favorable safety profile. SVR was high across all patient subgroups including African-Americans and those with cirrhosis.

<table>
<thead>
<tr>
<th>Exclusion Criteria (exclusive)</th>
<th>No (%) among Genotypes 1</th>
<th>No (%) among Genotypes 1, 2 &amp; 3</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific cART Regimens*</td>
<td>380 (54)</td>
<td>484 (55)</td>
<td></td>
</tr>
<tr>
<td>Active drug abuse within 12 months (excluding marijuana use)</td>
<td>320 (46)</td>
<td>402 (45)</td>
<td></td>
</tr>
<tr>
<td>HIV VL&gt;50 copies/mL</td>
<td>175 (25)</td>
<td>225 (25)</td>
<td></td>
</tr>
<tr>
<td>HBA1c&gt;15%</td>
<td>171 (24)</td>
<td>217 (24)</td>
<td></td>
</tr>
<tr>
<td>APRI** of &lt;1 or ≥2</td>
<td>129 (18)</td>
<td>171 (19)</td>
<td></td>
</tr>
<tr>
<td>CD4 T-cell count &lt;200 cells/mm³</td>
<td>106 (15)</td>
<td>136 (15)</td>
<td></td>
</tr>
<tr>
<td>Decompensated liver disease</td>
<td>23 (3)</td>
<td>27 (3)</td>
<td></td>
</tr>
</tbody>
</table>

* SOF trial: entecavir/tenofovir plus azatavir/rilpivirine; or darunavir/rilpivirine; elavir/rilpivirine. SIM trial: excluded all boosted PIs and allowed only raltegravir, salsula and ribavirine.
** Aspartate aminotransferase/platlet ratio index (APRI) <1 defined as non-cirrhotic or ≥2 defined as cirrhotic based on SOF trial.

<table>
<thead>
<tr>
<th>Table 1: Exclusion Criteria &amp; Inclusion Criteria</th>
<th>All Patients (N=128)</th>
<th>GT1a (N=144)</th>
<th>GT4 (n=144)</th>
<th>GT6 (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVR12*</td>
<td>207/218 (95%)</td>
<td>164/177 (93%)</td>
<td>60/77 (79%)</td>
<td>13/17 (77%)</td>
</tr>
<tr>
<td>%</td>
<td>95.0%</td>
<td>94.4%</td>
<td>85.5%</td>
<td>65.0%</td>
</tr>
<tr>
<td>95% CI</td>
<td>91.2-97.5</td>
<td>93.9-97.6</td>
<td>84.5-92.2</td>
<td>51.1-89.7</td>
</tr>
<tr>
<td>LTFU or unrelated to VIF**</td>
<td>4</td>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Relapse‡</td>
<td>5</td>
<td>4</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Renal‡</td>
<td></td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

1. HCV RNA assessed vs COBAR1 Tarfig v2.0 [lower limit of quantitation <15 IU/mL]
2. FAS (Full Analysis Set): all patients who received at least one dose of GZR/EBR
3. N: Number of subjects included in the analysis
4. %: Number of subjects who achieved SVR2 and the percentage calculated as n/N*100.
5. Two subjects were lost to follow-up; one patient was discontinued for taking a prohibited concomitant medication, and one patient’s PT/INR was outside the analysis window
6. All baseline in the NAA gene; 1 of the relapses had L151M, 1 of the relapses had the Y93S. 3 of the 3 relapses had the Y93S NAA baseline.

**Table 1. SVR12 by Genotype**
TUAB0207LB
Daclatasvir plus sofosbuvir with or without ribavirin in patients with HIV-HCV co-infection: interim analysis of a French multicenter compassionate use program


1AP-HP Hôpital Saint-Antoine, InsERM U897, UMPC - Paris VI, France, 2Hôpital Armand-Trousseau, Paris, France, 3Hôpital Broussais, Villejuif, France, 4Hôpital Bichat, Paris, France, 5Pitié Salpêtrière Hospital, Paris, France, 6Cochin Hospital, Paris, France, 7Pitié Salpêtrière Hospital, Paris, France, 8Archet Hospital, University Hospital of Nice, Nice, France, 9Pitie-Salpetriere Hospital, Paris, France, 10Georges Pompidou European Hospital, Paris, France, 11Saint-Eloi University Hospital, Montpellier, France, 12Saint-Jean Hospital, Perpignan, France, 13Hôpital Montjoly, Crèteil, France, 14UMPC Tenon Hospital, Paris, France, 15Pays d’Aix Hospital, Aix-en-Provence, France, 16Sainte-Musee Hospital, Toulon, France, 17Pitie-Salpetriere Hospital, Paris, France, 18Hotel-Dieu University Hospital, Nantes, France, 19INSERM U097, Bordeaux, France, 20Necker Hospital, Paris, France, 21Bristol-Myers Squibb Research and Development, Rueil-Malmaison, France, 22Necker Hospital, Paris, France, 23Bristol-Myers Squibb Research and Development, Rueil-Malmaison, France, 24Saint Antoine Hospital, Department of Internal medicine and Infectious diseases, Paris, France

Background: All-oral regimen with daclatasvir (DCV; NSSA replication complex inhibitor)+sofosbuvir (SOF; NSSB polymerase inhibitor)+weight-based ribavirin (RBV) has demonstrated high sustained virologic response (SVR) rates in HCV mono-infected patients. This analysis reports SVR and S212 results from an ongoing multicenter compassionate use program (ATU) in France.

Methods: HCV/HIV co-infected patients with advanced liver disease from 221 centers have been included since March 2014. All patients received DCV+SOF QD for 12 or 24 weeks, with RBV added at the physician’s discretion. Baseline characteristics, virological response rates and adverse events were collected through a standardized form. We report interim SVR rates at 4 and 12 weeks after the end of treatment for patients who have completed treatment to date.

Results: Of 562 patients enrolled, 73.8% were males, median age was 52.3 years (30-74), 39(1)% were cirrhotic and 460 (82.6%) were treatment-experienced. Child Pugh was completed treatment to date. Of 562 patients enrolled, 73.8% were males, median age was 52.3 years (30-74), 39(1)% were cirrhotic and 460 (82.6%) were treatment-experienced. Child Pugh was completed treatment to date. Of 562 patients enrolled, 73.8% were males, median age was 52.3 years (30-74), 39(1)% were cirrhotic and 460 (82.6%) were treatment-experienced. Child Pugh was completed treatment to date.

Background: Young women in southern Africa have high rates of sexually transmitted infections, including herpes simplex virus type-2 (HSV-2) and HIV. We investigated whether conditional cash incentives (CCIs) reduced the incidence of HSV-2 and HIV in high school students in South Africa.

Methods: An open-label, matched-pair, cluster randomized controlled trial (CAPRISA 007) was undertaken in 3,217 consenting male (n=1,517) and female (n=1,700) grade 9 and 10 students. A locally-developed HIV prevention program, “My Life! My Future!” was actively implemented in all 14 schools. Seven schools (n=1,592 students) were randomly assigned to receive, in addition, cash incentives (maximum of $175 over 2 years) for fulfilling any combination of 4 conditions: annual HIV testing, performance in school tests, participation in “My Life! My Future!” and a written report on their community involvement project. HSV-2 and HIV serology was undertaken at baseline, 12 months and 24 months. In the intent-to-treat analysis, incidence rate ratios (IRRs) and p-values were adjusted for the matched-pair cluster design.

Results: HSV-2 prevalence at baseline was 9.0% in CCI schools and 7.3% in control schools. During follow-up, there were 319 new HSV-2 infections, with an incidence rate of 6.2 per 100 person-years in CCI schools compared to 8.7 per 100 person-years in control schools (IRR=0.70, 95%CI: 0.57 - 0.86; p<0.007). HSV-2 incidence was 7.1 per 100 person-years in the 760 students who received <$65, 6.3 per 100 person-years in the 304 students who received $65-$95, and 4.2 per 100 person-years in the 265 students who received >$95 (Trend p=0.12). The lower-than-anticipated overall HIV incidence rate of 1.6 per 100 person-years was similar in both groups of schools (IRR=1.26, 95%CI: 0.86 - 2.39; p=0.419). A four-fold larger study would be required for 80% power to observe a 35% HIV incidence reduction.

Conclusions: CCI schools had 30% lower HSV-2 incidence. Students who received larger cash incentives had lower HSV-2 incidence rates. The impact of CCI on HIV could not be adequately assessed as incidence was lower than expected, likely due to HIV lowering effects of both study-initiated and background community HIV interventions.
TUAC0103
Estimating the population-level effect of homelessness on HIV viral suppression among people who use drugs: an observational study
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Background: Homelessness has been identified as an important structural barrier to effective antiretroviral therapy (ART) utilization among HIV-infected people who use drugs (PWUD). However, the potential effect of reducing homelessness on viral suppression rates at the community level is unknown. We used an imputation-based marginal modeling approach to estimate change in the prevalence of viral suppression among HIV-infected PWUD, if homelessness were eliminated from the population.

Methods: We used data from a cohort study of community-recruited PWUD in Vancouver, Canada. Of note, HIV/AIDS treatment and care is provided free of charge in this setting. Persons were eligible to participate if they were HIV-infected and used an illicit drug in the month prior to enrollment. We assessed self-reported baseline housing status in the past six months. Viral suppression was defined as HIV RNA viral load < 50 copies per mm3 at first study visit. We estimated the effect of homelessness on viral suppression using modified-Poisson regression, adjusting for demographics, socioeconomic characteristics, trauma history, depression, addiction treatment, and other confounders. Then, a marginal modeling approach was applied. First, we imputed the outcome probability for each individual while manipulating the exposure (homelessness) to never exposed, and then averaged these probabilities across the population. Bootstrapping was conducted to calculate 95% confidence limits.

Results: Of 718 eligible individuals enrolled between January 2005 and December 2013, the majority was male (66%), white race/ethnicity (55%), and had a history of injection drug use (84%). At baseline, 230 (32%) reported homelessness. The prevalence of viral suppression was 35% (95%CL: 31%-39%). Adjusted marginal models estimated a 14% relative increase (95%CL: 10%-24%) in viral suppression prevalence in the entire sample—to 40% (95%CL: 36%-45%)—if all homeless individuals were housed. Among those homeless at baseline, adjusted marginal models estimated that eliminating this exposure would increase viral suppression from 19% (95%CL: 14%-24%) to 37% (95%CL: 33%-42%).

Conclusions: Reducing homelessness among HIV-infected PWUD could have significant population-level benefits on outcomes in the HIV care continuum. Low threshold shelter and housing support programs should be considered as key components in comprehensive strategies to increase population-level viral suppression for people who use drugs.

Methods: We analyzed data collected from in-person interviews between December 2013 and December 2014 with food-insecure, HIV-infected adults who initiated ART in the past 90 days. Temporal discount rate, the rate at which individuals discount future costs and benefits, was measured using a bidding process to assess the acceptable percent increases of a hypothetical monetary offer they would receive in three months compared to a smaller amount received today. Future health expectations were assessed for one year from now, and intrinsic motivation for ART adherence was measured as the mean score (range: 0-3) on a Likert-scale using questions in the Treatment Self-Regulation Questionnaire.

Results: Overall, 511 food-insecure recent ART initiates were interviewed (mean age: 37, 64% female). Nearly all (99%) expected their health to be somewhat (55%) or much better (44%) one year from now. Excluding those who initiated treatment on the same day of the interview, mean internal motivation was 2.75 (standard deviation 0.36; n=423). Temporal discount rates (n=489) fell into four ranges: < 5% (8%), 5-100% (37%), 101-200% (54%), and >200% (2%).

Conclusions: These data indicate high levels of both intrinsic motivation for ART adherence and optimism towards future health among food-insecure ART initiates in Tanzania, suggesting that interventions designed to strengthen and sustain intrinsic motivation may be appropriate. The high discount rates indicate a greater focus on the present, thus, interventions aiming to overcome the short-term cost barriers to adherence and care (e.g. time, transport, competing needs) in order to achieve future gains may be highly effective among this population.

TUAC0104
Applying principles of behavioral economics to ART adherence: discount rate, future expectations, and intrinsic motivation for adherence among ART initiates in Shinyanga region, Tanzania
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Presenting author email: ncraiciuc@berkeley.edu

Background: Behavioral economic theory suggests that understanding motivations and future preferences of people living with HIV infection (PLHIV) can inform the development of interventions supporting adherence to treatment and care. For example, PLHIV with high levels of intrinsic motivation to ART may require less external motivation, such as cash incentives. In addition, PLHIV who disproportionately value the present and heavily discount the future may be less likely to adhere to ART, a behavior with future benefits and present costs. We measured these constructs among antiretroviral therapy (ART) initiates at four HIV care and treatment clinics in Shinyanga Region, Tanzania.

Methods: We analyzed data collected from in-person interviews between December 2013 and December 2014 with food-insecure, HIV-infected adults who initiated ART in the past 90 days. Temporal discount rate, the rate at which individuals discount future costs and benefits, was measured using a bidding process to assess the acceptable percent increases of a hypothetical monetary offer they would receive in three months compared to a smaller amount received today. Future health expectations were assessed for one year from now, and intrinsic motivation for ART adherence was measured as the mean score (range: 0-3) on a Likert-scale using questions in the Treatment Self-Regulation Questionnaire.

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Conclusions: These data indicate high levels of both intrinsic motivation for ART adherence and optimism towards future health among food-insecure ART initiates in Tanzania, suggesting that interventions designed to strengthen and sustain intrinsic motivation may be appropriate. The high discount rates indicate a greater focus on the present, thus, interventions aiming to overcome the short-term cost barriers to adherence and care (e.g. time, transport, competing needs) in order to achieve future gains may be highly effective among this population.

TUAC0105
Negative impact of South Africa’s disability grants on HIV/AIDS recovery
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1Harvard School of Public Health, Global Health and Population, Boston, United States, 2Wellcome Trust Africa Centre for Health and Population Studies, 3Wellcome Trust Africa Centre for Health and Population Studies, Health Systems and Impact Evaluation, Mbabane, Swaziland, Africa
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Background: The South African disability grant (DG) has been theorized to incentivize poor recovery by tying grant receipt to AIDS sickness. Prior to 2008, many official guidelines defined qualifying AIDS disability as a CD4 count below 200mmHg, and this recommendation persists unofficially. We make two predictions: 1) The population distribution of CD4 counts will have an observable discontinuity with excess mass just below the CD4 qualification threshold of 200mmHg; and, 2) individuals receiving the grant will recover more slowly around this threshold than those who do not, due to threat of grant loss.

Methods: The analysis utilizes a two-stage panel regression methodology to absorb individual trends and identify differential recovery rates around the CD4 threshold of 200mmHg. The dataset for this analysis utilizes the Africa Centre Demographic Information System (AC-DIS), an open cohort health and demographic monitoring program consisting mainly of annual surveys, individually matched with an HIV-focused clinical informatics system in rural KwaZulu-Natal, South Africa. Data are restricted to HIV+ individuals from 2004-2011 who have at least four observed CD4 counts, with at least one observed CD4 count above and below 200mmHg.

Results: The cohort for this analysis consists of 11,160 observations from 1,450 individuals. The distribution of CD4 counts shows clear excess mass just below a CD4 count of 200mmHg, with more pronounced for CD4 counts occurring in 2008 or earlier. Among observations around the threshold, the rate of recovery of those receiving DGs is 0.23mmHg/year lower (p=.020) than that of those not receiving DGs, controlling for individual recovery trends, age, education, time, household assets, and employment. Stratifying on gender, the effect is seen much stronger among women with a differential recovery rate of 58mmHg/year (p=.018). The effect is significantly larger for observations in 2008 or earlier.

Conclusions: This study finds that the South African disability grant system resulted in a modest but significant manipulation of CD4 counts in order to qualify for the grant. While policy changes have likely reduced the severity of the effect, policy makers should ensure that incentives from grants are aligned with health incentives to reduce poor outcomes, infectivity, and drug resistance.
TUAC0106LB
HPTN 068 conditional cash transfer to prevent HIV infection among young women in South Africa: results of a randomized controlled trial

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Background: Young women in South Africa face a particularly high risk of HIV infection. Structural factors such as school leaving, socio-economic status (SES) and financial dependence on partners contribute to this risk. Cash transfers have shown promise in reducing HIV risk in young women by addressing these factors. HPTN 068 is the first randomized trial to examine the impact of conditional cash transfers on HIV incidence among young women.

Methods: HPTN 068 is a phase III individually randomized trial to assess the impact of a conditional cash transfer on the acquisition of HIV among South Africa young women. Young women and their parent/guardian in the intervention arm received a monthly cash transfer conditional on 80% school attendance, which was verified using school attendance rosters. The intervention ran from April 2011 to March 2015. Participants enrolled in the study were aged 13-20, in school, not married or pregnant, and resident in the Agincourt Health and Demographic Surveillance System (AHDSS) site in ruralMpumalanga Province. Participants were seen at baseline, then annually for up to three follow-up visits, where HIV and HSV-2 testing were conducted and an interview was completed using Audio Computer Assisted Self Interviewing (ACASI). The interview assessed sexual behavior including partner sexual characteristics, mental health, SES and gender power dynamics. Participants were tested for HIV infection using two HIV rapid tests with Western blot confirmation. Stored samples from all participants at all visits were also tested at the HPTN Laboratory Center using assays that included an HIV antigen/antibody test and a qualitative HIV RNA test. To compare treatment arms, time to first HIV detection was analyzed using a Cox proportional hazards model.

Results: We will present the impact of the conditional cash transfer on HIV incidence, unprotected sex, pregnancy, age difference with partners, number of sex partners, transactional sex, age of sexual debut and school attendance.

Conclusions: Cash transfers are increasingly being included as part of the package of prevention services that should be offered to young women to reduce HIV risk in sub-Saharan Africa. The evidence from this RCT will have important implications for HIV prevention policy and practice.

TUAC0202
Adherence, sexual behavior and HIV/STI incidence among men who have sex with men (MSM) and transgender women (TGW) in the US PrEP demonstration (Demo) project

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Background: Pre-exposure prophylaxis (PrEP) has demonstrated efficacy in reducing HIV acquisition in MSM and TGW. Little is known about adherence, sexual behavior, and HIV/STI incidence among those who elect to take PrEP in real-world settings.

Methods: The Demo Project is the first US multi-site open-label study assessing PrEP delivery in municipal STD (San Francisco, Miami) and community-health (Washington, DC) clinics. HIV-uninfected MSM/TGW were offered 48 weeks of PrEP. HIV incidence was assessed in dried blood spots (DBS) in a random sample of participants (pts). Correlates of adherence were assessed using multivariable logistic regression. Sexual behaviors, PrEP discontinuations, and HIV/STI incidence are described.

Results: From 9/2012-10/2014, 557 pts enrolled, with 83% retained for the final visit (458.8 person-years [py]). Longitudinal drug levels, sexual behavior, and STI incidence are shown (figure). Among 147 pts with DBS testing, 65% had drug levels consistent with taking ≥4 doses/week at all visits, 3% always had DBS levels <2 doses/week, and 32% had an inconsistent pattern. Black pts, being self-referred to the PrEP program, and having a greater number of condomless anal sex (AS) partners were independently associated with DBS <4 doses/week (all p<0.05). Median AS partners in the past 3 months declined from baseline to week 48 (5 to 4, P<0.0002). Two-thirds reported condomless receptive AS (CRAS) at baseline, which remained stable during follow-up (p=0.96). Twenty pts chose to stop PrEP due to low self-perceived HIV risk, however 85% of these pts reported CRAS in the prior 3-6 months. Three participants were acutely infected at enrollment, and one seroconverted during follow-up (HIV incidence 0.21/100 py). This subject had DBS <2 doses/week at all prior visits. Overall, 27.5% had early syphilis, GC, or CT at screening, and 38% had ≥1 STI during follow-up; incidence was high (47.9, 42.8, and 12.6/100 py for CT, GC, and syphilis) but did not increase over time (p=0.87).

[Figure. Adherence, risk behaviour, and STI incidence over time in the demo project]
TUAC0203
Characteristics and oral PrEP adherence in the TDF2 open-label extension in Botswana
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Background: The TDF2 Study was a randomized, double-blind, placebo-controlled trial of daily oral coformulated tenofovir disoproxil fumarate (300 mg)/emtricitabine (200 mg) (TDF/FTC) for pre-exposure prophylaxis of HIV infection (PrEP) among young heterosexual adults in Gaborone and Francistown, Botswana. TDF2 completed follow-up in 2011, demonstrating 62% overall protective efficacy.

We describe final results of a 12-month open-label extension (OLE).

Methods: Between February and May 2013, former TDF2 participants were screened and offered 30-day supplies of TDF/FTC for up to 12 months. OLE exclusion criteria included HIV infection, pregnancy/breastfeeding, and abnormal serum creatinine clearance or phosphorus. Demographic and sexual behavior data were collected at baseline. Dual rapid fingerstick HIV testing, sexual behavior questionnaires, and self-reported adherence measures were conducted monthly. Dried blood spots (DBS) were collected monthly.

Tenofovir levels were measured from DBS for a subset of 30 randomly selected participants at months 1, 3, 6, 9, and 12.

Results: Of 1219 TDF2 participants, 736 were contacted, and 229 (Male: 55.5%) were eligible and started drug. 71.2% were single, and 23.9% were married/cohabitating. 60.3% of participants completed at least 10 monthly visits. Across all visits, 71.2% reported 1 sex partner in the prior 30 days; 8.7% reported 2 partners, and 2.4% reported ≥ 3 partners. For the prior three days, 87.8% reported taking TDF/FTC daily, while 5.5% reported taking it 1-2 times and 6.7% reported taking none. Overall, 58.3% reported ‘very good’ adherence in the prior 30 days, and 32.3% reported ‘good’ adherence.

Conclusions: High oral PrEP adherence was observed, and results support the need for a long-term adherence program for such populations.

TUAC0204LB
An HIV pre-exposure prophylaxis (PrEP) demonstration project and safety study for young men who have sex with men in the United States (ATH 110)
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Background: Young men who have sex with men (YMSM), particularly racial/ethnic minority YMSM, are a key population for implementation of domestic PrEP interventions. This open-label PrEP study examined uptake and adherence to PrEP and assessed sexual risk behavior among a diverse sample of YMSM in 12 US cities.

Methods: ATN110 combined PrEP with evidence-based behavioral risk reduction interventions along with frequent sexual health and adherence promotion counseling. Eligible participants were 18-22 year old HIV-uninfected MSM who reported HIV transmission risk behavior in the past 6 months. Participants were recruited and screened for preliminary eligibility through venue-based outreach, community presentations, and online advertising. Laboratory screening determined final eligibility.

Study visits occurred at baseline, monthly through week 12, then quarterly through week 48. Dried blood spots (DBS) were sent to the PrEP Research Core for the quantification of tenofovir diprophosphate (TFV-DP) blood levels.

Conclusions: PrEP adherence was high and HIV incidence was low in this cohort at ongoing high sexual risk for HIV. STIs were common during PrEP use, highlighting the importance of screening and treatment. Strategies for counseling on appropriate PrEP discontinuation are warranted.

TUAC0205LB
Pre-exposure prophylaxis (PrEP) uptake and associated factors among MSM and TGW in the PrEP Brasil demonstration project
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Background: In Brazil, men who have sex with men (MSM) and transgender women (TGW) are the populations most heavily affected by the AIDS epidemic. Although the WHO recommends PrEP for these populations, the feasibility and interest in this prevention strategy in real-world settings in low and middle-income countries are unknown. This study aims to describe PrEP uptake and associated factors in Brazil.

Methods: PrEP Brasil is a demonstration project to assess the feasibility of implementing PrEP provided at no cost to high risk MSM and TGW within the Brazilian public health system. The project was advertised through social and other media. Participants were assessed for PrEP eligibility at FIOCRUZ-RJ, CRT-SP and USP-SP. At USP, 100% participants were self-referring, while at FioCruz and CRT they were either self-referring or assessed for participation during HIV-testing or post-exposure prophylaxis provision. Predictors of PrEP uptake were assessed using a Poisson regression model.

Results: Of 986 MSM/TGW approached between April 2014 - April 2015, 798 were potentially eligible and 409 were enrolled. PrEP uptake was 51.26%. Median age at enrollment was 29 years (IQR 25-35); 93.5% had ≥12 years of education; 83.9%, 8.8% and 5.9% identified themselves as homosexual, bisexual or TGW, respectively (Table); syphilis prevalence, rectal Chlamydia and Gonococcal detection were 21.3%, 6.2% and 4.7%, respectively. In multivariate analysis, factors associated with PrEP uptake were: recruitment at CRT-SP (aRR 1.27; 95% CI 1.09-1.42) vs. FIOCRUZ-RJ, having a steady partner (aRR 1.45, 95% CI 1.18-1.75); having an HIV-test within the last 12 months (aRR 1.33, 95% CI 1.01-1.74); prior PrEP awareness (aRR 1.27, 95% CI 1.01-1.59); and having 2 male condoms at sex within the last 12 months (aRR 1.65, 95% CI 1.32-2.06).

Conclusions: This is the first PrEP demonstration project for MSM and TGW in a middle-income country. Overall, PrEP uptake was high. The higher uptake among those at higher risk and with an existing awareness of PrEP emphasizes the importance of establishing strategies to improve HIV risk perception and PrEP awareness in the MSM and TGW communities in Brazil.
Methods: MTN-014 is a phase 1 cross-over, randomized trial comparing the pharmacokinetics and pharmacodynamics of tenofovir gel, when used consistently as a vaginal microbicide, and tenofovir disoproxil fumarate (TDF) film, when used consistently as a rectal microbicide, in women, data on TFV concentrations and anti-HIV activity in the rectal compartment following coadministration of TFV reduced-glycerin (RG) 1% gel following 14 days each of daily rectal versus vaginal dosing. Women were enrolled at the Bronx Prevention Center in New York City and 13 completed all study procedures. Of the 392 ex-

Results: Fourteen HIV-uninfected women, mean age 34 years, were enrolled at the Bronx Prevention Center in New York City and 13 completed all study procedures. Of the 392 ex-

Background: Tenofovir (TFV) gel, when used consistently as a vaginal microbicide, prevents HIV infection. As unprotected anal intercourse is prevalent among heterosexual women, data on TFV concentrations and anti-HIV activity in the rectal compartment following vaginal application, and vice versa, are needed.

Methods: MTN-014 is a phase 1 cross-over, randomized trial comparing the pharmacokinetics of TFV reduced-glycerin (RG) 1% gel following 14 days each of daily rectal versus vaginal dosing. Vaginal and rectal fluid and blood samples were collected 24 hours after the end of each phase and analysed for TFV and TFV-diphosphate (TFV-DP) concentrations. Vaginal and rectal fluid were tested for HIV inhibition using a TZM-bl assay.

Results: Fourteen HIV-uninfected women, mean age 34 years, were enrolled at the Bronx Prevention Center in New York City and 13 completed all study procedures. Of the 392 expected doses, 91% were DOD, 2.0% were missed and the remaining doses were reported as used. Mean plasma TFV concentrations were similar after 14 days of either dosing route as used. Mean plasma TFV concentrations were similar after 14 days of either dosing route as used.

Conclusion: Cross-compartmental concentrations of TFV and TFV-DP were low in this study comparing rectal and vaginal DOD TFV RG 1% gel and pharmacodynamics activity was not noted only in the vaginal fluid compartment. Whether these low tissue concentrations are potentially resulting in progressive deterioration of the overall HIV epidemic among MSM.

Background: Recent upsurge of new HIV infections among men who have sex with men in China: implication for real time action

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Background: Recent upsurge of new HIV infections among men who have sex with men (MSM) is a major concern in China. Paucity of national-level information regarding the burden and predictors of this progressive epidemic of new infections called for a multi-centric, comprehensive investigation.

Methods: Mixed methods were used to recruit MSM (Engaged in sex with men (oral and/or anal) within the last one year, aged 18 years or older and agreed to provide written informed consent) from seven cities (Shanghai, Nanjing, Changsha, Zhengzhou, Jinan, Shenyang and Kunming) in different regions of China between 2012 and 2013. Early and established HIV infections were determined by Western Blot and BED HIV-1 capture enzyme immunoassay. Syphilis and herpes simplex virus-2 (HSV-2) were also tested. The study process and content were approved (No. 2011/36) by the Ethics Committee of The First Affiliated Hospital of China Medical University.

Results: A total of 4496 eligible MSM were recruited. The majority was aged ≤35 years (77%), migrants (60.3%), never married (69.8%), and played receptive role in anal sex (77.5%). Migrants (60.3%), never married (69.8%), and played receptive role in anal sex (77.5%), and compared with those who were born in the same city, had a shorter duration of residence in Shanghai. The majority had not been circumcised (77.5%). Among men who had been circumcised (60.3%), migrants (60.3%), never married (69.8%), and played receptive role in anal sex (77.5%), and compared with those who were born in the same city, had a shorter duration of residence in Shanghai. The majority had not been circumcised (77.5%); migrants (60.3%); never married (69.8%); and played receptive role in anal sex (77.5%).

Background: Worsen epidemic of early HIV infection among men who have sex with men in China: implication for real time action

X. Xu, W. Tang*, H. Zou, T. Mahapatra, Q. Hu, G. Fu*, Z. Wang, L. Lu*, M. Zhong*, X. Chen*, J. Fu*, Y. Yu*, J. Lu*, Y. Jiang*, W. Geng*, X. Han*, H. Shang* The First Affiliated Hospital of China Medical University, Shenyang, China; University of North Carolina, Project-China, Guangzhou, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Janssens Pharmaceutical Development Center, Gent, Belgium; China, University of North Carolina, Project-China, Guangzhou, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Guangzhou University of Chinese Medicine, Guangzhou, China; Chinese University of Hong Kong, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Nanjing Medical University.

Results: A total of 4496 eligible MSM were recruited. The majority was aged ≤35 years (77%), migrants (60.3%), never married (69.8%), and played receptive role in anal sex (77.5%). The prevalence of HIV was 9.6% and 6.2% were recently infected, with HIV incidence of 8.9/100 Person-Years. The prevalence of HSV-2 and syphilis were 12.5% and 8.5%, respectively. Recent HIV seroconversion prevalence was 4.1% (95% CI 3.0%-5.3%). Among men who had been circumcised (60.3%); migrants (60.3%); never married (69.8%); and played receptive role in anal sex (77.5%).

Background: Recent upsurge of new HIV infections among men who have sex with men in China: implication for real time action

X. Xu, W. Tang*, H. Zou, T. Mahapatra, Q. Hu, G. Fu*, Z. Wang, L. Lu*, M. Zhong*, X. Chen*, J. Fu*, Y. Yu*, J. Lu*, Y. Jiang*, W. Geng*, X. Han*, H. Shang* The First Affiliated Hospital of China Medical University, Shenyang, China; University of North Carolina, Project-China, Guangzhou, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Janssens Pharmaceutical Development Center, Gent, Belgium; China, University of North Carolina, Project-China, Guangzhou, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Guangzhou University of Chinese Medicine, Guangzhou, China; Chinese University of Hong Kong, China; University of California at Los Angeles, Epidemiology, Los Angeles, United States; Nanjing Medical University.
in China. Interventions specifically targeting high-risk MSM especially those having high-risk behaviors (especially multiple partners and recreational drug use), syphilis or HIV-2 infection and anal bleeding were urgently required for efficient control of HIV among MSM in China.

**TUAC0302**

**Repeat HIV voluntary counseling and testing within one year among men who have sex with men, Bangkok, Thailand 2006-2013**

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**Background:** Current Thailand Ministry of Public Health (MOPH) recommendations state that men who have sex with men (MSM) should repeat HIV testing every 6-12 months. We investigated the proportion and trend of repeat HIV voluntary counseling and testing (VCT) within 12 months among Thai MSM attending Silom Community Clinic @TropMed.

**Methods:** Silom Community Clinic @Trop Med has been located in downtown Bangkok since late 2005, with easy access and convenient operating hours for MSM. It provides free-of-charge, confidential and rapid HIV VCT by MSM-friendly staff. We advertise the clinic via website, Facebook, outreach, and friend referrals. For first-time testers, we recommend that they repeat VCT every 6-12 months. For this analysis, we included men with an initial HIV test who had visited the clinic for >212 months and had a baseline HIV-negative result; the first VCT visit occurred between 2006-2013 with follow-up period through October 2014. On a yearly basis, we looked at the number and proportion of first-time testers who had another VCT visit within the next 12 months. We used chi-square test for trend to test changes in the proportion of repeat testing within 12 months by calendar year.

**Results:** Between 2006-2013, 9,345 MSM were tested by our testing services and 4,597 met the criteria above and were included in this analysis. Most (87.1%) were 25 years and older, and most (87.9%) lived in Bangkok or nearby provinces at time of first test. Among these MSM, 2,016 (43.9%) repeated VCT. The number of new testers increased annually from 340 men in 2006 to 880 in 2013. The proportion of MSM who repeated VCT within one year varied between 15.3% to 26.1% by calendar year (mean = 22.2%) and there was a statistically significant increasing trend from 2006-2013 (p<0.01) (Figure).

**Conclusions:** Between 2006-2013, the number of new testers doubled, and the proportion of men who repeated VCT significantly increased. Given that roughly one-fifth of MSM repeated VCT within 12 months, counseling to emphasize repeating VCT according to Thailand MOPH recommendations should be strengthened and systematic strategies to retain testers should be implemented.

**TUAC0303**

**Dramatic declines in lifetime HIV risk and persistence of racial disparities among men who have sex with men (MSM) in King County, Washington, USA**

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**Background:** In the US, HIV disproportionately affects MSM, who account for >60% of new cases. Although recent data suggest HIV incidence is declining nationally, rates in MSM are stable, and the proportion of cases occurring in black MSM is increasing. Because sexual mixing is largely age-assortative, using life tables to estimate risk within birth cohorts may be useful in assessing and anticipating trends in the population’s risk.

**Methods:** We constructed life tables for the period 1982-2012 to estimate the cumulative risk of HIV diagnosis among MSM in King County born 1940-1994. We used U.S. Census data to define the size of the white and black male populations of King County, Washington, national and local survey data to estimate the proportion of men who are MSM, and local surveillance data to define the number of HIV diagnoses in MSM each year.

**Results:** We estimated that 6% of the local male population was MSM. Age-specific risk of HIV diagnosis increased in birth cohorts from the 1940s until the mid-1960s and thereafter declined, plateauing among cohorts born after the mid-1970s (Figure).

**Conclusions:** Comparing birth cohorts, cumulative HIV risk among MSM in King County has declined approximately 65% in those born after the mid-1960s, although racial disparities persist. Our findings highlight the importance of evaluating HIV risk within birth cohorts and demonstrate remarkable local progress in HIV prevention.

![Cumulative Risk of Acquiring HIV Among MSM in King County](image-url)
TUAC0304
Ethical considerations for research on men who have sex with men under the age of 18 in epidemiological research: evidence from six sub-Saharan African countries

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Background: In many settings, laws or institutional review board policies require parental consent for youth < 18 years to participate in research. Individual and social risk factors for HIV acquisition often occur before age 18. Youth may be unwilling to participate in HIV epidemiological research requiring parental consent due to the sensitive nature of risk factors such as sexual behaviors and experiences of violence. Young men who have sex with men (MSM) are at especially high risk for HIV acquisition and are often unwilling or unable to disclose their sexual orientation or practices to their parents. In sub-Saharan Africa, where HIV prevalence among MSM is high and sex between men is criminalized or highly stigmatized in many countries, epidemiologic research on this vulnerable population of young MSM is particularly relevant and sparse. One strategy for assessing the potential size of the population of young (≤18) MSM is to ask adult MSM retrospective questions about the age at which they first had anal sex with a man.

Methods: MSM aged 18 or older were recruited using respondent-driven sampling in Burkina Faso, Togo, and Swaziland. MSM aged 15 and above were recruited using snowball sampling in The Gambia. Participants completed a survey that included a question asking how old they were when they first had anal sex with another man. This variable was dichotomized and tabulated to assess the prevalence of anal sex under the age of 18.

Results: Across settings, 40.20% (1106/2751) of MSM had anal sex with a man before the age of 18. Further research on this group, including a waiver of requirements for parental consent for inclusion of men under the age of 18 in a setting where this was feasible, additional outreach strategies such as web-based recruitment may be necessary.

 TUAC0305

Nuanced seroadaptive behaviors among Seattle men who have sex with men (MSM): sexual decision-making based on ART use/viral load and recency of partner HIV testing

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Background: Seroadaptive behaviors among men who have sex with men (MSM) may protect against HIV acquisition. Anecdotally, some MSM incorporate partners’ antiretroviral therapy (ART)/viral load (VL) or HIV testing frequency into sexual decision-making. The frequency and effect of these strategies is unknown.

Methods: HIV-negative men with HIV-negative partners, we examined if the timing of the partner’s last HIV test was associated with condomless anal intercourse (CAI). Of those with HIV-positive partners, we asked (in aggregate) if respondents’ decision to have sex or use condoms was based on partner ART use or VL (i.e., ART/VL serosorting). We compared proportions with chi-square tests.

Results: We enrolled 888 (88%) of 1,715 eligible HIV-negative MSM. The mean age was 33 and 62% were white, non-Hispanic. Most (69%) had CAI with HIV-negative partners, 18% had CAI with HIV-positive partners, and 22% reported no CAI. The majority (86%) asked HIV-negative partners when the partner last tested negative. CAI was more common among men whose most recent partner tested ≤ 3 months ago compared to men whose partner tested > 3 months ago or the partner did not know when he last tested (48% vs. 40%, P=0.02). Of 222 men with HIV-positive partners, 60% and 64% decided whether to have sex/used condoms based on their partners’ ART use or VL, respectively. CAI with an HIV-positive partner was more common among men who reported ART/VL serosorting compared to those who did not (59% vs. 57%, P=0.03), but testing newly positive for HIV was less common among men who reported ART/VL serosorting compared to men who did not (11/20% vs. 23% 2/3% 9).

Conclusions: Among Seattle MSM, nuanced seroadaptive behaviors such as ART/VL serosorting and using the recency of a partner’s HIV test to inform sexual decision-making are common. The high prevalence of these behaviors suggests they could impact HIV incidence rates, but the individual- and population-level effects of these behaviors are uncertain.

 TUAC0306

Viral load awareness and risk behaviour in male serodiscordant couples in Australia, Brazil and Thailand

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Background: There are very limited data from homosexual male serodiscordant couples (HMSDC) on the impact of antiretroviral therapy (ART) and viral load (VL) on HIV transmission risk, and on risk behaviours within such couples. To date, no studies have investigated the issue in middle income countries.

Methods: Opposites Attract is an ongoing multisite cohort study of HM-SDC in Australia, Brazil and Thailand. HIV-positive partners (HPP) had VL tested; HIV-negative partners (HNP) had HIV antibody tests and reported sexual behaviour and perception of the HPP’s most recent VL test. Undetectable VL (UVL) was defined as < 200 copies/mL. We compared couples from the three countries; baseline differences were examined with bi-variate logistic regression.

Results: By January 2015, 242 couples were enrolled (Australia=137, Brazil=53, Thailand=52). The majority of HPP were taking ART (62.2%), this was lower in Thailand than in Australia and Brazil (p<0.001), accompanied by higher proportions with UVL in Australia (88.2%) and Brazil (85.0%) than in Thailand (69.2%, p=0.008). Overall, 61.2% of HNP perceived their HPP’s last VL test result to be undetectable. Brazilian and Thai HNP were more likely not to know the result (17.0% and 38.5%) compared to Australians (5.1%, p<0.001). Australian HNP reported more sex with other partners than Brazilians (p=0.013) but not Thai HNP (p=0.183). Australian HNP reported more condomless anal intercourse (CAI) with outside partners compared to both Australians (p<0.002) and Thais (p=0.012). 54.6% of HNP reported CAI with outside partners compared to both Brazilians (p=0.003) and Thais (p=0.003).
Overall, 63.5% of HNP who perceived the HPP’s VL to be undetectable reported CLAI in the last 3 months, compared to only 40.4% of HNP in which the HPP’s VL was perceived to be detectable/unknown (OR=0.39, 95%CI=0.23-0.66, p=0.001). While this was strongly associated amongst Australian couples (p=0.002), there was no such association in Brazil or Thailand.

**Conclusions:** Australian HNP were more aware of their partner’s VL results. Australian HM-SDC with perceived UVL practiced more CLAI, suggesting they may be acting upon beliefs that treatment-as-prevention is effective. This pattern was not seen in Brazil and Thailand.

**Methods:** Given the lack of a gold standard, we synthesized four independent methods to estimate the number of PWID: unique object multiplier, wisdom of the crowd, sequential sampling, and literature review. The unique object estimate is calculated as the number of objects distributed to PWID pre-survey, divided by the proportion of survey participants who reported receiving the objects. The wisdom of the crowd method polls the participants on how many people they believe inject drugs in each city (responses equal to the personal network size were excluded). The sequential sampling method applies a Bayesian approach to the self-reported PWID network size of each participant to infer the size of the hidden population. In the literature review, estimates were based on proportions of adults who are PWID from other African locations applied to the 2014 census projections for Maputo and Nampula. A consensus meeting among stakeholders agreed that the median of all four methods was the best estimate incorporating GEE to account for clustering.

**Results:** HIV prevalence was 50.3% (95% confidence interval [CI]: 40.7-58.9) and 36.8% (CI: 24.3-49.3) in Maputo and Nampula, respectively. The numbers of PWID were estimated at 1445 (0.19% of adults) [acceptable bounds: 1281 (0.17%) - 1608 (0.22%)] and 465 (0.14%) [acceptable bounds: 354 (0.10%) - 572 (0.19%)]. Using these population size estimates, there are 727 and 171 PWID infected with HIV and in need of care and/or treatment services in Maputo and Nampula, respectively.

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With each year increase in age, the hazard increased by 5% (p<0.001) and, with each injection episode in the past 30 days, the hazard increased by 0.8% (p=0.02). Those who were sexually active in the last 30 days had a 26% reduced hazard (p=0.03).

Conclusions: The combined network-based peer intervention and was more efficacious in reducing HIV incidence among PWID in Ukraine than TAC alone.

TUAC0403
Factors associated with initiation of antiretroviral therapy among HIV-infected people who use illicit drugs
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Background: Treatment-as-Prevention-based efforts to reduce HIV/AIDS-associated morbidity, mortality and HIV viral transmission among people who use illicit drugs (PWUD) rely on prompt engagement in antiretroviral therapy (ART). However, the longitudinal factors that promote or block initiation of ART among PWUD are not well described. Thus, we sought to identify factors associated with time from seroconversion to ART initiation among PWUD.

Methods: Using data from two observational prospective cohorts of illicit drug users linked to comprehensive ART dispersion networks, we included HIV-seroconverters at baseline who seroconverted during follow-up. We fit multivariable Cox proportional hazards models adjusted for a time-updated measure of clinical eligibility for ART to identify factors independently associated with time to treatment initiation following seroconversion.

Results: We included 133 individuals of whom 98 (73.7%) initiated ART during follow-up at a rate of 17.6 per 100 person-years. In a multivariable model adjusted for clinical eligibility, living in the HIV epicenter (Adjusted Hazard Ratio [AHR] = 1.82, 95% Confidence Interval [CI] = 1.01 - 2.58), methadone maintenance therapy (AHR = 2.37, 95% CI = 1.16 - 3.60) and a later year of interview (AHR = 1.07, 95% CI = 1.02 - 1.13) were associated with shorter time to ART initiation. Barriers to ART initiation were illicit income generation (AHR = 0.51, 95% CI = 0.32 - 0.79) and incarceration (AHR = 0.52, 95% CI = 0.28 - 0.97).

Conclusions: In this sample of community-recruited HIV-positive PWUD with well-defined dates of seroconversion, we found that illicit income generation and incarceration were barriers to ART initiation while MMT and living in the HIV epicenter promoted ART initiation independent of clinical eligibility. Current efforts to scale-up HIV treatment among PWUD should consider these factors in order to reduce HIV/AIDS-associated morbidity, mortality and HIV viral transmission.

TUAC0404
Periodic HIV testing and immediate antiretroviral therapy among people who inject drugs in Vietnam
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Background: In Vietnam, injecting drug use is the leading cause of HIV transmission. Multiple local transmission models suggest periodic HIV testing and counselling (HTC) and initiating antiretroviral therapy (ART) irrespective of CD4 count in people who inject drugs (PWID) can markedly reduce HIV-related mortality and transmission. Programme experience with this approach in Vietnam is limited. Therefore, the acceptability and feasibility of this approach was assessed in two high-burden provinces. We present preliminary ART outcomes.

Methods: Village health workers, PWID peer educators, and health staff were educated on the new approach and the benefits and risks of immediate ART initiation. Since April 2014, HTC has been recommended to PWID every six months, and immediate ART, i.e. initiation irrespective of CD4 count, has been offered to PWID living with HIV in Thai Nguyen and Thanh Hoa provinces. Following consent, PWID were followed for 12 months. HIV viral load (VL) was assessed before ART start (baseline) and at months six and 12.

Results: Of 232 identified HIV-positive PWID, 218 (94%) agreed to participate and initiate immediate ART, among which 102 initiated ART before 30 June 2014. Of this cohort, 97.1% were males, median age was 36 years, 47.1% reported methadone use in the past three months, 38.2% had baseline CD4 counts greater than 350 cells/mm3 and median baseline VL was 4.1 (IQR 2.3-5.2) log10 copies/ml. 91 of the 102 participants (89.2%) were retained after six months (eight died and three lost-to-follow-up). Retention was 84.1% and 97.4% among PWID with baseline CD4 counts below and above 350 cells/mm3, respectively (Figure). Excluding five patients who transferred to other care sites and seven patients whose samples were not available due to logistical issues, 67 of the 79 participants (84.5%) achieved viral suppression (i.e. VL < 1000 copies/ml) at month six. Viral suppression was 84.4% and 85.3% among PWID with CD4 counts below and above 350 cells/mm3, respectively (Figure)

Conclusions: The preliminary results suggest high uptake and adherence to ART irrespective of CD4 count among PWID, however, late presentation to care remains a critical problem. The results are informing the revision of the national guidelines to include immediate ART in key populations.

TUAC0405
Social and socio-economic benefits of antiretroviral therapy adherence among HIV-infected people who use illicit drugs in Vancouver, Canada
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Background: There is extensive documentation of the direct clinical benefits of antiretroviral therapy (ART) adherence leading to plasma HIV RNA-1 viral load suppression. However, very little is known about the social, socio-economic and ancillary clinical benefits of ART adherence, particularly among people who use illicit drugs (PWUD).

Methods: We used longitudinal data from a prospective cohort of community-recruited HIV-positive PWUD in Vancouver, Canada, a setting of free and universal access to HIV care. Participant data were linked to comprehensive HIV clinical monitoring and ART dispensation records. We developed a series of generalized linear mixed effects models, adjusting for potential confounders. Models examine whether, among ART-exposed individuals, becoming optimally adherent to ART medication (i.e., ≥95% using a validated measure of pharmacy dispensation) resulted in associated social, socio-economic and ancillary clinical benefits, such as relationship initiation, transitioning out of homelessness, entering employment, ceasing involvement in illegal or prohibited income generation activity (e.g., street-based income generation, sex work, drug dealing or other illegal activities), and enrolling in addiction treatment.

Results: Between December 2005 and November 2013, of the 724 eligible study participants, 241 (33.3%) self-reported as women and 404 (58.5%) as Caucasian, with 463 (64.0%) individuals becoming ≥95% adherent to ART at least once during the study period. In final multivariable models, becoming adherent to ART was positively and significantly associated with ceasing prohibited or illegal income generation activities (adjusted odds ratio [AOR]: 1.52, 95% confidence interval [CI]: 1.20 - 1.94) and transitioning out of homelessness (AOR: 1.38; 95% CI: 1.15 - 1.68), with each injection initiation, transitioning out of homelessness, entering employment, ceasing involvement in illegal or prohibited income generation activity (e.g., street-based income generation, sex work, drug dealing or other illegal activities), and enrolling in addiction treatment.

Conclusions: These findings suggest that becoming adherent to ART results not only in virologic suppression among HIV infected PWUD, but also increases the likelihood of reducing key drivers of social and socio-economic vulnerability. These secondary benefits of ART adherence hold the potential to reinforce ongoing engagement in HIV care and support significant improvements in quality of life and individual health among this marginalized population. Finding ways to reinforce the clinical and non-clinical importance of promoting access and adherence to ART among HIV-positive individuals who use illicit drugs.
TUAC0406LB
Modelling the impact of improvements in the cascade of care for chronic hepatitis C among people who inject drugs (PWID) in Montréal, Canada

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Background: Since 2010, HCV incidence among active (i.e. injection past six months) PWID in Montréal remains greater than 15/100 person-years (p-y). The arrival of direct acting antivirals (DAAs) with high sustained virological response rates and improved tolerability raises the question of whether treatment could be used to prevent HCV transmission. Our objective was to assess how improvements in the cascade of care can impact future HCV incidence, prevalence and complications among PWID in Montréal.

Methods: We used a dynamic model to simulate HCV transmission and natural history among active PWID in Montréal from 2015. The reference scenario (scenario 1) was the current cascade of care including new DAA as standard treatment (see Table). HCV prevalence and incidence after 10 years and the number of liver complications avoided after 40 years were estimated under different conditions: decreased time from chronic infection to diagnosis (scenario 2), greater adherence to treatment (scenario 3), improved treatment rate (scenarios 4 and 5) and a combination of these interventions (scenario 6). Due to a lack of data on time to linkage to care (time between diagnosis and first consultation related to hepatitis C), simulations considered three such intervals: 1, 3 and 5 years. A thousand simulations were performed per scenario.

Results: Scenarios 2 and 3 showed similar results for HCV prevalence (53.3% to 59.5%) and incidence (8.1 to 10.3/100 p-y) after 10 years, and less than a 3.4% difference in the number of liver complications after 40 years relative to the reference scenario. mejorar access to care (scenarios 4 and 5) demonstrated a great decrease in all outcomes. When combining all interventions (scenario 6), prevalence and incidence decreased until 26.9% and 4/100 p-y respectively, and the number of liver complications until 39.3%, depending on the time to linkage to care.

Conclusions: Our results suggest that decreasing time to diagnosis or improving treatment adherence is not sufficient to impact HCV prevalence, incidence and complications among PWID in Montréal. The current level of treatment access in the cascade of care is limiting a massive decrease in disease burden and transmission. A substantial treatment scale-up is necessary in this population.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Average time before linkage to care (years)</th>
<th>Prevalence after 10 years (% mean [95% CI])</th>
<th>Incidence after 10 years (100 persons-years) mean (95% CI)</th>
<th>% of complications avoided compared to Scenario 1 over 40 years mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scenario 1 (Reference)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>New DAAs under the current cascade of care:</td>
<td></td>
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<tr>
<td>average time from chronic infection to diagnosis</td>
<td>1</td>
<td>54.6 (54.4; 54.8)</td>
<td>9.4 (9.1; 9.6)</td>
<td>/</td>
</tr>
<tr>
<td>δ=0.2 years</td>
<td>3</td>
<td>57.7 (57.5; 57.8)</td>
<td>10.1 (9.8; 10.4)</td>
<td>/</td>
</tr>
<tr>
<td>annual lost to follow-up probability γ=14%; initiation of treatment if linked to care α=5%; SVR rate with current adherence to treatment (SVR) = 81.3%</td>
<td>5</td>
<td>59.5 (59.4; 59.7)</td>
<td>10.3 (10.1; 10.6)</td>
<td>/</td>
</tr>
<tr>
<td>Scenario 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decrease in treatment from chronic infection to diagnostic</td>
<td>1</td>
<td>53.5 (53.3; 53.7)</td>
<td>9.1 (8.5; 9.4)</td>
<td>0.9 (-2.2; 2.0)</td>
</tr>
<tr>
<td>δ=0.5 years</td>
<td>3</td>
<td>56.8 (56.7; 57.7)</td>
<td>9.9 (9.6; 10.1)</td>
<td>1.7 (0.6; 2.6)</td>
</tr>
<tr>
<td>annual</td>
<td>5</td>
<td>58.7 (58.6; 58.9)</td>
<td>10.1 (9.9; 10.4)</td>
<td>1.7 (0.7; 2.7)</td>
</tr>
<tr>
<td>Scenario 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve adherence to treatment:</td>
<td>1</td>
<td>53.3 (53.1; 53.5)</td>
<td>9.1 (8.8; 9.4)</td>
<td>2.7 (1.6; 3.8)</td>
</tr>
<tr>
<td>SVR rate likewise in clinical trials (SVR=90%)</td>
<td>3</td>
<td>56.6 (56.5; 56.8)</td>
<td>9.6 (9.4; 9.9)</td>
<td>3.2 (2.2; 4.2)</td>
</tr>
<tr>
<td>δ=0.5 years</td>
<td>5</td>
<td>58.5 (58.3; 58.7)</td>
<td>9.8 (9.5; 10.1)</td>
<td>3.2 (2.4; 4.3)</td>
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<tr>
<td>Scenario 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improve treatment rate:</td>
<td>1</td>
<td>45.6 (45.4; 45.8)</td>
<td>7.8 (7.6; 8.0)</td>
<td>15.8 (14.7; 16.3)</td>
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<tr>
<td>γ=10%/year</td>
<td>3</td>
<td>50.5 (50.3; 50.7)</td>
<td>8.4 (8.2; 8.7)</td>
<td>14.6 (13.7; 15.4)</td>
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<td>Scenario 5</td>
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<td></td>
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<tr>
<td>Improve treatment rate:</td>
<td>1</td>
<td>34.1 (33.9; 34.3)</td>
<td>6.1 (5.9; 6.3)</td>
<td>29.6 (28.9; 30.2)</td>
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<tr>
<td>improvement</td>
<td>3</td>
<td>41.4 (41.2; 41.6)</td>
<td>7.3 (7.1; 7.5)</td>
<td>27.2 (26.3; 28.0)</td>
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<tr>
<td>δ=0.5 years</td>
<td>5</td>
<td>45.7 (45.5; 45.9)</td>
<td>7.8 (7.6; 8.1)</td>
<td>24.3 (23.6; 25.1)</td>
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<td>Scenario 6</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Combined scenario</td>
<td>1</td>
<td>26.9 (26.7; 27.0)</td>
<td>4.9 (4.8; 5.1)</td>
<td>39.3 (38.8; 39.8)</td>
</tr>
<tr>
<td>scenario 2,3 and 5</td>
<td>3</td>
<td>35.7 (35.5; 35.8)</td>
<td>6.4 (6.2; 6.6)</td>
<td>34.8 (34.2; 35.4)</td>
</tr>
<tr>
<td>Scenario 2,3 and 5</td>
<td>5</td>
<td>41.2 (41.4; 41.4)</td>
<td>7.2 (7.1; 7.4)</td>
<td>31.6 (30.8; 32.4)</td>
</tr>
</tbody>
</table>

TUAD01 Innovations in Methods of Implementation Science

TUAD0101
Where to strengthen care: model-based triangulation of trends in the HIV care cascade

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Background: The HIV ‘cascade of care’ comprises a framework for identifying priority areas for improvement of HIV services. In sub-Saharan Africa, the cascade has yet to be characterized nationally due to challenges such as distinguishing first initiation of care from re-initiation absent unique patient identifiers. Lacking direct data characterizing the cascade, we hypothesize that national-level temporal trends in care can be triangulated based on epidemiological, actuarial, and programmatic information fed into a quantitative model.

Method: We simulated the HIV care cascade in South Africa using an epidemiological model calibrated to age- and gender-specific HIV prevalence and mortality, national population dynamics, and monitoring data from the public-sector HIV treatment program. Data were available up to 2012, beyond which we assumed continuation of current trends in scale-up. HIV-associated mortality in the model was classified into those dying without initiating care, having initiated late (CD4<200), lost to follow-up (LTFU) after previous initiation, or currently in care.

Results: Failure to initiate care constituted the largest but most rapidly declining category of HIV mortality, predicted to decline from 47% of HIV-associated deaths in 2015 to 37% in 2020. Late initiation was the second-largest and declined more slowly because increasing CD4 counts at initiation were partially offset by growing numbers of patients initiating care. LTFU was the third-largest but the most rapidly-growing category of HIV mortality. Programmatic data about re-initiation of care is lacking, but under the assumption that half of patients LTFU will re-initiate care, deaths LTFU were not expected to surpass deaths due to late initiation by 2020. Those receiving care constituted 3% of HIV-associated deaths, mostly among those receiving treatment rather than in pre-ART care. This proportion remained constant over time because the growing population on treatment was offset by improvements in treatment quality, such as expansion of virological monitoring and availability of second-line regimens.

[Figure: HIV mortality along the care cascade]
Conclusions: More data are required to fully characterize the spatial heterogeneities and dynamics of the care cascade. Nevertheless, trends revealed by model-based triangulation were consistent with findings in well-studied populations such as demographic surveillance sites. Failure to access care remains the largest but most rapidly declining category of HIV mortality.

TUAD0102
Optimizing tools for measuring short-term antiretroviral therapy adherence from pharmacy refill data to predict virological outcomes in resource-limited settings

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Background: Estimates of adherence to antiretroviral therapy (ART) using pharmacy refill data have outperformed self-report and can identify patients at risk for virologic failure, especially in settings where viral load testing is limited. Uncertainty exists about the best method to estimate adherence using pharmacy refill data and the optimal duration of data to predict virologic outcomes.

Methods: We identified individuals over 18 on first and second line ART from a national private sector (AfA for AIDS) and regional public sector (Khayelitsha) program. The area under (AUC) the receiver operating characteristic (ROC) curves for virologic suppression (VSS) (viral load <400 copies/mL) was used to compare three short-term adherence estimate methods: 1) ‘crude’ - refills divided by months, 2) ‘average’ - days ART dispensed plus unused ART from prior dispensing divided by interval duration, and 3) ‘gap’ - interval duration less the number of days without ART coverage, divided by interval duration.

The ‘gap’ method is different to the ‘average’ method as it does not allow the adherence estimate to be artificially increased by additional ART dispensed after a possible ‘gap’ in ART coverage. The interval for pharmacy refill varied from 3 to 12 months.

Results: We included 56,472 individuals from the private program (median 1.7 years, 65% female) and 24,466 from the public program (median 2.1 years, 65% female). The ‘gap’ method consistently outperformed the other 2 methods (see figure 1). In the public program, the ‘gap’ method was 12% less potent due to significant data capture errors. Longer pharmacy refill intervals outperformed shorter intervals (‘gap’ ROC 0.837 [12 months], 0.812 [3 months]) in the more powered private dataset. When further separated by regimen line, the ‘gap’ method for second line was superior but the ROC AUCs estimated did not vary by the pharmacy refill interval. We identified possible cut-points for virological failure (VLS>1000 copies/mL) in the private program: 83% and 72% for first and second line therapy, respectively.

Conclusions: Adherence measures that identify gaps in pharmacy data were superior and consistent across programs and regimen lines and could be used to identify people at risk of poor ART outcomes.

TUAD0103
Estimating national coverage of antiretroviral therapy among HIV-infected persons using multiple methods, Kenya 2012

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Background: Accurate estimates of antiretroviral therapy (ART) coverage are needed to track progress towards global targets from the Joint United Nations Programme on HIV/AIDS (UNAIDS) which aim for 90% of HIV+ persons on ART by 2020. ART coverage is reported annually to UNAIDS using mathematically-modeled estimates of the number of HIV+ persons eligible for ART based on an assumed distribution of CD4 counts in the HIV+ population and the number of persons receiving ART in health facilities. We compared ART coverage reported to UNAIDS with coverage estimated from a nationally representative survey in Kenya using two independent methods.

Methods: The 2012 Kenya AIDS Indicator Survey was a population-based household survey of persons aged 15-64 months-64 years conducted from 10/2012-2013. Interviews collected data on ART use for persons reporting HIV+ status. Blood samples were tested for HIV, and HIV+ samples tested for ART by High Performance Liquid Chromatography coupled to Tandem Mass Spectrometry. We estimated and compared ART coverage among HIV+ persons aged 15-64 years based on: 1) routine program monitoring data; 2) self-report; and 3) biological confirmation of ART eligibility in the survey was defined as: CD4 count 350 cells/mm3 or having active tuberculosis. Estimates were weighted to adjust for survey design and non-response.

Results: According to ART program monitoring data, 549,000 adults were receiving ART in 2012, covering 39.6% (confidence interval [CI] 36.8-43.0) of HIV+ persons and 78.3% (CI 74.8-82.5) of those ART-eligible. Of 11,620 survey respondents, 548 (4.5%) were HIV+ and 559 (9.8%) had samples available for ART testing. Among those, 42.5% (CI 44.7-47) tested positive for ART while 34.2% (CI 32-1-39) reported receiving ART. Based on biological confirmation of ART, coverage among ART-eligible persons was 71.0% (CI 63.2-78.5) or 444,000 persons while coverage based on self-report was 63.3% (CI 53.2-73.8) or 374,000 persons.

Conclusions: Self-report underestimated ART coverage by 70,000 persons while program data may overestimate coverage by up to 105,000 persons. Until monitoring systems for the national ART program are strengthened and mathematical models are updated to reflect actual need for ART, surveys that provide biological confirmation of ART may be required to accurately track national estimates of ART coverage.

TUAD0104
Crowdsourcing to spur first-time HIV testing among men who have sex with men and transgender individuals in China: a non-inferiority pragmatic randomized controlled trial

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Background: Improving first-time HIV testing among key populations, especially young men who have sex with men (MSM) and transgender (TG) individuals, is a global health priority. However, most HIV testing campaigns do not reach untested populations and have minimal input from key populations. Crowdsourcing, the process of taking a task performed by an individual and opening it to a large group in the form of a contest, may enhance HIV testing interventions. We organized a non-inferiority, pragmatic randomized controlled trial to compare first-time HIV testing rates among MSM and TG individuals who received either a crowdsourced HIV test promotion intervention or a health marketing intervention.

Methods: Participants were recruited through three large MSM web portals in China. We randomly assigned 721 MSM and TG individuals (≥16 years old, never before tested for HIV) to one of two video interventions. The crowdsourced video was developed using an open contest and formal transparent judging while the evidence-based health marketing video was designed by experts. We followed up four weeks post-intervention via text message to assess HIV test uptake. Descriptive statistics and sensitivity analyses for missing data were carried out to as-
The Effect of a Population-Based Health Department Data-to-Care Intervention to Increase HIV Care Engagement and Antiretroviral Use: A Controlled Evaluation

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Background: The US CDC promotes the use of HIV surveillance data to identify out-of-care persons and return them to care (“Data-to-Care”).

Methods: We used stepped wedge cluster randomization to institute a Data-to-Care program in Seattle-King County, Washington, USA. We attempted to provide the intervention to all eligible persons in IA as soon as possible, by either a nurse or a trained peer educator (the cluster). Eligible persons had no CD4 or viral load (VL) reported for ≥12 months or 2 VL >500 and CD4 <350 at last report. Program staff contacted patients to offer assistance relinking to HIV care and treatment. The primary study outcome was time to viral suppression (first VL <200 reported to surveillance), starting from the program implementation date. The secondary outcome was care reengagement (first VL or CD4 reported). We used Cox Proportional Hazards to compare outcomes during control periods (before initiation of each case’s provider cluster) to intervention periods (after initiation of the cluster). We censored cases at the time of ascertaining of relocation or death, or end of the observation period. The intention-to-treat (ITT) analysis included all eligible cases, the modified ITT (mITT) analysis excluded cases of ascertainment of relocation or death, or end of the observation period. The intention-to-treat (ITT) analysis included all eligible cases, the modified ITT (mITT) analysis excluded cases found to have died or moved.

Results: The ITT and mITT analyses included 1008 and 824 persons, respectively (Figure). The ITT analysis included all eligible cases; the modified ITT (mITT) analysis excluded cases of ascertainment of relocation or death, or end of the observation period. The intention-to-treat (ITT) analysis included all eligible cases; the modified ITT (mITT) analysis excluded cases found to have died or moved.

The effect of a Population-based Health Department Data-to-care Intervention

Results:

ITT Analysis (N=1008) 30% 1.27 (0.99 - 1.60)
mITT Analysis (N=824) 37% 1.18 (0.83 - 1.68)
No labs for 12 months, Relinkage
mITT Analysis (N=276) 41% 0.99 (0.74 - 1.34)
No labs for 12 months, Viral Suppression
mITT Analysis (N=276) 28% 0.79 (0.40 - 1.55)
Last VL<500 in past year, Viral Suppression
mITT Analysis (N=548) 41% 1.4 (0.96 - 2.19)

Conclusion: We provide proof of principle for using crowdsourcing as a tool to enhance community engagement and improve HIV testing services. Crowdsourcing may be a cost-effective method to optimize HIV interventions, especially interventions targeting young key populations.

TUAD0105LB

The Effect of a Population-Based Health Department Data-to-Care Intervention to Increase HIV Care Engagement and Antiretroviral Use: A Controlled Evaluation

TUAD02 Optimizing PMTCT Programme Implementation

TUAD0201

Retaining mother-baby-pairs in care and treatment: the mothers2mothers Mentor Mother Model

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Background: Retaining HIV-positive mothers and their babies in PMTCT care is critical for the elimination of mother-to-child-transmission. mothers2mothers is a peer education and psychosocial support programme operating in six Option B+ countries in Africa. m2m Mentor Mothers are women living with HIV who have recently experienced PMTCT. They are trained and employed to support other mothers and their families through the same process. In 2014 the m2m Mentor Mother Model implemented under the STAR-EC Programme in Uganda was evaluated externally in order to investigate whether maternal and infant PMTCT outcomes and maternal psychosocial well-being outcomes were associated with exposure to m2m Mentor Mothers.

Methods: A quasi-experimental matched area comparison design was used. PMTCT outcomes were measured retrospectively among 2,282 mother-baby-pairs who accessed PMTCT services between January 2011 and March 2014 in 31 intervention facilities (where m2m Mentor Mothers provided peer education and psychosocial support) and 31 matched control facilities (where no peer education and psychosocial support were provided). Furthermore, 796 pregnant women and new mothers accessing PMTCT between June 2012 and March 2014 across both study arms participated in facility based Psychosocial Wellbeing surveys. Bivariate and multivariate inferential statistical analysis was done using STATA 12. Propensity Score Matching was used to investigate the net effect attributable to the m2m standard-of-care.

Results: Comparison of the intervention and control sites indicated that clients in m2m-supported health facilities showed improved uptake of PMTCT services (see Table 1).
TUAD0202

Effectiveness of conditional cash transfers to increase retention in care and adherence to PMTCT services: a randomized controlled trial

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Background: Novel strategies are needed to increase retention in, and adherence to, maternal and infant care and health-seeking behaviour of HIV-positive pregnant women and mothers. The m2m model has developed and refined a simple, scalable, adaptable and sustainable model of peer education and psychosocial support that improves uptake of PMTCT services and addresses the challenges facing HIV-positive pregnant women and mothers. The evidence shows that m2m’s psychosocial peer support helps HIV-positive pregnant women and new mothers and their families cope more effectively with HIV and enhances their psychosocial wellbeing. Integration of peer education and psychosocial support into clinical PMTCT standard-of-care is recommended.

Methods: Newborns diagnosed with HIV-infected women, ≤32 weeks pregnant, were recruited at antenatal care clinics in Kinshasa, Democratic Republic of the Congo, and randomly assigned in a 1:1 ratio to an intervention group that received compensation on the condition they attend scheduled clinic visits and accept offered PMTCT services ($5 plus $1 increment at each subsequent visit) or a control group that received usual care. Outcome assessed included: retention in care measured by loss-to-follow-up (LTU), and adherence to PMTCT services (attend all scheduled clinic visits and accept proposed services) through six weeks postpartum.

Results: Between April 2013 and August 2014, 612 potential participants were identified, 545 were screened, and 433 were enrolled and randomized (Figure 1). Participants in the two groups had similar characteristics at baseline. As of January 5, 2015, 407 had completed their six weeks postpartum visit or were no longer in care. Analysis of complete data showed that by six weeks postpartum, a lower proportion of participants in the intervention group (17.7%) than the control group (27.0%) were LTU (unadjusted odds ratio (OR), 0.58; 95% confidence interval (CI), 0.36-0.94). Similarly, a higher proportion of participants in the intervention group (70.8%) than the control group (64.9%) attended all scheduled visits and accepted proposed services (OR=1.91, 95% CI, 1.21-2.87). Results were similar after adjusting for maternal status, age, and education (Table 1).

Conclusions: Among newly diagnosed HIV-infected women, small, incremental cash incentives resulted in increased retention along the PMTCT cascade and adherence to available services. The overall effects of these incentives on HIV-free survival and cost-effectiveness warrant further investigation.

TUAD0203

Using the critical path for rapid expansion and optimization of a PMTCT program towards elimination of new HIV infections in children

R. Musarandega1, A. Mahovina1, J. Robison1, E. Tumbare1, P. Dave Sen1, A. Hakobyan1, A. Mushavi1


Background: Elizabeth Glaser Pediatric AIDS Foundation (EGPFAF) partnered with the Children’s Investment Fund Foundation (CIFF) and Zimbabwe Ministry of Health and Child Care (MOHCC) to roll out the WHO 2010 and later 2013 PMTCT guidelines. EGPFAF, MOHCC...
and CIFF developed a “critical path” with a prioritised set of performance indicators, with popu-
lation-based targets, that are the main drivers of impact. The indicators are reviewed quarterly,
as they largely draw on routine monitoring data. If performance is lagging in a particular indica-
tor, a diagnosis is undertaken to identify the reason, and corrective action explored. Critical path
indicators and results for quarter 2, 2012 are in Figure 1. The EGPAF-CIFF goal was to reduce
mother-to-child transmission (MCTT) of HIV from about 25% in 2009 to less ~9% by 2015.

**Methods**: Health facilities were supported to implement the guidelines through training
and mentoring during site visit supports, among other assistance. PMTCT data were collected
quarterly from all supported health facilities, and performance of each indicator compared with
established targets during data-driven program reviews held by EGPAF, partner program of-
icers and MOHCC district staff. Reasons for under-performance and improvement strategies
were identified and implemented in subsequent quarters through mentoring and coaching of
health facility staff to improve service provision and patient follow-up.

**Results**: By October 2014, EGPAF was supporting 1,480 out of 1,560 sites to provide WHO
2013 PMTCT guidelines (Option B+). Service uptake in all critical path indicators increased
significantly (p<0.001) from 2009/10 to 2013/14 as follows: ANC bookings 68% - 100%, HIV
testing 85% - 98%, ART prophylaxis 32% - 91%, CD4 testing 41% - 67%, ART initiation for
pregnant mothers 18% - 85%, EID 3% - 71%, mothers’ adherence on ARV prophylaxis 34% -
77%. The national MCTT rate fell to ~9.0% in 2013.

**Conclusions**: Through use of the critical path cascade, EGPAF and CIFF supported the
MOHCC to achieve a rapid scale-up of PMTCT services. There is a need to maintain cover-
age and quality PMTCT services and ensure that children needing ART are actively identified,
started and maintained on treatment. EGPAF is intensifying support in these new areas.

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**TUAD0205**

**Evaluation of early experience implementing Option B+ in the northwestern and southwestern
regions of Cameroon 2013-2014**

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Public Health/US Centers for Disease Control and Prevention, Douala, Cameroon, 4Ministry of
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**Background**: The Cameroon Ministry of Public Health began implementation of life-long
antiretroviral treatment (ART) for HIV-positive pregnant and breastfeeding women (Option B+)
in 2013. This evaluation assesses early ART acceptability, retention, and mother-to-child-trans-
mission. Results will guide subsequent phases of the national rollout.

**Methods**: From October, 2013 - June, 2014, we recruited participants from 22 purposefully
selected health facilities in the Northwest and Southwest Regions for an observational cohort
evaluation. HIV-positive pregnant and breastfeeding women, not currently on antiretrovirals
(prophylaxis or treatment), were eligible to participate in the assessment. Option B+ was offered
to all eligible participants and a descriptive analysis was performed.

**Results**: Of 1,287 HIV-positive pregnant or breastfeeding women identified, 669 (53%)
were eligible for the evaluation. Of those who were offered Option B+, 666 (98%) accepted life-
long ART and 3 (<1%) accepted ART only during pregnancy and breastfeeding. As of October
2014, 569 (85%) women remained alive and on treatment, 8 (1.2%) died, 17 (3%) discontinued
ART and 34 (5%) were lost to follow-up. 56 (8%) did not return for their first refill after ART
initiation; this percentage varied from 2% to 8% between facilities. The six month retention for
currently on antiretrovirals (prophylaxis or treatment), were eligible to participate in the assessment. Option B+ was offered
to all eligible participants and a descriptive analysis was performed.

**Results**: Of 1,287 HIV-positive pregnant or breastfeeding women identified, 669 (53%)
were eligible for the evaluation. Of those who were offered Option B+, 666 (98%) accepted life-
long ART and 3 (<1%) accepted ART only during pregnancy and breastfeeding. As of October
2014, 569 (85%) women remained alive and on treatment, 8 (1.2%) died, 17 (3%) discontinued
ART and 34 (5%) were lost to follow-up. 56 (8%) did not return for their first refill after ART
initiation; this percentage varied from 2% to 8% between facilities. The six month retention for
women 18% - 85%, EID 13% - 71%, mothers’ adherence on ARV prophylaxis 34% -
77%. The national MCTT rate fell to ~9.0% in 2013.

**Conclusions**: Following adoption of Option B+, ART attrition in Haiti was higher than
that described in published reports from other resource-limited settings. Early, sustained, and
tailored interventions are urgently needed to reduce ART attrition in Haiti, particularly among
pregnant women.

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**TUAD0204**

**Attrition from antiretroviral treatment services among pregnant and non-pregnant patients
following adoption of Option B+ in Haiti**

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Public Health/US Centers for Disease Control and Prevention, Douala, Cameroon, 4Ministry of
Health, Department of Disease Control and Prevention, Division of Global HIV/AIDS, Atlanta, United States. Presenting author email: vie5@cdc.gov

**Background**: Attrition from antiretroviral treatment (ART) services is an important deter-
minant of HIV treatment outcomes. This study assessed factors associated with attrition among
pregnant and non-pregnant patients initiating ART following adoption of Option B+ (universal
ART eligibility for HIV-infected pregnant women) in October 2012 in Haiti.

**Methods**: Electronic medical records of all patients initiated on ART from October 2012
to August 2014 at 73 health facilities (HF) from 8 of 10 Haitian administrative departments were
analyzed. Within a survival analysis framework, attrition was defined as the first instance
of failure to attend a HF visit for 90 days after a missed clinical or pharmacy-dispensing appoint-
ment, or an officially-recorded program discontinuation, whichever came first. Known transfers
to alternative HF were treated as censored observations, not attrition cases. ART interruptions
during the first three months of ART were deemed Option B+ cases. Kaplan-Meier method and Cox proportional hazards regression, stratified by HF, were used to determine attrition and associated factors.

**Results**: Among 17,084 patients who initiated ART, 7,719 (45.2%) were non-pregnant
women, 5,825 (34.7%) were men and 3,445 (20.2%) were pregnant women. At 6 months, attrition was 15.8% (95% confidence interval (CI): 14.8-16.4) for non-pregnant women, 17.0% (16.1-18.0) for men, and 30.1% (28.5-31.7) for pregnant women. At 12 months, attrition was 31.8% (95% CI: 30.6-33.0), 34.5% (33.2-35.8), and 50.8% (49.5-52.6) respectively. Adjusted
for patient-level factors and HF, attrition risk was 63% higher among pregnant women and 16% higher among men, compared to non-pregnant women (p<0.001). Significant protective factors included: receiving psychosocial counseling (hazard ratio (HR): 0.84, p<0.001); cotrimoxazole prophylaxis (HR: 0.83, p<0.001); tuberculosis treatment (HR: 0.88, p<0.001) before ART initia-
tion; having an HIV-positive household member (HR: 0.80, p<0.05); living in the same com-
mune as the HF (HR: 0.94, p<0.05), and greater duration of pre-ART enrollment (HR: 0.99 for
each 30-day increase, p<0.001).

**Conclusions**: Following adoption of Option B+, ART attrition in Haiti was higher than
that described in published reports from other resource-limited settings. Early, sustained, and
tailored interventions are urgently needed to reduce ART attrition in Haiti, particularly among
pregnant women.
TUAD0206LB
Improving early ANC attendance through community engagement and dialogue: project ACCLAIM in three African countries

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Background: Timing of first antenatal clinic (ANC) attendance in sub-Saharan Africa averages 24-25 weeks; however, to effectively prevent HIV transmission to infants, earlier ANC attendance and initiation of antiretroviral therapy are necessary. Advancing Community Level Action for Improving Maternal and Child Health (MCH)/Prevention of Mother-to-child HIV Transmission (PMTCT), known as ACCLAIM, a three-arm randomized trial in 45 clusters across Swaziland, Uganda and Zimbabwe, aims to improve access, uptake and retention in MCH/PMTCT services.

Methods: The study randomized clusters and evaluated three interventions:
1) Community Leader Engagement (participation in the Community Leaders Institute, mentoring to engage in community action);
2) Community Days and dialogues (community event with structured dialogues on MNCH/PMTCT, and provision of health services); and
3) Male and Female MCH Classes (set of four structured sessions led by peer facilitators).

This sub-study analyzed early ACCLAIM results on earlier access to ANC services. Baseline gestational age (GA) data at first ANC visit were collected from health facilities before implementation and quarterly after implementation. We compared proportions of women attending ANC during first half of pregnancy (≤20 weeks gestation) at baseline and 6-12 months after interventions.

Results: 277 trained community leaders held >7,000 community meetings and engaged >27,000 individuals in dialogues at Community Days, identifying and addressing barriers, misperceptions and harmful gender norms. The proportion of women attending ANC ≤20 weeks gestation across the three countries increased by 36% from baseline; this trend was significant across the quarters observed (p< 0.0001). Attendance during the first trimester (≤12 weeks) also increased, from 11.7% (84/719) to 14.1% (102/721) in Swaziland (p=0.163), and from 3.4% (24/705) to 12.0% (97/809) (p<0.0001) in Zimbabwe (Uganda data not available). Community dialogues actively focused on the benefits of early ANC and addressed norms of waiting until the woman “shows” before seeking ANC.

Gestational age at first ANC

<table>
<thead>
<tr>
<th></th>
<th>Baseline July-September 2013 (January-March 2014, Uganda)</th>
<th>6-12 months of Implementation October-December, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=5071</td>
<td>n=4799</td>
</tr>
<tr>
<td>&lt;20 weeks</td>
<td>1532 (30.2%)</td>
<td>1975 (41.2%)</td>
</tr>
<tr>
<td>p-value</td>
<td>p &lt;0.0001</td>
<td>p &lt;0.0001</td>
</tr>
<tr>
<td>21+ weeks</td>
<td>3539 (69.8%)</td>
<td>2824 (58.8%)</td>
</tr>
</tbody>
</table>

Conclusions: In our study, community based interventions have resulted in significant greater than one-third increase in ANC ≤20 weeks gestation in three African countries. Ongoing data analysis will provide data on the full potential of open community dialogues by trained community leaders to change community norms and health-seeking behaviors such as early access to ANC and MCH/PMTCT services.
Tuesday 21 July
Oral Poster Discussions

TUPDA01 Restricting the Virus inside and out

Association between CSF and peripheral markers of immune-activation/inflammation and elevated intrathecal HIV-RNA levels in a cohort of HIV-infected antiretroviral-naive individuals

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Background: Since the association between high HIV-RNA replication in central nervous system and immune activation/inflammation has not yet been established, we aimed to investigate the inflammatory milieu in CSF and peripheral blood of HIV+ antiretroviral-naive subjects with high CSF viremia compared to those with low CSF viremia, in the attempt to identify biomarkers that might be used as diagnostic tools.

Methods: 150 HIV+ cART-naïve pts underwent lumbar puncture for CSF HIV-RNA quantification and were tested for peripheral T-cell immune-phenotypes (CD38/CD45RA/CD45R0/CD127 on CD4/CD8, flow cytometry). In a subgroup of 64 patients CNS/PBNA Tnf-a, IL-6, sCD14, IFNg, MCP-1, IP-10, neopterin, S100beta (ELISA, Luminex) were measured. We defined: high CSF HIV-RNA ≥10.000.000cp/mL (H-CSF), low CSF HIV-RNA < 10.000.000cp/mL (L-CSF), viral escape (VE) CSF/plasma HIV-RNA >1 log10, p<0.05. Statistical analyses: Chi-square, Mann Whitney test and univariate/multivariate logistic regression.

Results: 48/150 pts (32%) resulted H-CSF. VE was found in 5/150 pts (3%). No differences in gender, risk exposure categories, viral hepatitis co-infections, HIV duration, age and CD4+ nadir were found between L-CSF and H-CSF. H-CSF pts displayed higher plasma HIV-RNA (p=0.032) and VE (p=0.018). The univariate logistic regression showed that H-CSF are characterized by lower central memory CD127+CD4% (p=0.026) and naïve CD8+CD45RA% (p=0.017) and higher activated CD8+CD38% (p=0.08) and memory activated CD8+CD3+CD45R0% (p=0.021). In multivariate analysis, lower proportion of naïve CD4+ Tcells, independently associated with higher CSF Viral Load, might be included in a panel of biomarkers useful to identify patients at major risk of high CSF replication, if confirmed by larger studies.

Conclusions: The low percentage of naïve CD4+ Tcells, independently associated with higher CSF Viral Load, might be included in a panel of biomarkers useful to identify patients at major risk of high CSF replication, if confirmed by larger studies. Besides, the finding of higher peripheral and CSF activation/inflammation in H-CSF group indicate a more complex scenario, where both districts cooperate in maintaining the inflammation within CNS, possibly affecting neuronal function, and therefore deserves further investigations.

TUPDA0102 Receptor mediated endocytosis directs subcellular trafficking and TLR signaling of HIV-1 in plasmacytoid dendritic cells

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Background: Dysregulated type I interferon (IFN) responses contribute to immunopathology in chronic HIV infection, therefore it is critical to dissect the molecular mechanisms underlying HIV-induced IFN production. We examined the spatiotemporal regulation of IFN secretion by plasmacytoid dendritic cells (pDC), specialized cells that secrete high levels of IFN upon HIV recognition through TLR7.

Methods: Human pDC were purified from peripheral blood and were stimulated with GFP labeled: HIV, HIV pseudotyped with influenza hemagglutinin envelope (HA-HIV), and PR8 influenza. TLR7 expressing HEK NF-kB reporter cells, stably transduced with CD4 mutants with cytoplasmic tails directing trafficking to early endosomes (EE) or lysosomes, were activated with HIV and controls. Analysis included ELISA, flow cytometry and fluorescent microscopy. Cells were imaged using the Advanced Precision imaging system and images were analyzed using ImageJ.

Results: We compared the effects and spatiotemporal trafficking in pDC of HIV, influenza, and HA-HIV. We demonstrate that HA-HIV strongly activates maturation pathways (NF-κB) in pDC and traffics rapidly to lysosomes, similarly to influenza but unlike HIV, suggesting that viral envelope directs trafficking and resultant phenotype of sRNA virions in pDC. We studied HIV-CD4 interactions in a HEK reporter cell system expressing TLR7 with functional NF-κB signaling, which we co-transfected with CD4 mutants whose cytoplasmic tails either directed CD4 trafficking to EE or lysosomes. We show that wild type (WT) CD4 localizes to EE, whereas CD4 mutated with either DE-205 or LAMPI tail localizes to lysosomes. HIV traffics to EE in WT CD4 expressing TLR7 HEK cells and fails to stimulate NF-κB signaling, whereas HIV traffics to lysosomes in DE-205 or LAMPI mutated CD4 expressing TLR7 HEK cells as a result of NF-κB signaling, suggesting that rerouting of HIV (via CD4) to lysosomal compartments triggers NF-κB rather than IFN pathways.

Conclusions: CD4 receptor mediated endocytosis targeting early endosomes determines HIV intracellular localization and observed interferon-producing phenotype of HIV-activated pDCs.

Tuesday 21 July
Late Breaker Posters

TUPDA0103 HIV-1 Vpu exploits the crosstalk between BST2 and the ILT7 receptor to inhibit innate sensing of infected T cells by plasmacytoid dendritic cells

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Background: Plasmacytoid dendritic cells (pDCs) constitute a major source of type-I interferon (IFN-I) production during acute HIV infection. Their activation results primarily from IFN-I mediated sensing of HIV-infected cells. BST2/Tetherin, a G protein-coupled receptor with mysterious functions, is a major HIV-1 Vpu target that suppresses HIV release by cross-linking virions at the cell-surface. HIV-1 overcomes BST2 antiviral activity through Vpu, which partially downregulates BST2 cell-surface expression. Apart from its direct antiviral activity, BST2 was shown to bind to the ILT7 pDC-specific inhibitory receptor and repress IFN-I production by activated pDCs. Here, we examined whether Vpu-mediated BST2 antagonism could modulate innate sensing of HIV-infected cells by pDCs.

Methods: PBMCs or isolated pDCs were co-cultured with T cells infected with wild type or Vpu-defective HIV-1 and innate sensing was evaluated by monitoring IFN-I production. BST2-mediated activation of ILT7 signaling was analyzed using an ILT7-reporter cell system.

Results: We show that Vpu attenuates the production of IFN-I during sensing of HIV-1 infected cells by pDCs. This control of innate sensing by Vpu could be prevented by: 1) depletion of BST2 from infected donor cells; 2) depletion of ILT7 in pDCs; or 3) blocking BST2/ILT7 interaction using anti-BST2 antibodies or soluble ILT7. Using a BST2 mutant that cannot cross-link budding virions but yet retains the capacity to repress IFN-I production by pDCs, we show that virus trapping on infected donor cells prevents BST2 from eliciting an inhibition of IFN-I production by pDCs. Interestingly, confocal microscopy analysis of virus producing cells reveals that in presence of Vpu there is a residual pool of surface BST2, which is excluded from viral budding sites and thus potentially accessible for interaction with ILT7 on pDCs. Lastly, using an ILT7 reporter cell system, we provide evidence that Vpu-mediated BST2 antagonism modulates the levels of available surface BST2 capable of engaging and activating ILT7 upon cell-to-cell contact.

Conclusions: Overall, this study sheds light on a novel Vpu-BST2 interaction that allows HIV to control innate sensing of infected cells by pDCs via the negative signaling exerted by the ILT7-BST2 pair. This mechanism of innate immune evasion is likely to be critical for efficient viral dissemination and establishment of viral reservoirs during acute infection.
**TUPDA0104**  
**HIV-1 transcriptional silencing caused by TRIM22 inhibition of Sp1 binding to the promoter**  
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**Background:** HIV-1 latency is a multifactorial process resulting by the interplay between cellular transcription factors and the viral regulatory protein Tat. We have previously described the interferon-inducible restriction factor TRIM22 as a suppressor of basal and phorbol ester-dependent LTR-mediated transcription independently of NF-kB and of Tat/TAR interaction. As basal HIV-1 transcription is mainly driven by the binding of the cellular transcription factor Sp1, we have investigated whether TRIM22 could interfere with such Sp1-driven transcriptional activation of HIV-1 LTR.

**Methods:** 293T cells, lacking of endogenous TRIM22, were co-transfected with a TRIM22-expressing plasmid together with reporters vectors driven by the HIV-1 promoter containing either wild-type or mutated Sp1 binding sites or lacking of either one or two sites; reporter expression was assessed 48 hours post-transfection. Endogenous TRIM22 was knocked-down (KD) in SupT1 cells that were subsequently infected with HIV-1 molecular clones engineered to be dependent on an incorporated Tet-On gene expression system for activation of transcription while being independent of Tat/TAR interaction. Virus replication was monitored up to 32 days post-infection. Cells extracts from TRIM22-transfected 293T was subjected to:

- i) immunoprecipitation,
- ii) Western blotting,
- iii) DNA pull-down and;
- iv) Chromatin Immunoprecipitation (ChIP).

**Results:** TRIM22 overexpression suppressed Sp1-driven transcription of HIV-1, as its inhibitory activity was lost in the absence of Sp1 binding sites. In contrast, TRIM22 KD increased the replication of infectious clones that were exclusively dependent upon Sp1 binding to the promoter. Furthermore, immunoprecipitation experiments showed that TRIM22 and Sp1 can interact physically although this interaction does not affect the level of expression of endogenous Sp1 or its phosphorylation state. TRIM22 did not directly bind to the HIV-1 LTR by either in vitro pull-down experiments or in ChIP experiments, however TRIM22 expression drastically prevented the binding of Sp1 to the HIV-1 LTR.

**Conclusions:** TRIM22 inhibits Sp1-dependent transcription by interacting with Sp1 and preventing its binding to the HIV-1 LTR. Our findings bear relevance for the discovery of new therapeutic approaches aimed at targeting the reservoir of infected cells laterally infected with replication-competent proviruses.

**TUPDA0105**  
**Polymorphisms in TRIM22 are associated with HIV-2 acquisition and disease progression**  
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**Background:** Tripartite motif-containing protein 22 (TRIM22) is an E3 ubiquitin ligase with activity against HIV-1; high levels of TRIM22 expression are associated with reduced viral set-point following acute HIV-1 infection. The TRIM22 gene has been greatly shaped by positive selection, and its expression is sensitive to retroviral infection, Type 1 and Type 2 interferon. The mechanism by which TRIM22 exerts its antiviral effect is poorly understood. Further, the impact of TRIM22 genetic variation in the context of HIV-2 disease is unknown.

**Methods:** To test the hypothesis that TRIM22 expression antagonises HIV-2 infection and that polymorphisms in TRIM22 significantly modify this effect, we conducted three studies. Firstly, TRIM22 was genotyped in sixty HIV-2 patients, comparing viral controllers and rapid progressors, and a similar number of age and sex matched controls from the same community in rural Guinea-Bissau. Using regression modelling, polymorphisms were analysed alongside immunological and virological data. Secondly, a model of TRIM22 was constructed using computational methods and the polymorphisms observed in vivo were mapped and analysed. Finally, baseline cDNA and protein levels of TRIM22 from C8166 cells were measured using quantitative RT-PCR and flow cytometry respectively. The cells were subsequently infected with HIV-2, and measurements repeated to determine whether TRIM22 gene expression is sensitive to HIV-2 infection.

**Results:** The data show that TRIM22 polymorphisms rs1063303 and rs7935564 are significantly associated with HIV-2 acquisition and disease progression. Further, polymorphisms observed in vivo cluster in functional regions that our modelling studies suggest may interact with the HIV-2 capsid. Finally, we show that TRIM22 gene expression is upregulated in the presence of HIV-2, in a lymphobocyte cell line.

**Conclusions:** Taken together, our data show that TRIM22 expression is sensitive to HIV-2 infection and that polymorphisms in TRIM22 genes are significantly associated with HIV-2 acquisition and disease progression. Further the study has computationally characterised positively selected polymorphisms observed in vivo and the data show that these polymorphisms have the potential to significantly alter protein structure and function. These data provide the first analysis of TRIM genetic variation in the context of HIV-2 infection.

**TUPDA0106LB**  
**The negative checkpoint receptor TIGIT marks exhausted T cells during SIV infection and correlates with SIV disease progression**  
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**Background:** During chronic-viral infections, high antigenic load continually stimulates T cells resulting in T cell exhaustion. Exhausted T cells increase expression of negative checkpoint inhibitors such as PD-1, which raise the threshold for activation and contribute to suppressed immune responses. Another recently discovered immune checkpoint receptor, TIGIT, is up-regulated on T cells in neoplasms and chronic LCMV infection. We hypothesise that TIGIT functions as a negative checkpoint receptor marking dysfunctional T cells during SIV infection, and that modulation of TIGIT would restore anti-SIV-specific T cell responses.

**Methods:** Spleen, lymph node (LN) and PBMCs from SIV-naive and SIV-infected rhesus macaques (RMs) were examined for surface expression of TIGIT. In vitro cytokine production was assessed via intracellular cytokine staining. Proliferative capacity was determined through CFSE dilution assays in the presence of antibodies blocking TIGIT and PD-1 pathways (anti-TIGIT mAb and anti-PD-1 mAb).

**Results:** TIGIT expression was significantly up-regulated on CD8+ T cells derived from the spleen and LN, but not PBMC in SIV-infected animals. The frequency of TIGIT+ CD8+ T cells in the LN significantly correlated with SIV viral load, and TIGIT expression was driven primarily by g-chain cytokines such as IL-2. TIGIT was expressed on <40% of SIV-specific CD8+ T cells, even in animals with full cART suppression of viral replication. While Ki-67 expression did not differ between TIGIT+ and TIGIT- CD8+ T cells, TIGIT+ CD8+ T cells produced significantly more IFNγ compared to TIGIT- CD8+ T cells. Single and dual blockade of TIGIT and/or PD-1 signal pathways restored proliferative capacity of SIV-specific T cells in vitro.

**Conclusions:** TIGIT is a negative checkpoint receptor that marks a novel population of functionally exhausted SIV-specific CD8+ T cells and is associated with SIV disease progression. The enhancement of virus-specific T cell proliferative responses in the presence of single or dual blockade of TIGIT and/or PD-1 suggests that targeting the TIGIT pathway is a viable therapeutic approach to reverse T cell dysfunction. Given the high sequence homology of rheostatin and TIGIT pathways restored proliferative capacity of SIV-specific T cells in vitro.

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TUPDB0101
Prolongation of QTc interval in HIV-infected individuals compared to the general population is not caused by antiretroviral therapy

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Background: Prolongation of the QTc interval (QTc) increases the risk of cardiovascular events. The incidence of CVE is higher in HIV-infected (HIV+) patients compared with the general population. The impact of different antiretroviral therapies (ART), co-medication and HIV-infection on the electrical activity of the heart is rarely investigated in large HIV+ cohorts.

Methods: We compare QTc of HIV+ outpatients of the HIV HEART study (HIVH) and of controls of the population-based Heinz Nixdorf Recall study (HNR, both recruited from the German Ruhr area since 2000. HIVH cases are age- and sex-matched with HNR controls in a 1:2 ratio. QTc was measured and corrected using the Bazett’s formula. We used crude and adjusted linear mixed models to account for the matched design and adjusted for QTc interval prolonging medication (QTc-PM, no ART). Differences in QTc between HIV specific factors and ART were evaluated using ANOVA in the HIVH subpopulation. All analyses were stratified by sex.

Results: 496 HIV+ participants (83.3% male, aged 54.5±17) matched with 992 HNR controls. We observed a longer QTc in HIVH subjects compared with HNR controls: 424±23 ms vs 411±15 ms for male and 435±20 ms vs 416±17 ms for female subjects (<0.001 for both sexes). HIV+ males used QTc-PM more often (22.3%, 17.6% for HNR) than HIV+ females (13.3% vs 24.7% for HNR). However, adjusting for QTc-PM the mean differences in QTc remained significant with 13 (95%CI: 11.5 to 14.24) ms for male and 19 (95%CI: 19.95 to 14.24) ms for female subjects. Prolongation of QTc (male >440 ms, female >460 ms) was pathologic in 22.8% vs 1.8% of the males (13.3% vs 24.7% for HNR). However, adjusting for QTc-PM the mean differences in QTc remained significant with 13 (95%CI: 11.5 to 14.24) ms for male and 19 (95%CI: 19.95 to 14.24) ms for female subjects. Prolongation of QTc (male >440 ms, female >460 ms) was pathologic in 22.8% vs 1.8% of the males (13.3% vs 24.7% for HNR). However, adjusting for QTc-PM the mean differences in QTc remained significant with 13 (95%CI: 11.5 to 14.24) ms for male and 19 (95%CI: 19.95 to 14.24) ms for female subjects. Prolongation of QTc (male >440 ms, female >460 ms) was pathologic in 22.8% vs 1.8% of the males (13.3% vs 24.7% for HNR). However, adjusting for QTc-PM the mean differences in QTc remained significant with 13 (95%CI: 11.5 to 14.24) ms for male and 19 (95%CI: 19.95 to 14.24) ms for female subjects.

Conclusions: HIV+ patients have longer mean QTc and more often pathological prolonged QTc compared with age- and sex-matched controls from the general population even after adjustment for intake of non-antiretroviral QTc-PM. ART, HIV infection remained significantly associated with greater adjusted BMD decline rate at lumbar spine (LS) and total hip (TH) during the first 96 weeks of ART (both p<0.01). Subsequently, on follow-up DXA, HIV infection remained significantly associated with greater adjusted BMD decline rate at LS (-0.29%/year vs -0.69%/year, p<0.001) but not at TH (p>0.83). In the HIV group, the rate of BMD decline slowed after the first 96 weeks of ART (-0.96%/vs vs Late Change: LS: -0.79%/year vs -0.19%/year, p=0.04, TH: -1.29%/year vs -0.30%/year, p<0.001). After adjustment for baseline 25OHD and demographics, at week 48 DRV/r monotherapy was associated with a +3.5 (95% CI 0.5, 6.4) ng/ml increase in 25OHD compared to Atipila (p=0.02). Subjects in the DRV/r arm experienced increases in BMD (mean between-arm difference 0.02 [0.03, 0.04] g/cm2 at the lumbar spine, p<0.03, and 0.03 [0.06, 0.08] g/cm2 at the neck of femur, p<0.02), and reductions in parathyroid hormone (PTH) (-20.4 [-38.8, -20.0] ng/ml, p<0.003), bone-specific alkaline phosphatase (-7.4 [-9.5, -4.5] IU/L, p<0.001) and serum type 1 pro-collagen (-16.9 [-26.5, -7.4] μg/ml, p<0.0008), as compared with subjects on Atipila. No significant difference in RTD (urine retinol-binding protein/resiniferatoxin ratio and phosphate reabsorption) was observed. Reasons for discontinuation in the DRV/r arm included side effects (n=4) and virus load rebound (n=2), all of which resolved with DRV/r discontinuation or regimen intensification.

Conclusions: A switch from Atipila to DRV/r resulted in significant improvements in 25OHD and PTH, and a 2-3% increase in BMD. DRV/r monotherapy provides a bone-friendly treatment option to patients with osteoporosis or increased fracture risk.
TUPDB0104

Prevalence of nonalcoholic fatty liver disease and liver fibrosis among perinatally HIV-infected Asian adolescents with history of transaminis.

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Background: Liver disease is an important non-AIDS related morbidity in HIV-infected adults. Non-alcoholic fatty liver disease (NAFLD) is a clinical-pathological syndrome which may progress toward liver fibrosis and cirrhosis. The study objective was to determine the prevalence of NAFLD and liver fibrosis among perinatally HIV-infected adolescents with a history of transaminis.

Methods: A cross-sectional study was conducted at 4 pediatric HIV centers in Thailand (Bangkok, Chiang Mai, Khon Kaen) and Indonesia (Jakarta). HIV-infected adolescents aged 10-25 years with virologic suppression and had transaminis (ALT >30 U/L or AST >50 U/L) within past 12 months were enrolled. Adolescents with history of hepatitis B/C co-infection or significant alcohol consumption were excluded. The assessments included liver ultrasonography (USG-evaluation of fatty liver); transient elastography (TE-evaluation of liver stiffness), serum liver function test. Aspartate aminotransferase-to-platelet ratio index (APRI-biomarker of liver fibrosis) was calculated. Liver stiffness was defined as any liver fibrosis (TE ≥5.1 kPa) and significant liver fibrosis (TE >7.4 kPa). APRI >0.5 and >1.5 were defined as mild/moderate fibrosis and advanced fibrosis, respectively. Correlation of APRI and TE result was assessed.

Results: From August to December 2014, 39 adolescents were enrolled. Median (IQR) age was 17.2 (14.6-19.4) years, 47% were male. Median (IQR) duration of ART was 7.8 (4.4-11.2) years; 47% were male. Median (IQR) duration of ART was 7.8 (4.4-11.2) years. Median (IQR) current CD4 cells count was 691 (535-979) cells/mm3. 3. Fatty liver was assessed.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age (yrs)</th>
<th>BMI (kg/m2)</th>
<th>ALT (U/L)</th>
<th>AST (U/L)</th>
<th>Fatty Liver by USG</th>
<th>TE (kPa)</th>
<th>APRI</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>23</td>
<td>36.2</td>
<td>160</td>
<td>87</td>
<td>Sever 1</td>
<td>3.0-0.3</td>
<td>0.63</td>
</tr>
<tr>
<td>F</td>
<td>17</td>
<td>21.3</td>
<td>36</td>
<td>24</td>
<td>Sever 1</td>
<td>5.7</td>
<td>0.21</td>
</tr>
<tr>
<td>M</td>
<td>15</td>
<td>17.6</td>
<td>36</td>
<td>42</td>
<td>Mild 5.9</td>
<td>3.9</td>
<td>0.39</td>
</tr>
<tr>
<td>F</td>
<td>12</td>
<td>15.4</td>
<td>36</td>
<td>31</td>
<td>Mild 5.7</td>
<td>4.2</td>
<td>0.42</td>
</tr>
<tr>
<td>F</td>
<td>20</td>
<td>17.8</td>
<td>46</td>
<td>35</td>
<td>Mild 4.3</td>
<td>4.7</td>
<td>0.47</td>
</tr>
<tr>
<td>M</td>
<td>20</td>
<td>20.5</td>
<td>71</td>
<td>33</td>
<td>Mild 3.3</td>
<td>3.3</td>
<td>0.33</td>
</tr>
<tr>
<td>M</td>
<td>17</td>
<td>25.8</td>
<td>50</td>
<td>45</td>
<td>Normal 8.6</td>
<td>6.0</td>
<td>0.60</td>
</tr>
<tr>
<td>F</td>
<td>18</td>
<td>19.4</td>
<td>23</td>
<td>25</td>
<td>Normal 8.0</td>
<td>3.0</td>
<td>0.34</td>
</tr>
<tr>
<td>M</td>
<td>14</td>
<td>17.8</td>
<td>23</td>
<td>32</td>
<td>Normal 7.9</td>
<td>2.7</td>
<td>0.27</td>
</tr>
<tr>
<td>M</td>
<td>18</td>
<td>18.5</td>
<td>29</td>
<td>22</td>
<td>Normal 7.6</td>
<td>0.7</td>
<td>0.17</td>
</tr>
<tr>
<td>F</td>
<td>23</td>
<td>18.0</td>
<td>19</td>
<td>18</td>
<td>Normal 7.7</td>
<td>0.3</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Abbreviation: M, male; F, female; BMI, body mass index; ALT, alanine aminotransferase; AST, aspartate aminotransferase; USG, ultrasonography; TE, transient elastography; APRI, aspartate aminotransferase-to-platelet ration index.

Table 1: Characteristics of perinatally HIV-infected adolescents with non-alcoholic fatty liver disease or liver fibrosis

Conclusions: About one-third of perinatally HIV-infected adolescents with a history of transaminis meet criteria of fatty liver or liver fibrosis. Longitudinal follow-up to monitor for progression and provide appropriate interventions in a timely manner is needed.

Remark: This study is funded by CIPHER Grants (2014), International AIDS Society

TUPDB0105

Fixed dose combination EVG/CObi/TDF/FTC does not affect insulin resistance: the STRIBILD-IR study

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Background: The incidence of insulin resistance (IR) and diabetes mellitus in HIV-patients, both contributing to cardiovascular morbidity and mortality, has been associated with antiretroviral therapy (ART). Only limited data exists on metabolic effects of regimens including newer drugs such as fixed dose combination drugs, particularly concerning IR.

Methods: In this prospective, open-label, randomized phase-I-study we investigated the effects of the recently available fixed dose combination of tenofovir disoproxil fumarate, emtricitabine, elvitegravir and cobicistat (TDF/FTC/EVG/Cobi, group I) on IR in comparison to established ART with TDF/FTC+Lopinavir/ritonavir (TDF/FTC, group II) and TDF/FTC+Darunavir/ritonavir (DRV/FTC, group III). N=30 healthy, male volunteers were randomly assigned into one of the 3 study arms. IR was measured using golden standard method of hyperinsulemic euglycemic clamp before and 14 days after initiation of study medication. Briefly, a constant insulin infusion (2 mU/(kg*min)) was infused over 2h, glucose infusion was adjusted as necessary to achieve stable glucose levels (target 90±5 mg/dl). All volunteers took the study medication, as verified by pill counting. IR was evaluated using the mean glucose disposal rate normalized to body weight (g/kg/min), as calculated during the clamp. To test for statistical significance of global and pairwise differences in IR analyses of variances and the Student’s t-test was used. To test for significant changes in IR within study arms, the paired t-test was used.

Results: The enrolled volunteers were young, non-obese, healthy males; no significant differences were detected concerning baseline characteristics (s. Table 1).

Table 1: Baseline Characteristics

<table>
<thead>
<tr>
<th>Group/ Parameter</th>
<th>(Mean±SD) I: TDF/FTC/EVG/Cobi</th>
<th>II: TDF/FTC+Lopinavir/ritonavir</th>
<th>III: TDF/FTC+Darunavir/ritonavir</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>20.3 (±4.8)</td>
<td>27.3 (±4.8)</td>
<td>27.2 (±2.3)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>75.3 (±4.8)</td>
<td>70.2 (±8.3)</td>
<td>72.3 (±7.6)</td>
</tr>
<tr>
<td>Body height (cm)</td>
<td>183.1 (±6.2)</td>
<td>178.9 (±5.7)</td>
<td>180.0 (±5.5)</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>22.4 (±1.1)</td>
<td>21.9 (±2.2)</td>
<td>22.3 (±1.5)</td>
</tr>
<tr>
<td>Fasting blood glucose (mg/dl)</td>
<td>82.0 (±5.1)</td>
<td>82.3 (±6.7)</td>
<td>83.3 (±6.0)</td>
</tr>
</tbody>
</table>

Mean IR did not differ between the groups before treatment (I vs. II vs. III: 11.2±3.2 (SD, standard deviation), n=10 vs. 12.3±5.3, n=9 vs. 11.8±2.5, n=9). The medication was well tolerated, 2 patients were excluded from analysis due to medical (hypothyroidism) and technical (insulin pump error) reasons. TDF/FTC+LPV/r significantly affected IR after 14d of treatment as compared to baseline (9.2±1.8 vs. 12.5±3.3; n=10 vs. 12.5±3.3; n=9 vs. 11.6±2.5; n=9). The medication was well tolerated; no significant differences were detected concerning baseline characteristics (s. Table 1).

Conclusions: Our study shows for the first time that neither treatment with the fixed dose combination TDF/FTC/EVG/Cobi nor with TDF/FTC+DRV/Cobi affects IR as compared to the established regimen TDF/FTC+LPV/r.

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Molecular investigation for HIV-1 cross-group transmissions during the outbreak period (2011-2014) in Athens metropolitan area: introduction of subtype A from Eastern Europe

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Background: New diagnoses of HIV-1 infections among people who inject drugs (PWID) increased in Athens metropolitan area, Greece during 2011. Our aim was to identify potential cross-group transmissions between PWID and other risk groups using molecular methods.

Methods: HIV-1 subtypes were determined for 711 HIV-1(+) PWID sampled during 2011-2014. Cross-group transmissions among the PWID were those that originated from other groups as estimated by phylogenetic trees. Specifically cross-group transmissions corresponded to viral lineages from PWID that didn't fall into the outbreak transmission networks or the PWID recombinants. Further phylogenetic analyses were conducted for the sequences from cross-group transmissions.

Results: Among the 711 HIV-1(+) PWID, 630 (88.6%) sequences fell within 4 IDU transmission networks belonging to CRF14_BG (n=356, 50.1%), CRF35_AD (n=123, 17.3%), subtype B (n=106, 14.9%) and A (n=45, 6.3%); 48 (6.8%) were recombinants consisting of partial regions originating from the PWID-specific clades. On the other hand, sequences from 33 (4.6%) PWID didn't belong either to the PWID transmission networks or the recombinants, suggesting that they are evidence of potential cross-group transmissions. Phylogenetic analyses (n=28) for subtypes A and B detected most frequently among the cross-group transmissions suggested that most of these infections originated from non-PWID transmission networks in Greece and the former Soviet Union countries (Anew). On the other hand, sequences from 33 (4.6%) PWID didn't belong either to the PWID transmission networks or the recombinants, suggesting that they are evidence of potential cross-group transmissions. Phylogenetic analyses (n=28) for subtypes A and B detected most frequently among the cross-group transmissions suggested that most of these infections originated from non-PWID transmission networks in Greece and the former Soviet Union countries (Anew). Specifically we found that 9 (75.0%) of the subtype B infections originated from Greece, whereas 8 (50.0%) and 7 (43.8%) of subtype A strains were of Anew and Greek origin, respectively (Figure). The gender distribution didn’t differ significantly between those infected within PWID networks (F: n=99; M: n=579) or the cross-group transmission. Neither PWID recombinants. Further phylogenetic analyses were conducted for the sequences from cross-group transmissions.

Conclusion: During the four year period of the HIV-1 outbreak among the PWID in Athens metropolitan area, we estimated that 33 (4.6%) of the infections in this group are due to cross-group infections. Notably, half of these cross-group infections due to subtype A originate from the large IDU epidemic in Eastern Europe (Anew). For subtype B however the majority of cross-group infections originated from Greece.

TUPDC0102

Clusters of HIV transmission among high-risk populations in Pakistan

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Background: In Pakistan, people who inject drugs (PWID) have a high HIV prevalence (~27%) and the prevalence among sex workers (SW) has recently increased. There is considerable geographic heterogeneity of HIV prevalence, which may reflect multiple subepidemics with unique trajectories, characterized by specific risk contexts, behaviours, and sexual or syringe-sharing networks. This study uses genetic clustering to identify and characterize these HIV subepidemics of ongoing transmission.

Methods: Mapping and integrated behavioral and biological surveillance took place among 16,756 PWID and male (MSW), female (FSW) SW across Pakistan in 2011. Of the 1,637 persons who tested HIV positive (5.8%), we were able to analyze 414 sequences from 1,153. These sequences were aligned to a reference sequence: HXB2. We identified sequences that were highly similar (~1% pairwise Tamura Nei 93 genetic distance) and deemed these persons potential transmission partners. Transmission clusters were constructed by connecting persons who share potential transmission partners. Clusters were characterized in terms of high risk population group membership and city. Logistic regression was used for tests of statistical significance.

Results: The prevalence of HIV in Pakistan was determined to be 27.3%, 5.2%, 1.6%, and 0.6% among PWID, MSW, FSW, and FSW respectively. Of the 1,153 sequences, 652 were clustered (56.5%) into 87 unique clusters ranging in size from 2 to 56 sequences. Average cluster size was 7.5 (s.d.=15), although clusters of 2 predominated. Compared with MSW, PWID were more likely to be clustered (Odd Ratio = 1.6, p < 0.01). Larger clusters were more likely to span multiple cities and include SW, with an average mixed PWID/MSW cluster size of 23.6, compared with cluster sizes of 5 or 2 for clusters composed entirely of PWID or SW, respectively. Most SW in clusters were in large clusters of nine or more individuals, whereas MSW and MSW tended to be in clusters of diverse sizes.

Conclusions: A comprehensive understanding of HIV transmission in Pakistan will be critical to design strategically targeted HIV prevention programs. Clusters may be indicators of ongoing transmission and thus an effective strategy for prevention programs could be to target the cities and population groups with high clustering.

TUPDC0103

Transmission networks of HIV-1 among men who have sex with men in East and Southeast Asia

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Background: The epidemic among men who have sex with men (MSM) is spread at an alarming rate in Asia. Understanding the dynamics of HIV-1 transmission among MSM through viral transmission analyses may provide essential information on the origin of viral lineages and the characteristics of disease spread.

Methods: We determined transmission networks of HIV-1 among MSM across countries in East and Southeast Asia. A total of 1,856 HIV-1 polymerase gene sequences were obtained from TREAT Asia Studies to Evaluate Resistance - Monitoring (TASER-M) sites in Hong Kong, Thailand, Malaysia, and the Philippines between 2006 and 2011. Time-stamped sequence databases of HIV-1 subtype B (n=144) and CRF01_AE (n=138) from antiretroviral-naive MSM were identified and subjected to spatiotemporal analysis using Bayesian phylodynamic methods.
transmission network was defined as a phylogenetic cluster (≥2 isolates) supported by >90% bootstrap values and Bayesian posterior probability value of 1 at the tree node.

Results: Phylogenetic reconstructions showed that 68% of HIV-1 subtype B and 40% of CRF01_AE sequences were grouped in 50 transmission networks of various sizes (mean size=5.6, range=2-32 sequences), with subtype B sequences having a higher tendency to form a network (p < 0.0001). With additional representative sequences from China, Mongolia and Myanmar from the Los Alamos National Laboratory HIV Sequence Database, 34 networks involving 154 subtype B-infected individuals and 16 networks involving 125 CRF01_AE-infected individuals were observed. Location mapping showed that the MSM networks in East and Southeast Asia were mostly localized (78%) in their respective countries, with 22% spanned beyond a single country. Genealogy-based analysis to estimate the divergence time for each transmission network indicated the continued emergence of new networks over the past three decades. The uninterrupted growth of sub-epidemics of various cluster sizes suggests the role of transmission networks as a continuous driving force of the epidemic among MSM in Asia.

Conclusions: Despite expanded access to antiretroviral therapy in Asia, our analysis showed continued regional emergence of recent HIV-1 subtype B and CRF01_AE networks among MSM. Strategies such as early diagnosis and treatment as prevention to reduce transmission risks among sero-discordant partners need to be expanded across the region.

TUPDC0104
Estimating the size of men who have sex with men (MSM) using modified capture-recapture method based on network sampling in the capital city of Georgia in 2014
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Background: Estimates of the number of people at high risk for HIV infection are crucial for prevention, treatment and care planning. Taking into consideration that Georgia is the country, where HIV epidemic is concentrated among MSM and information on the size of this key population was lacking, we conducted the study using seven different population size estimation methods in Tbilisi, Georgia. We want to focus on a new method proposed by Dombrowski et al. (2015) (estimation methods in Table 1). Among MSM, we first time applied this method with few modifications. The purpose of this study was to assess the degree to which variance in men’s IPV perpetration was attributed to camp membership and to determine the effect of camp-level factors (gender norms and IPV attitudes) on IPV perpetration.

Methods: We used 2-level hierarchical linear models to model the relationship between individual and camp-level characteristics and past-year physical IPV perpetration, assessed using an adapted version of the World Health Organization violence against women instrument. Camp-level gender norms were computed by averaging responses among all camp members to an adapted version of the Gender Equitable Men Scale. All individual-level variables were group-mean centered to facilitate decomposition of between and within-camp effects. We estimated an unconditional random effects model to determine the proportion of IPV variance attributable to camp membership. Subsequent models sequentially introduced individual-level demographic/control variables, camp-level norms, and individual-level norms.

Results: A significant proportion of variance in IPV perpetration (3.1%) was due to between-camp differences (τ₀₀=-0.0094, p=0.04). Increasing levels of camp equitable gender norms were significantly associated with decreasing IPV perpetration (p=0.167, p=0.04), and this association remained after controlling for individual-level gender norms. Camp-level norms regarding IPV acceptance were not associated with IPV perpetration.

Conclusions: Studies have found a strong association between IPV and HIV. We found that membership in social groups with equitable gender norms reduced men’s risk of perpetrating IPV, even after adjusting for their own views about gender norms and the acceptability of violence. This finding highlights the importance of multilevel HIV and IPV interventions that simultaneously address individual risk factors while making gender norms more equitable within social networks.

TUPDD001 Gender Matters: When, Why, and How

TUPDD001
Gender differences in HIV testing behaviors by community-level and individual-level stigma in rural South Africa
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Background: Despite national testing campaigns and increased access to HIV treatment, stigma remains a significant barrier to testing in South Africa. A nuanced understanding of stigma and testing is instrumental in refining intervention programming. Stigma can be examined at either the individual or community level and may operate differently by gender. Further, estimating HIV testing uptake achievable through stigma reduction interventions is critical for understanding potential impact.

Methods: We examined the relationship between anticipated HIV stigma at individual and community levels on recent HIV testing, stratified by gender, using data from a population-based sample of 1,126 adults aged 18-35 residing in 22 villages in Mpuumalanga, South Africa.
Anticipated HIV stigma, or expectations of discrimination should one become HIV positive, was measured using a 9-item scale and dichotomized as any versus no stigma. Community-level stigma was defined as the proportion of individuals within each village reporting any anticipated stigma. We assessed associations of community and individual stigma and HIV testing for men and women. We then used multilevel regression models to estimate the potential effect of changing community-level stigma to improve testing uptake using the g-computation algorithm. Analyses were weighted to account for the survey design.

Results: Men tested less frequently (OR 0.22, 95% CI 0.14-0.33) and reported more individual anticipated stigma (OR 5.1, 95% CI 2.8-10.1) than women. Men reporting no individual-level stigma (vs some) were 45% more likely to have tested (p=0.08). For women, testing behavior was not associated with individual anticipated stigma but for each percentage point reduction in community-level stigma the likelihood of testing increased by 3% (p=0.03). We modeled gains in HIV testing at different levels of community stigma (Figure 1).

For example, results indicate a potential 15% intervention gain in HIV testing among women if community-level stigma decreased by 5%. Changing community-level stigma did not result in significant gains for men.

Conclusions: Our data indicates that HIV-related stigma influences HIV testing for men and women through different pathways. Stigma reduction programs may need to consider gender differences and tailor activities to the target population. Longitudinal research is needed to confirm projections and direction of effect.

TUPDD0102
Men “missing” from population-based HIV testing: insights from qualitative research

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Background: Men’s uptake of HIV testing will be critical to the success of test and treat strategies in generalized epidemics. We used qualitative research methods to identify cultural factors and community-level processes that influence HIV testing uptake in the context of an ongoing test and treat trial of 334,479 persons in East Africa (SEARCH, NCT# 01864603).

Methods: In-depth interviews, participant observation, and focus group discussions were used to evaluate contextual factors in communities that influenced uptake of baseline HIV testing. The study used a hybrid model of mobile HIV testing including community health campaigns (CHC) followed by home-based testing (HBT) for non-CHC attendees. Data were collected in 8 rural communities in Uganda and Kenya, and interpreted using Atlas Ti software. Analytical codes were defined and applied by an 8-person research team on the basis of theory and the empirical data, and iteratively refined during the analysis process.

Results: Structural barriers to male participation in community health campaigns led to reduced participation in CHCs and HBT; informal sector labor opportunities for men often require extended absences from rural households. Participants reported for example that during planting season, men needed to guard fields from monkeys from dawn until nightfall; in lakeshore communities, fishermen travel long distances and off-load fish at multiple beaches, using multiple residences and temporary lodgings. Community leaders were critical in outreach to promote CHC attendance, but power differentials between elder and younger men may have contributed to heterogeneous mobilization. Cultural factors including male gender norms counter to health-seeking behaviors, and valorizing risk-taking, also served as barriers to HIV testing. Men often tested “by proxy”, inferring their HIV status from the test results of wives. Yet debates about HIV risks were vigorous, with many men questioning traditional masculine gender norms; moreover, the promise of antiretroviral therapy (ART) to prolong health appeared to motivate many men to participate in testing.

Conclusions: Mobile testing reduces but does not eliminate barriers to men’s participation; however, the promise of ART may be enabling changes in male gender norms related to testing. Findings may be useful for developing novel strategies to improve male engagement in test and treat efforts.

TUPDD0103
Examining the relationship between pediatric PMTCT outcomes and knowledge of partner status

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Background: The mothers2mothers’ Mentor Mother program empowers pregnant women and new mothers to make informed decisions about their maternal and reproductive health as well as their infants’ health, through provision of peer education and psychosocial support. m2m’s 2013 annual evaluation showed that discordancy was negatively associated with the uptake of pediatric PMTCT services. HIV-positive mothers who knew their male partners were HIV-negative were less likely to bring their infants for PCR testing at 6-8 weeks (OR=0.60, p=0.005), or for a follow-up test at 18 months (OR=0.75, p=0.017), compared to mothers who knew their partners were HIV-positive. The aim of this study is to further investigate the role that knowledge of one’s partner’s HIV status plays in the uptake of pediatric PMTCT services.

Methods: Secondary analysis of m2m’s 2013 internal program evaluation data was conducted. Data comprised of a representative random sample of 5,592 HIV-positive clients’ longitudinal records (routinely maintained by Mentor Mothers), enrolled from March through May 2012 in six African countries. The relationship between knowledge of partner status and uptake of pediatric PMTCT services was investigated through bivariate analysis (chi-square) and binary logistic regression analysis using STATA 12.

Results: Knowledge of partner HIV status was significantly associated with uptake of pediatric PMTCT services. Mothers who knew their partner’s HIV status were more likely to take up pediatric PMTCT services compared to those who did not know their partner’s status. The likelihood of improved uptake of PMTCT services was the highest among mothers who knew they were in a discordant relationship. There was no significant relationship between knowledge of partner status and uptake of infant ART.

(See Table 1)
Conclusions: Additional primary research on the effects of concordancy and discordancy on PMTCT outcomes is recommended. Our secondary analysis suggests that uptake of pediatric PMTCT services is more likely to occur amongst clients who know that they are in a concordant relationship. This evidence supports the inclusion of a tailored serodiscordant couples education and support intervention to facilitate mutual disclosure of HIV status in partners, especially in the context of Option B+; thus improving outcomes in the postnatal care cascade.

**TUPDD0104**

Who benefits from partner services in Mozambique? Results from a pilot program in a public, urban clinic

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Background: Notifying partners of persons newly diagnosed with HIV can help identify undiagnosed infections and link people to care. Assisted partner services (APS) offers persons with newly diagnosed HIV infection help notification and getting sex partners tested. APS is not widely available in sub-Saharan Africa, including Mozambique. We explore who benefits from APS as compared to passive services through a pilot program in an urban, public clinic in Maputo, Mozambique.

Methods: Between June-September 2014, four community health workers (CHWs) offered APS to 223 index patients (IPs) with recently diagnosed HIV: 220 accepted and 206 (94%) were retained at 8 weeks. CHWs used structured interviews to collect data at baseline, 4 and 8 weeks. At baseline, CHWs counseled IPs to notify partners and encourage their HIV testing, and did not offer to notify partners directly. At 4 weeks, with consent, CHWs notified partners to encourage testing. We used logistic regression, adjusted for clustering, to define the odds of IP reason to encourage testing. We used logistic regression, adjusted for clustering, to define the odds ofAPS as compared to passive services through a pilot program in an urban, public clinic in Maputo, Mozambique.

Results: From 206 IPs, 79% were female, 73% were married and 31% named > 1 sex partner. IPs named 283 partners, 278 had complete date: 59% are spouses. Of 192 people tested, 103 (53.4) were reported HIV positive diagnoses, 55 (53.6%) tested after APS at 4 weeks. Of 103 HIV positive diagnoses, 55 (53.6%) were reported to encourage testing. We used logistic regression, adjusted for clustering, to define the odds ofAPS as compared to passive services through a pilot program in an urban, public clinic in Maputo, Mozambique.

Conclusions: Among persons with multiple sex partners, a group in whom partner testing and HIV identification remained relatively low.

**TUPDD0105**

Male partner acceptance of home-based syphilis and HIV testing offered to couples during pregnancy

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Background: Testing partners for HIV in the antenatal period is an effective way to bring HIV services to couples. Leveraging antenatal HIV testing with point of care (POC) diagnostics for other sexually transmitted infections (STI) may improve male partner treatment services among couples.

Methods: We conducted a prospective study among male partners of women who received home-based couple HIV testing and education (HOPE) following a first antenatal visit in Nairobi, Kenya. From April to July 2014, rapid point of care (POC) syphilis testing (SD Bioline Syphilis 3.0) was added to the package of services for men and those with positive results were referred to the clinic for treatment. We assessed men’s acceptance of testing and intention to seek clinic-based treatment and calculated an odds ratio to examine correlation between uptake of syphilis and HIV testing.

Results: Data were available for 73 (83%) couples receiving a HOPE visit. Men were on average 26 years of age (OR: 0.02, 29). At entry study, most men reported having previously tested for HIV (93%, n=68), of whom 7% reported being of knowing HIV positive status (n=5), and 85% reported knowing their female partner’s HIV status (n=59). Of 73 men, 67 accepted HIV (82%) among whom 84 intended to attend clinic STI treatment if they received a positive syphilis result (95%). HIV prevalence among the men was 14.7% and one man (<1%) was syphilis positive. In this group, 61 (83%) accepted both syphilis and HIV tests. Three men (4%) refused both tests and three men (4%) accepted HIV alone. Six men (8%) accepted syphilis alone, of whom 2 reported having been previously tested as HIV-positive. If a man accepted HIV testing, he was 10-fold as likely to accept syphilis testing, compared to a man who refused HIV testing (OR: 0.10; 95% CI: 0.01-0.89: 3: p=0.02).

Conclusions: In a high HIV and low syphilis setting, home-based education and POC syphilis testing of male partners during pregnancy is highly acceptable when coupled with HIV testing and may encourage men to seek clinic-based STI services. Integration with HIV testing appears feasible, and syphilis test uptake is highly correlated with HIV test uptake.

**TUPDD0106**

Antiretroviral treatment uptake and correlates of adherence among men who have sex with men and transgender women in Mumbai, India

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Background: Understanding factors influencing ART adherence is needed to optimize treatment responses for HIV infected men who have sex with men (MSM) and Hijra/transgender women (TWG) in India. The objective of this formative study was to determine rates of ART uptake and adherence and explore potential factors associated with adherence in Indian MSM and TWG.

Methods: We conducted a cross-sectional survey in Hindi among all HIV positive MSM and TWG on ART accessing support services at a LGBT community based organization in Mumbai between July and September 2014. Non-adherence was measured by self-report and defined as missing any doses (i.e. <100% adherence) in the past 1 month and 3 months. Potential correlates of adherence assessed were sociodemographics, medication side-effects, depression (CESD-10), self-efficacy (GSE), internalized homophobia/stigma, and medication beliefs using chi-square or t-tests.

Results: Of the 300 individuals registered in the organization’s HIV support program, 28.3% (85/300) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI), with 22% (65/300) currently on ART. Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI). Of those on ART, 83% (54/65) were MSM and 17% (11/65) were eligible for ART by current country standards (e.g. CD4 ≤350 or having an OI).

Conclusions: In one of the first studies of adherence among MSM and TWG in India, ART uptake and adherence were suboptimal. Modifiable factors associated with adherence may serve as targets for interventions to support adherence. Further work is however needed to verify self-report measures with biological outcomes and confirm findings in other samples of Indian MSM and TWG.
**Tuesday 21 July**

**Poster Exhibition**

### Viral origins and evolution

**TUPEA049**

**Phylogenetic estimation of the temporal spread of hepatitis C genotype 1a in North America**

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**Background:** Timing of the initial spread of hepatitis C genotype 1a (GT1a) in North America (NA) is controversial. 75 percent of NA HCV infected adults are within the cohort composed of individuals born between 1946 and 1964 (baby boomers). How HCV reached such high prevalence in this cohort remains unclear. Previous studies have largely implicated injection drug use during the 1960s and 1970s as well as infected blood products prior to adoption of blood donor screening in the early 1990s. We sought to test the concordance between timing of the spread in NA and previously hypothesized periods of high incidence.

**Methods:** We obtained all publicly available HCV genotype 1a sequence data from public databases for 5 HCV genes, and screened these data for sequences sampled in NA with known dates of collection. Repeated sequences from the same individuals were filtered by a phylogenetic pruning method. For each gene-specific data set, we reconstructed the dynamics of the effective number of infections using a smoothing method (Bayesian skyline) implemented in BEAST. This number is expected to be proportional to prevalence at the exponential phase of an epidemic.

**Results:** Bayesian skyline plots of all HCV gene regions indicated that the exponential phase of the GT1a epidemic in NA occurred between 1940 and 1965, and that prevalence plateaued between 1965 and 1989 before declining during the early 1990s. Our phylogenetic analyses suggest that the GT1a epidemic in NA had already attained the bulk of its current distribution before 1965.

**Conclusions:** Our results elucidate the early HCV epidemic dynamics in NA. The expansion of GT1a prior to 1965 suggests that, in addition to injection drug use and contaminated blood products, other nosocomial or iatrogenic factors may have contributed to the high rate of HCV infections in NA baby boomers. The decline in the rate of transmissions in the early 1990s corresponds with blood donor screening, the potential impact of harm reduction initiatives and changes in the patterns of injection drug use. Availability and molecular phylogenetic analyses of archived specimens from the 1940s and onward would improve our ability to time the evolution of the NA GT1a HCV epidemic.

**TUPEA050**

**Origin and evolutionary history of HIV-2 in Cuba**

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**Background:** Infection with human HIV-2 is endemic in West Africa. The virus originated from West African sooty mangabeys during the first half of the 20th century and an epidemic initiation in Guinea Bissau that coincides with the independence war (1963-1974). The HIV-2 group A is categorized as epidemic group. The presence of HIV-2 group A in Cuba has been previously documented. However, is not known their origin and evolutionary history in Cuba. Here, we reconstructed the evolutionary history of HIV-2 group A to delineate the origin and epidemiology of this group in Cuba.

**Methods:** We used a Bayesian coalescent method to analyze the envelope gene of Cuban HIV-2 group A. The rate of nucleotide substitution was determined. And were used to date the phylogenies and reveal the evolutionary history of HIV-2 group A in Cuba.

**Results:** Multiple introductions of HIV-2 group A, mainly from Guinea Bissau and Portugal were detected. The most recent common ancestor of Cuban HIV-2 group A was dated back to about 1972 (95 % HPD: 1966-1978). The rate of nucleotide substitutions was 5.02 x 10^-3 substitutions per site per year (95 % HPD: 4.51-5.52 x 10^-3).

**Conclusions:** The results of this study allowed for the first time to estimated the evolutionary history of HIV-2 in Cuba and establish the basis for phylogeographic and phylodynamic studies.

**Viral diversity, phylogenetics, phyloodynamics**

**TUPEA051**

**Molecular epidemiology of clinical HIV-1 pol sequences isolated between January 2009 and July 2013 in Cuba**

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**Background:** The HIV-1 epidemic in Cuba exhibits an extraordinarily high genetic diversity. The objectives of this study were to determine the HIV-1 subtype distribution and evolution and to investigate associated risk factors.

**Methods:** Samples were isolated from 838 unique HIV-1 patients (277 therapy-naive and 561 therapy-experienced) attending the “Pedro Kouri” Institute in Cuba between January 2009 and July 2013. HIV-1 subtypes was determined using Rega Subtyping Tool version 2, and confirmed by manual phylogenetic analysis. Using CLUSTALX and the neighbor-joining method in MEGA version 5. The assignment of recombinant forms was done using Simplof version 2.5. Time trends were investigated using 5 year intervals. The association among virological, epidemiological and demographic variables was investigated using Fisher test and logistic regression analysis (statistical package SPSS version 19).

**Results:** The most prevalent HIV-1 genetic forms in this dataset were subtype B (32.2%), B5 recombinants (22.1%) and CRF19_cpx (17.2%). The distribution of subtypes and recombinants was not significantly different between therapy-experienced and therapy-naive patients. Subtype B infection was associated with male (p=0.022 OR: 1.6; CI: 1.1-2.5) and MSM (p< 0.001 OR: 1.2; 95%CI: 1.4-2.9), while subtypes A, F, G and H were associated with heterosexuals (p< 0.005). Subtype H was more frequently detected among patients living in the east part of the country (p=0.003 OR: 1.7; CI: 1.2-2.3). The prevalence of subtypes A, C, F, G and H among individuals diagnosed with HIV-1 dropped significantly after 1990 (p< 0.05), while CRF BGs (20, 23, 24) significantly increased since 2001 (p=0.001 OR:2.9; IC:1.9-4.5). Interestingly, viral variant CRF19_cpx, recently associated with rapid progression to AIDS in Cuba, significantly increased in samples taken since 2011 (15.3% to 22.0%, p=0.002, OR:3.3; IC:2.9-6.4). Conversely, subtype B showed a significant parabolic trend, increasing up to 2000, and decreasing again in subsequent years (p< 0.05).

**Conclusions:** This study indicates that the genetic diversity of the Cuban HIV-1 epidemic is still high. In recent years, the frequency of local recombinants is increasing while subtype B is decreasing.

**TUPEA052**

**The Local dissemination Impact of the HIV-1 env LDI tripeptide α4β7 binding motif**

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**Background:** α4β7, a gut homing receptor, plays a pivotal role on HIV pathogenesis during the acute phase of infection. HIV-1 uses a V2-loop LDI/V/X (AAs 179-181) tripeptide found in successfully disseminating subtypes A, C, F, G, H (179-V/L, 180-D, 181-I/I/I) and also a high prevalence of LDI over LDV in successfully disseminating subtypes BF (58%), BC (58%) compared to subtype B (30%) (p-values< 0.05). Isoleucine at position 180, 99.3%) and also a high prevalence of LDI over LDV in successfully disseminating subtypes B5 (95%), CRF01 (62%), Former Soviet Union (subtype A, 97%), China (CRF01, 69%; CRF07, 62%) and CRF01, 62%), Former Soviet Union (subtype A, 97%), China (CRF01, 69%; CRF07, 94%; CRF08, 84%) and South East Asia (CRF01, 77%) (p-values < 0.05). Although LDI was
TUPEA053
Evolution of the HIV-1 envelope gene during suppressive cART
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Background: The genetic diversity of HIV-1 presents currently a major obstacle for controlling and eventually curing infection. It has been claimed that sufficiently potent combination therapy (cART) blocks viral replication thus not allowing a molecular evolution of the targeted viral populations. In this context the viral cell tropism of HIV-1, affecting clinical infection events, has only rarely been addressed. Aim of this study was to monitor the sequence evolution of the V3 loop under cART, particularly of cell-associated virus.

Methods: The Illumina MiSeq platform was used to obtain deep sequencing results on proviral and cell-associated HIV-1 strains from patients in the Swiss HIV Cohort Study during periods of virologic suppression. Virus was fully suppressed throughout the study time, and all patients had experienced a good CD4 T cell recovery. Calculations were performed with MEGA6.0.

Results: Distance relatedness calculations between the dominant variant at baseline and all variants at follow-up time points revealed evidence for sequence-based provirus evolution in five (29.4%) of eight cases during the pre-treatment period. During cART, of the total 17 patients seven (41.2%) continued to show evidence for evolution in their proviruses. In five (29.4%) patients the virus developed a greater diversity over time and therapy. Evidence for sequence evolution was observed in half of the cases with an increase in proviral loads despite suppressive therapy.

Conclusions: Prior to treatment initiation we confirmed a genetic evolution of HIV-1 genomes. Unexpectedly, and not reported so far, we found evidence for evolution in the V3 loop also in almost half of the observed cases with fully suppressed viral load. Our findings suggest an ongoing evolution of the envelope gene, associating with increasing proviral loads even during sufficient cART. As therapy should allow at best very restricted virus propagation in the circulation, we suggest that HIV persistence may be driven by proliferating infected cells. This may also provide further evidence for ongoing active and cell-driven processes that permit viral “genetic modulation” and diversification, and thereby lends support to encouraging very early initiation.

TUPEA054
Multiplexed highly-accurate next-generation sequencing of mixtures of full-length HIV genotype variants
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Background: The third generation sequencing technology SMRT (Pacific Biosciences Inc.) provides the longest sequencing reads. However, the relatively high error rate in each read has precluded sequencing of genetic mixtures because true diversity is masked by high background noise. At the same time, this is the only NGS technology that could potentially provide full-length >9kb HIV genome sequencing. Our objective was to develop a workflow of novel computer algorithms that would allow highly accurate PacBio sequencing of full HIV genome mixtures.

Methods: Samples were obtained from the Zambia Emory HIV Research Project (ZEHRP) discordant couples cohort (Lusaka, Zambia). Forty Single Genome Amplicons (SGAs) were obtained by limiting dilution RTPCR from two linkedtransmission pairs. Library preparations were performed following standard protocols. Sequencing reads were initially filtered (SMRT Analysis v2.0.2) and then subjected to the analytical algorithms presented here (MATLAB v2012a in Ubuntu 10.04). All the sequencing was performed in duplicate.

Results: Overall, the final algorithm involves (i) statistical based differentiation of true diversity from background noise, (ii) weighted classifierify analyses and (iii) INDEL correction procedures.

Validation against Sanger sequencing of the same SGAs indicate that our algorithm is able to derive the sequence for each of the 40 full HIV genome variants in a mixture exhibiting various numbers of single nucleotide variations with an accuracy of >99.9%. This can be achieved using one single SMRT Cell. Results were identical between replicates. Neither in silico artificial sequences nor in silico recombination between different variants was observed. Importantly, our algorithm did not require the a priori definition of the number of sequences in order to get an accurate result and it was able instead to explore the entire data set and provide the real number of unique genetic variants present in the original sample. This was true even for variants differing by one single nucleotide. The methods described here did not require the barcoding of each SGA.

Conclusions: This novel approach can make full-length genome HIV sequencing more cost effective than Sanger sequencing of limited genomic segments and can facilitate the study of HIV quasispecies diversity at the whole-HIV genome level.
Reconstructed dynamics of HIV CRF07-BC epidemic in China

[Reconstructed dynamics of HIV CRF07-BC epidemic]

Conclusions: The simulation-based kernel-ABC method provides a highly versatile framework for fitting epidemic models to virus sequence variation. Model validation on simulated data demonstrated good performance relative to leading software for phylodynamics.

TUPEA057
Prevalence, evolutionary dynamics and transmission pattern of HCV, HIV-1 and HPgV among injecting drug users

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Methods: A total of 228 subjects with a history of intravenous drug exposure were recruited among injecting drug users in Kuala Lumpur, Malaysia between 2009 and 2010. Nested-PCR was performed to amplify the gag-pol gene of HIV-1.

Results: From a genotype screening of HIV-1 strains circulating among PWIDs recruited between 2010 and 2011, we found that 6/207 (2.9%) PRRTI sequences formed a monophyletic cluster with strong bootstrap support (>80%) in NJ analysis. Near full-length genome sequencing revealed that these strains had identical recombinant structure composed of CRF01_AE subtype B', with eight breakpoints dispersed in the gag-pol and nef regions. This new recombinant lineage was designated as CRF74_01B. Remarkably, this CRF shared four and two recombination hotspots with the previously described CRF33_01B and the less frequent CRF53_01B, respectively. Maximum-likelihood and Bayesian MCMC analyses in multiple genomic regions showed that CRF74_01B is closely related to both CRF33_01B and CRF53_01B. This observation suggests that CRF74_01B was probably a direct descendent from specific lineages of CRF33_01B, CRF53_01B and subtype B'. Since CRF33_01B has been proven by studies elsewhere to have expanded within various risk populations in Malaysia, it is highly probable for CRF33_01B to become implicated in the emergence of CRFs and other unique recombinant forms in the future.

Conclusions: We report a novel HIV-1 genotype designated as CRF74_01B among six epidemiologically-unlinked PWIDs in Kuala Lumpur, Malaysia. The characterisation of the novel CRF74_01B is of considerable significance towards the design of disease diagnosis, treatment and prevention strategies.
TUPEA059

Kive: a framework for version control of bioinformatic pipelines and data, and its application to HIV resistance genotyping

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Background: Bioinformatic pipelines have become essential tools in modern biomedical and clinical laboratories. However, pipelines are usually under constant development and there is no convenient framework for tracking which data sets were produced by which version of a pipeline. As a result, bioinformatic analyses are seldom reproducible. We present a new framework for the version control of pipelines and data, and its use in the development and validation of a pipeline for HIV resistance genotyping by next-generation sequencing.

Methods: Kive was developed in Python using the Django web framework. It acts as a web server that interacts with a PostgreSQL relational database. Kive features an intuitive web interface, including a point-and-click toolset for assembling and running pipelines. When pipelines are executed within Kive, it automatically records the digital fingerprints of the source code and filesystem locations of all intermediate data sets and results. This enables the easy retrieval of complete version information for every pipeline step that generated a specific set of results from raw data. Kive includes user and group administration to control data access privileges, and a queuing system for distributing jobs for parallel execution in a clustered computing environment.

Results: Kive was used to track the development and testing of a pipeline for processing HIV short read data from an Illumina MiSeq platform at the BC Centre for Excellence in HIV/AIDS. This complex pipeline comprised scripts in a variety of languages (Python, Ruby, R, and bash) passing data between several different software packages. Using Kive for the automated processing of MiSeq data greatly facilitated the validation and documentation of the impact of each change in bioinformatic methods on clinically significant variables (prevalence of HIV resistance mutations).

Conclusions: Clinical laboratory accreditation programs, such as the program maintained by the College of American Pathologists, have begun to issue new requirements for the documentation and archival of bioinformatic pipelines. As an open-source and inherently customizable framework, Kive provides a valuable tool for laboratories to meet these requirements in a cost-effective manner with minimal disruption to existing computing infrastructure. The public release of Kive will be available at: https://github.com/cfenet/Kive.

TUPEA060

Newly diagnosed HIV-1 infections in Spain frequently group in clusters of subtype B and non-subtype B genetic forms

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Background: A recent increase in phylogenetic clustering among new HIV-1 infections has been observed in many countries, frequently associated with men who have sex with men (MSM). Here we analyze phylogenetic clustering among newly diagnosed HIV-1 infections in 6 regions of Spain.

Methods: Samples were collected from HIV-1-infected individuals newly diagnosed in 2013 and 2014, attended in 19 hospitals from 6 Spanish regions (Galicia, Basque Country, Navarre, Castilla y León, Madrid, and Extremadura). RNA extracted from plasma was used for RT-PCR amplification and sequencing of protease and reverse transcriptase (PR-RT), env V3 region, or both. Phylogenetic analyses were performed via maximum likelihood with RAxML and PhyML, applying the GTR+G+I evolutionary model. Clusters were defined as those supported by bootstrap values ≥0.95 with RAxML and by aLRT SH-like values ≥0.9 with PhyML, and comprising ≥4 individuals with a majority being native Spanish. In these analyses, sequences from samples collected in previous years in Spain and sequenced by us were also included.

Results: A total of 430 samples from new HIV-1 diagnoses of 2013-2014 were sequenced, either both in PR-RT and V3 (n=262), only in PR-RT (n=144), or only in V3 (n=24). Most were from Basque Country (n=212), Galicia (n=133), and Navarre (n=50). Non-subtype B infections were 132 (31%). Ninety four clusters of ≥4 individuals were identified, of which 32 comprised ≥10 individuals. Eighteen clusters were of non-subtype B genetic forms, including the largest one, of subtype F (n=131). Viruses grouping in clusters of ≥4 and of ≥10 individuals were 223 and 122 (52% and 28%), respectively. Clustering among MSM was more frequent than among heterosexuals (60% vs. 41% and 37% vs. 16%, grouping in clusters of ≥4 and ≥10 individuals, respectively).

Conclusions: A high proportion of newly diagnosed HIV-1 infections in Spain group in clusters of subtype B and non-subtype B genetic forms, most frequently among MSM. The recent expansion of HIV-1 clusters in many countries reflects an active dynamic of viral propagation via sexual transmission, requiring the reinforcement of public health measures aimed at the prevention of high risk sexual behavior.

TUPEA061

Prevalence of defective HIV-1 genome in HIV-infected patients on long-term cART and correlation with characteristics of patients

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Background: ABOPEC3 protein family members restrict human immunodeficiency virus type 1 (HIV-1) replication through the induction of G-->A hypermutation inducing defective HIV-1 genomes; this phenomenon could be clinically relevant in long term non progressors or patients having an optimum virologic response under combination antiretroviral therapy (cART). The objective of our study was to estimate the prevalence of HIV-1 hypermutation in HIV-infected patients on successful cART, as well as to analyze the factors associated to a hypermutation score.

Methods: Peripheral blood mononuclear cells of HIV-infected patients on long term cART for at least 24 months were collected by Ficoll density gradient centrifugation. Bulk sequencing of the reverse transcriptase (RT) and the protease (PT) regions was used to detect the presence of G-->A hypermutation and to quantify hypermutation with the following published score: ratio of (number of G-->A substitutions/number of consensus G) to (number of mutations/number of nucleotides sequenced). Associations between age, sex, HIV-infection and cART duration, HIV clade, CD4 T cell count, CDB T cell activation and hypermutation score were analyzed using a linear regression model.

Results: Seventy patients under cART and 9 naïve patients were included in the study, male sex was predominant (51%), median age was 52 years (IQR 46-60) and median CD4 T cell count at entry was 564/mm3 (372-723). Cade B was prevalent (58%). Median duration of HIV infection was 16 years (9-22), and median cART duration was 12 years (7-16). Prevalence of hypermutation was 20% in treated patients with variable levels of hypermutations per patient (median 1; range 1-3), comparatively to a prevalence of hypermutation of 11% in naïve patients. The median value of hypermutation score was 1.3 (1.9-1.8) for RT region, and 1.2 (1.0-1.8) for RT region.

Factors associated with a higher hypermutation score of RT and PT in the multivariate analysis were age less than 45 years (p=0.018), shorter cART duration (p=0.066), higher CDB T cell activation (p=0.064), and viral clade B (p=0.038).

Conclusions: Hypermutation is frequent in treated HIV-infected patients. Duration of cART may decrease the prevalence of hypermutation. Understanding of mechanisms related to defective virus is crucial in order to advance in terms of HIV virus eradication.
Viral fitness

TUPEA063
Consequences of HLA-B*13-associated escape mutations on HIV-1 replication and Nef protein function

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Background: HLA-B*13, a protective HLA class I allele, selects CTL escape mutations across HIV-1, but their effects on viral replication and protein function remain incompletely understood. We assessed the impact of 10 published HLA-B*13 escape mutations in Gag, Pol, and Nef on viral replication.

We also assessed the impact of Nef mutations on cell-surface CD4 and HLA class I downregulation, and the latter's consequence for recognition of virus-infected cells by epitope-specific T-cells.

Methods: HLA-B*13 escape mutations in Gag (A146S, I147L), Pol (Prole-aLe36, RT-Q334N, T369A, K374R) and Nef (E24Q, Q107R) were engineered alone and in combination, for potential cross-class interactions.

Results: Inoculated with plasma that had been obtained from a 90-120-Ia-positive macaque (donor) and Nef on viral replication.

The novel insights afforded by the use of next generation sequencing techniques will have implications for HIV-1 vaccine design.

TUPEA065
SIV CTL escape mutations resulting in loss of viral fitness can be maintained after transmission into MHC-I-mismatched hosts

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Background: In HIV infections, cytotoxic T lymphocyte (CTL) responses exert strong suppressive pressure on viral replication and often select for mutations resulting in escape from CTL recognition with viral fitness costs. For our understanding of the mechanism of HIV evolution by transmission in population, it is important to investigate how the loss of viral fitness by these mutations affects in vivo viral replication and disease progression after viral transmission into MHC class I (MHC-I)-mismatched hosts. Here, we examined whether these mutations can be maintained and affect disease progression after transmission in a macaque AIDS model.

Methods: Four MHC-I haplotype 90-120-la-negative rhesus macaques (recipients) were inoculated with plasma that had been obtained from a 90-120-la-positive macaque (donor) one year after simian immunodeficiency virus mac239 (SIVmac239) challenge. Viriological and immunological analyses were performed in these macaques.

Results: Multiple mutations including eight 90-120-la-associated CTL escape mutations were dominant in the 90-120-la-positive donor at one year after challenge. Three (Gag216S, Gag34A, and Gag375M) of the eight mutations were confirmed to result in loss of viral fitness in vitro. One 90-120-la-negative recipient controlled viral replication, but the remaining three showed persistent viremia and developed AIDS in 14-22 months after the plasma transmission. Most of the CTL escape mutations were maintained without reversion until AIDS onset in the latter three animals; two of them showed no reversion. In the remaining one, two mutations reverted, but Gag24Ae and Gag375M were maintained.

Conclusions: SIV CTL escape mutations resulting in loss of viral fitness can be maintained after viral transmission into MHC-I-mismatched hosts. Even those viruses carrying these mutations with decreased replicative ability can induce persistent viremia and develop AIDS without reversion. These results would contribute to our understanding of the mechanism for accumulation of CTL escape mutations in HIVs by transmission in humans.
Antiretroviral resistance mechanisms

TUPEA066
Transmission dynamics of local networks of transmitted resistance to NNRTIs suggest an increasing incidence over time in Greece: the added value of molecular epidemiology to public health

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Background: HIV-1 transmitted drug resistance (TDR) to NNRTIs has been shown to compromise first-line response to treatment. The prevalence of resistance to NNRTI was previously estimated to be 15.9% among drug naïve individuals sampled during 2003-2013 in Greece. Our aim was to estimate the effective reproductive number (Re) and the transmission dynamics of four major transmission networks of NNRTI resistance in Greece.

Methods: Phylogenetic analysis was conducted in sequences from 179 individuals with NNRTI resistance and 959 cases without resistance infected with subtype A in Greece, and 797 sequences sampled globally. Phylodynamic analysis was performed using newly developed birth-death models (BDM) allowing estimation of important epidemiological parameters such as the effective reproductive number (Re).

Results: Phylogenetic analyses revealed that the majority of individuals infected with resistant strains belonged to monophyletic clusters. Specifically, 49 out of 54 (90.7%) of sequences belonged to one and three phylogenetic clusters (transmission networks), respectively. The prevalence of 103N showed a significant increase over time with 103N belonging to one and three phylogenetic clusters (transmission networks), respectively. Long-term infectivity assays showed similar decreases in HIV-1 viral fitness for both R263K and M184V/R263K combinations reduced infectiousness by 2.9 and 2.4-fold, respectively. Combining M184V with R263K did not significantly change levels of resistance conferred by single mutations against either drug. Single mutations decreased HIV-1 infectiousness by 1.5 to 2.1-fold whereas the M184I/R263K and M184V/R263K combinations reduced infectiousness by 2.9 and 2.4-fold, respectively. Long-term infectivity assays showed similar decreases in HIV-1 viral fitness for both combinations of mutations. Alu-mediated PCR results supported these observations.

Conclusions: Combining 3TC- and DTG-specific mutations resulted in a further decrease in HIV-1 infectiousness and replication capacity without conferring additional levels of resistance. This suggests that individuals failing 3TC:DTG-based therapy may exhibit lower viral loads than those observed with other combinations of drugs and supports the use 3TC or emtricitabine in combination with DTG.

TUPEA067
HIV resistance pathways support the use of lamivudine (3TC) and dolutegravir (DTG) in combination

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Background: A single daily regimen combining lamivudine (3TC), abacavir and dolutegravir was recently approved for treatment of HIV-positive individuals. Given that both the M184V/RTV/3TC:RTV-associated resistance mutations and the R263K/nnr/3TC-associated resistance mutation negatively affect HIV replication capacity, we investigated the effects of combining M184V/R263K with R263K on HIV-1 susceptibility to 3TC and DTG, respectively, in 3TC and DTG resistance network studies.

Methods: Methods: 24 TCV-FA infected cells were infected with WT, M184I, M184V, R263K, M184V/R263K and M184I/R263K viruses to measure infectious and resistance against 3TC and DTG. Viral fitness was measured in long-term infectivity assays with 3TC and 3C. Integration efficiency was assessed using 3TC:RTV-based PCR.

Results: Our experiments revealed that 3TC and 3CTG synergize to inhibit HIV-1 replication. The M184V and R263K mutations conferred high-level resistance against 3TC (>100-fold) and low-level resistance against DTG (2-2-fold), respectively. Combining M184V with R263K did not significantly change levels of resistance conferred by single mutations against either drug. Single mutations decreased HIV-1 infectiousness by 1.5 to 2.1-fold whereas the M184I/R263K and M184V/R263K combinations reduced infectiousness by 2.9 and 2.4-fold, respectively. Long-term infectivity assays showed similar decreases in HIV-1 viral fitness for both combinations of mutations. Alu-mediated PCR results supported these observations.

Conclusions: Combining 3TC- and DTG-specific mutations resulted in a further decrease in HIV-1 infectiousness and replication capacity without conferring additional levels of resistance. This suggests that individuals failing 3TC:DTG-based therapy may exhibit lower viral loads than those observed with other combinations of drugs, but that the use 3TC or emtricitabine in combination with DTG.

TUPEA068
Evolution of HIV-1 integrase following selection of R263K with further dolutegravir treatment: a case report from the P1093 study

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Background: Recent clinical and in vitro reports have identified R263K in HIV-1 integrase (IN) as a key treatment-emergent resistance-associated mutation (RAM) for dolutegravir (DTG). Given the low incidence of this mutation in the clinical setting, little is known of the impact this IN mutation has on further IN evolution under DTG treatment. Here we report on integrase resistance evolution over 3 years of DTG and Truvada treatment in a 12 year old adolescent from P1093 study.

Methods: Methods: P1093 is a phase III, multicenter, open-label pharmacokinetics (PK), safety, dose-finding study of DTG plus optimized background regimen in pediatrics. Longitudinal HIV-1 RNA (VL), clonal IN genotypes, DTG fold-change (FC) in IN, and IN replication capacity (RC) were investigated.

Results: The patient had a history of NRTI and PI use but the pretreatment genotype showed no primary RAM’s to NRTI’s or PI’s. Intermittent adherence to both Truvada and DTG was reported throughout study. PK data collected through Week 24 showed adequate DTG exposure. Entry VL was 7739 copies/mL and fell below 400 copies/mL during the first 24 weeks. However, the median VL over 3 years was 3940 copies/mL. Virologic failure was confirmed on Week 36 with an acquisition of R263K/R and the patient remains on study for an additional 2 years. Integration clonal analysis with corresponding DTG FC was conducted at Pretreatment, Week 36 and Week 136.
Host genetics of HIV susceptibility and disease progression

TUPEA069
Degradation of HIV-1 Nef by ubiquitin (Ub) specific protease 15 (USP15)

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Background: Previous studies have demonstrated that HIV-1 Nef is essential and may be sufficient for HIV-1-associated AIDS pathogenicity; that is, genetic or physical knockout of Nef alone can protect HIV-infected patients from AIDS. However, molecular methods of incapacitating Nef in the infected hosts have not appeared to date.

Methods: Cellular proteins interacting with HIV-1 Nef were identified by the yeast two-hybrid followed by co-immunoprecipitation analysis. Protein degradation was determined by Western-Blot analysis, and replicability of HIV-1 was measured by monitoring reverse transcriptase (RT) activity in the culture supernatants.

Results: Our yeast two-hybrid screening followed by co-immunoprecipitation analysis demonstrated that Nef interacted with ubiquitin specific protease 15 (USP15) which stabilizes proteins by deubiquitination and by preventing auto-ubiquitination of substrates. Association of Nef with USP15 suggests that Nef and USP15 must be a pivotal regulator in regulation of viral/cellular protein decay. In fact, Nef and USP15 were reciprocally degraded, although USP15-mediated degradation of Nef was more dramatic than Nef-mediated USP15 degradation. Further, USP15 degraded not only Nef but also HIV-1 structural proteins, Gag and Env, thereby significantly inhibiting HIV-1 replication. In contrast, Gag and Env did not degrade USP15, indicating that the Nef and USP15 complex, not any other viral protein, plays an integral role in coordinating viral protein degradation and hence HIV-1 replication. Moreover, Nef and USP15 globally suppressed ubiquitination of cellular proteins, indicating that these proteins are critical determinants for the stability of not only viral but also cellular proteins.

Conclusions: Taken together, these data indicated that one or more defined motifs of USP15 can be regulated to abrogation of Nef and that elucidation of the molecular mechanisms of Nef/USP15-mediated degradation of viral and cellular proteins will provide insights on the nature of pathobiologic and defense strategies of HIV-1 and HIV-infected host cells, respectively, and clues for development of therapeutic agents against AIDS.

TUPEA070
Independent association of host immunogenetic factors with vertical HIV transmission

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Background: In India, various intervention programs are introduced to reduce mother to child HIV transmission. Despite this many children (5%) still acquire the infection, indicating possible association of genetic factors such as HLA and Cytokines genes. Present study aimed to evaluate if these factors are associated with vertical HIV transmission.

Methods: Infants of HIV positive women attending the PPTCT and ICTC of Seth G.S. Medical College and K.E.M. Hospital, Mumbai, India, between January 2010 and June 2014 were enrolled with their mothers’ consent. Clinical history of mothers, blood samples within 24 hours of delivery for viral load analysis and blood from the infants was collected for HIV screening, analysis of HLA alleles and single nucleotide polymorphisms in 13 cytokine genes at 22 loci using PCR-SSP method. SPSS, Haploview and PyPop software were used for statistical analysis.

Results: Thirty HIV positive and 60 HIV negative children at the end of their 18th month follow up were considered for this study. The type of treatment given to the mothers and their viral load at the time of delivery had significant (p<0.001) influence on transmission. CT and CC genotype at IL1R (rs22346950), GG and GA at TNF-a (rs1800629) were significantly associated either with susceptibility/protection. Haplotypes of IL1- and TNF genes also showed an association with transmission or protection. HLA-A01’,B*40’,B*37 and DRB1*09 were associated either with transmission or protection. Logistic regression analysis further confirmed significance independent association of HLA-B*40 (p = 0.022) with protection and HLA-DRB1*09 (p = 0.019) with susceptibility. Few HLA haplotypes were exclusively present in either of the groups.

Conclusions: This study possibly for the first time reports association of specific SNPs of IL-1R and TNF-a gene with risk of vertical HIV transmission. Specific HLA alleles and haplotypes were also associated either with susceptibility or with protection from HIV transmission. Besides confounding factors, these genetic factors are independently associated with HIV infection. Allelic polymorphisms of these genes could be associated with altered immune response leading to either transmission or protection. These findings update the knowledge of host immune genes association with perinatal HIV transmission. The identified factors can further be exploited as possible susceptible/protection markers.

TUPEA071
Expression analysis of a4 integrin and related genetic polymorphisms in HIV acquisition and disease progression of infected individuals

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Background: HIV gp120 can interact with the a4β7 integrin, providing a favorable enviroment for virus transmission. a4β7 is important during the initial course of HIV infection, when intense viral replication and lymphocyte depletion occur in gut-associated lymphoid tissue. A study with multiple sclerosis patients showed a higher prevalence of CC genotype in the SNP-rs1449263, located in the promoter region of the itga4 gene (a4 integrin), possibly related to a higher expression of this gene. In this study we assessed the distribution of SNP-rs1449263 different genotypes and if they influence itga4 gene expression.

Methods: Distribution of SNP-rs1449263 genotypes was assessed in three cohorts. Seroconversion cohort: 222 HIV- adults from USP; pediatric cohort: 89 children from IPPMGUFRJ and HSE/RJ, where 61 were HIV+ and 28 were exposed-uninfected (EU) born to HIV-infected mothers; and a control group: 68 HIV- adults from Rio de Janeiro. A DNA fragment containing the SNP-rs1449263 was PCR-amplified and sequenced. Allelic and genotypic frequencies were calculated. Itga4 gene expression was assessed by real-time PCR. Surface protein expression was investigated by flow cytomtery.

Results: A higher prevalence of CT (54%), followed by TT (29%) and CC (17%) was found in HIV+ adults. Patients carrying the C allele had less CD4+ T-cells in the early phase of infecion when compared to those who do not carry it. Among HIV- adults, we observed 41% CT, 33% TT and 26% CC. Among pediatric HIV+ patients, we found 54% CT, 30% CC and 16% TT, while among EU, we found 53% CT, 37% TT and 10% CC. Fifty-one samples submitted to itga4 gene expression analysis showed a higher expression in the CC genotype group compared to the others. The same was observed for individuals carrying the C allele compared to carriers. Five samples were subject to flow cytomtery analysis to assess the presence of a4 protein on the cell surface, and the results corroborated those obtained in the real-time PCR.
Conclusions: We show that the CC genotype increases IgG1 gene expression, and that may differ among HIV+ and HIV- subjects. Further analysis is required to assess the influence of IgG4 expression on progression to AIDS.

TUPEA072
Human leukocyte antigen (HLA) typing and novel allele description by next generation sequencing in HIV-1-infected individuals from Southern Brazil

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Background: The human leukocyte antigen (HLA) system plays an important regulatory role in the immune response. The classical HLA genes A, B and C are involved in T-cell mediated cytolytic immunity controlling HIV-1 viremia. Studies show that the B*35 and B*53 alleles lead to a rapid disease progression, whereas “protective” alleles of the host such as B*27 and B*37 are associated with immune control of infection and slower progression. Next-generation sequencing (NGS) enables resolving the ambiguity of genotypes caused by the large number of existing polymorphisms, and provides a high-resolution typing. Our project aims to determine the HLA-A, B and C alleles by NGS, evaluating different methodologies for assembly, reconstruction and identification of novel alleles of HIV+ patients from southern Brazil.

Methods: HIV+ patients have been followed at Hospital das Clínicas de Porto Alegre from 2002-2003 up to present. HLA-A, B and C genes were PCR-amplified, and libraries were sequenced in an Illumina HiSeq 2500. Generated reads were analyzed in FastQC and trimmed with Sickle. The Omixon-Target algorithm was used for allele typing based on the IMGT/HLA database. Reads were assembled with reference with BWA. Variants sites were detected with GATK using the UnifiedGenotyper tool. All alignments and variant determination results were visually inspected with IGV.

Results: Eighty-six patients have their HLA-A, B and C alleles PCR-amplified and sequenced. Eighty-one samples had their data analyzed and trimmed. Allele frequencies were similar to those reported in southern Brazil. Ten samples were homozygous for HLA-A (12%), 11 for HLA-B (13%) and 10 for HLA-C (12%). HLA-B*35 was found in 19 patients (11%). Until now, 162 (33%) alleles have been tested for reconstruction of new alleles, and six (4%) are indicative of possible new alleles.

Conclusions: Different algorithms have been tested for HLA allele reconstruction and typing. HLA studies in HIV-infected patients with an ethnic background of the southern region of Brazil, are relevant to a better understanding of host genetic factors that respond to this viral infection.

TUPEA073
Absence of an association between mannose binding lectin deficiency and HIV-1 disease progression in an adult population in Zimbabwe

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Background: Deficiency in plasma Mannose Binding Lectin (MBL) due to single nucleotide mutations at the MBL exon1 gene structural region and promoter region is a common opsonic defect. HIV disease progression is influenced by host genetic factors. Relationship between MBL deficiency and HIV disease progression in Zimbabwean adults is not known. We assessed association between MBL deficiency and disease progression in Zimbabwean ART-naive adult males and females enrolled in the Mupfurwah Schistosomiasis and HIV cohort (MUSH cohort), established between 2001 and 2007.

Methods: We analysed blood samples of the MUSH cohort for plasma MBL levels using ELISA assays, MBL1 genotypes and promoter region alleles were detected by allele-specific oligonucleotide PCR (ASO-PCR) where specific sequences were used for each allele, HIV-1 status, viral load and CD4+ T cell counts. Generalised Estimating Equations (GEE) models were used to test the association between MBL deficiency and HIV-1 disease progression.

Results: We assessed 198 HIV positive adults, 83% (164) women, median age (IQD) of 31 (27 to 39) years old. Prevalence of HIV-1 in this population was 18% and plasma MBL deficiency was also 18%. Among these HIV infected individuals we found no association between plasma MBL deficiency (p=0.626), MBL2 structural genetic variants (p=0.633), MBL2 promoter region variants (p=0.602) and change in CD4+ T cell count and viral load from baseline to 3 years follow up.

Conclusions: Plasma MBL deficiency and MBL2 genetic variants had no effect on disease progression in this population.

TUPEA074
Global mapping of HIV-1 and host-cells molecular interactions

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Background: HIV-1 in vitro models using human primary cells are strongly limited by the low rate of productive infection occurring even with large amounts of virus. Thus, only 2 to 20% of activated CD4 T-cells or macrophages appear to offer a favorable environment for successful replication of HIV-1 (productive cells). Among a large majority of “bystander” cells (uninfected and abortively infected cells not expressing HIV-1 proteins), a weak fraction of the total population integrates the virus and remains in a latent state by redirecting the cell chemotactic machinery. To date, very little is known about cellular events leading to successful virus replication and latency in primary cells due to the difficulty of studying separately productively HIV-1-infected cells from the latent and “bystander” cells.

Methods: We developed a collection of replicative reporter viruses allowing the sorting of these different populations (productive, bystander and latent cells) through an immunomagnetic capture of small surface epitopes (HA, HSA) or flow-cytometry sorting of fluorescent proteins (ZsGreen, E2-Crimson) co-expressed with the viral genome in productive and latent cells. We used this method to isolate infected CD4 T-cells and MDMs and analysed their transcriptionic and proteomic profiles using a high throughput RNA sequencing analysis and 2D-gel separation combined with mass spectrometry.

Results: Integrated bioinformatics analysis of -omics data allowed us to detect with a high resolution the modulated transcripts and proteins controlling the successful replication of HIV-1 in CD4 T-cells and macrophages. We identified several new genes, mRNA, IncRNA and proteins, as well as extracellular markers specifically expressed at the surface of infected cells that could be keys for a specific eradication of infected and latent cells. The different targets are currently validated by RNA interference for their functions affecting HIV-1 transcription and latency.

Conclusions: The acquired data shed new light on HIV-1 replication mechanisms and will allow the emergence of new specific inhibitory strategies against the constitution of persisting virus reservoirs and AIDS propagation. Identification of surface proteins specifically expressed in infected cells are also interesting candidates for a vaccine targeting HIV-1 host cells instead of the virus itself that is known to be highly variable.
Preclinical drug development

TUPEA075

TLR7 agonist GS-9620 is a potent inhibitor of acute HIV-1 infection in human PBMCs

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Backgrounds: GS-9620 is a potent and selective oral TLR7 agonist that activates plasmacytoid dendritic cells (pDCs) to produce various cytokines including interferon-α (IFN-α). GS-9620 induced prolonged suppression of hepatitis B virus (HBV) in animal models of chronic infection and is now being tested in patients with chronic HBV infection. GS-9620 has also been shown to activate HIV expression in peripheral blood mononuclear cells (PBMCs) from virally suppressed patients and is being evaluated clinically for HIV-1 latency reversal. To further support the clinical testing of GS-9620 we investigated its effect on acute HIV-1 infection in vitro.

Methods: Anti-HIV-1 activity was tested in PHA-activated PBMCs or purified total CD4+ T-cells using multi-cycle and single-cycle infection assays. Specific immune cell subsets (pDC, NK, NB or CD8+ T-cell) were depleted from PBMCs by negative selection prior to anti-viral testing. Conditioned supernatants from GS-9620-treated complete or pDC-depleted PBMCs were tested for anti-viral effect on purified HIV-infected CD4+ T-cells. Cytokines were quantified by ELISA or Luminescence assay. Blocking antibodies against IFN-α or IFN-α receptor were used to access the role of IFN-α signaling in anti-HIV-1 activity.

Results: GS-9620 potently inhibited HIV-1 in multi-cycle infection of PBMCs (mean EC50 = 0.030 µM, 95% CI = 0.021–0.039 µM, n=2 donors). In a single-cycle PBMC infection assay, 48-hour pre-treatment significantly improved the potency of GS-9620 (EC50 = 0.027 µM, 95% CI = 0.021–0.031 µM, n=2 donors), consistent with a block in virus entry or early-stage HIV-1 replication. Depletion of pDCs, but not other immune cell subsets, reduced GS-9620 activity (21 to 277-fold, n=4 donors). IFN-α was not detected in GS-9620-treated total PBMC cultures, but not in pDC-depleted cultures. Although GS-9620 was inactive in purified CD4+ T-cells, HIV-1 replication was potently inhibited by GS-9620-conditioned PBMC media or recombinant IFN-α. IFN-α blocking antibodies abolished GS-9620 antiviral activity.

Conclusions: GS-9620 is a potent inhibitor of HIV-1 replication in primary PBMCs. Its anti-viral activity is dependent on interferon-α produced by activated pDCs. Immune modulatory effects of GS-9620 leading to simultaneous activation of HIV-1 expression and inhibition of acute HIV-1 infection are important considerations for its clinical evaluation since the antiviral effect may help restrict potential local spread of virus upon in vivo latency reversal.

TUPEA076

A novel acyclguanidine-based inhibitor of HIV-1 egress

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Background: Discovery of new antiretroviral drugs is necessary to enhance treatment options and counter resistance. Here, we investigate the anti-HIV activity of a novel acyclguanidine compound, SM111, and characterize its ability to block viral egress.

Methods: The ability of SM111 to alter replication of WT NL4.3, NL4.3ΔVpu, and recombinant NL4.3 strains encoding major protease (PR), Reverse Transcriptase (RT) and Integrase (INT) inhibitor resistance mutations was assessed using GFP-reporter cells. Experiments were performed using primary and recombinant human PBMCs. Passage experiments in PBMCs were performed to select NL4.3 mutants with decreased susceptibility to SM111. To assess virus release in the presence or absence of SM111, intracellular and extracellular p24 was measured at 48 hours post-transfection using 293T cells. Results: SM111 caused minimal cytotoxicity, but reduced replication of WT NL4.3-AS well as PR-, RT- and INT-resistant strains in a dose-dependent manner (>50% reduction in Gag cells and 57% in PBMC). Passage experiments led to outgrowth of three independent NL4.3 variants harboring gross mutations in Vpu’s transmembrane domain, including a 5AA deletion spanning Vpu codons 13-17 (strain A), a stop codon at highly conserved V22 (strain C) and a substitution (I17R) (strain H). Notably, SM111 retained partial activity against NL4.3ΔVpu in CEM cells and PBMCs (52% and 30% reduction, respectively) as well as passaged strains A, C and H (92% 54%, and 15% reductions in CEM-T cells versus 65%, 11%, and 10% in PBMC, respectively). Intracellular p24 expression in transfected 293T cells was comparable between SM111 and no-drug control; however, a dose-dependent reduction in supernatant p24 of up to 10-fold was observed in the presence of SM111.

Conclusions: SM111 inhibited WT HIV-1 as well as drug-resistant strains. It selected major mutations in Vpu’s transmembrane domain, but these mutants and NL4.3ΔVpu remained partially sensitive to the drug in T cell lines and PBMCs. SM111 blocked virus release in 293T cells. Together, these results indicate that SM111 displays a unique mechanism of action, targeting a step in the HIV-1 life cycle that may be modulated by Vpu and require interaction with an unknown host cell factor(s).

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TUPEA077

Novel CD4-mimetic small molecules show enhancement of the neutralization activity of anti-cryptic V3 neutralizing antibody, KD-247

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Background: CD4 mimetic small molecules, such as NB6-566, inhibit the gp120-CD4 interaction and can also induce conformational changes in gp120 by exposing masked epitopes of neutralizing antibodies on the Env protein.

Methods: Nineteen YIR compounds were designed and synthesized to interact with the conserved residues in the Phe43 cavity of gp120 using our previously reported method. A chimeric clone containing the primary KP-SP virus isolate (subtype B, R5) gp160 with a PNL4-3 backbone was constructed. The susceptibility of the infectious clone to entry inhibition and neutralization sensitivity to the anti-cryptic V3 neutralizing monoclonal antibody (mAb) KD-247, in the presence of the YIR compounds, was determined using the TZM-bl assay. Results were compared to the parental NB6-566 compound.

Results: All 19 YIR compounds inhibited the KP-SP infectious clone with an IC50 in the range of 2-8.6 µM. YIR compounds showed an almost 5-fold improvement activity compared to NB6-566. Neutralizing activity of KD-247 against the KP-SP clone was also measured in the absence or presence of YIR compounds (range: 125-1,000 nM). KD-247 neutralizing activity was much less potent against the KP-SP clone (IC50 of <200 µM). However, when pretreated with at least 125 nM of the YIR compounds the KP-SP clone became highly sensitive to KD-247, exhibiting an IC50 in the range of 3.3-23 µM. These results suggest that YIR compounds render primary HIV-1 sensitive to neutralization by mAbs directed against the V3 region involved in co-receptor binding, similar to the potent NB6-566.

Conclusions: The CD4 mimetic small molecules, YIR compounds, may be useful in inhibiting HIV-1 infection not only by directly obstructing the interaction between gp120 and CD4, but also enhancing sensitivity to neutralizing antibodies.

TUPEA078

BMS-955176: characterization of a 2nd-generation HIV-1 maturation inhibitor

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Background: BMS-955176 is a 2nd-generation HIV-1 maturation inhibitor (MI). A 1st-generation MI, bimatoprost, showed efficacy in early-phase studies, but ~50% of subjects had virus with reduced susceptibility associated with naturally occurring Gag polymorphisms. As such, designed to target a specific subset of residues in the HIV-1 envelope that is highly conserved among retroviral species, including the HIV-1 envelope that is highly conserved among retroviral species, including the HIV-1 envelope that is highly conserved among retroviral species.

Methods: BMS-955176 inhibition of Gag cleavage in HIV-1-infected cells and specific binding to Gag in virus-like particles (VLPs) was assessed in the presence of anti-HIV-1 activity. Activity of BMS-955176 was also assessed against a series of clinical isolates in peripheral blood mononuclear cells (PBMCs) and a panel of antiretroviral-resistant viruses. Serum effect was assessed in 10% fetal bovine serum (FBS) and 27 mg/mL human serum albumin (HuSA).

Results: BMS-955176 inhibits HIV-1 protease cleavage at the CA/SP1 junction within Gag in HIV-1-infected cells and binds tightly and reversibly to Gag in purified HIV-1 VLPs. The average EC50 was 3.9±3.4 µM over a range of 877±220 µM in recombinant substrate B viruses containing 96% of subtype B polymorphic Gag diversity near the CA/SP1 cleavage site. The susceptibility of HIV-1 and 1-subtype B viruses to BMS-955176 was determined using the V3 region and in the presence of the YIR compounds.

Conclusions: The CA/SP1 cleavage site is a key target of BMS-955176 in the presence of CD4 mimetic small molecules, such as NB6-566, and the 2nd-generation MI, broad coverage of HIV-1 subtypes, and low human serum binding. These data support further clinical development of BMS-955176.
**TUPEA079**

Small molecule activator of protein phosphatase 1 (SMAP1) activates latent HIV-1 provirus


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**Background:** Eradication of latent HIV-1 provirus requires reactivation of transcriptionally silent proviruses that are not affected by antiretroviral drugs. In latently infected T cells, the lack of host transcription factors and viral protein Tat lead to the reduction in viral gene expression. We previously showed that protein phosphatase-1 (PP1) activates HIV-1 transcription by controlling CTD phosphorylation. We developed a small library of molecular compounds targeted to a novel site of PP1 and found a molecule (SMAP1) that activated latent HIV-1.

**Methods:** Chronically infected with HIV-1 cells ACH2 and OM1.0.1 and latently infected Jurkat T-cells and THP-1 cells were treated with the compounds and HIV-1 transcription was monitored. SMAP1 binding to PP1 was analyzed using Biacore, in vitro PP1 assay and in silico docking analysis. The effect of SMAP1 on T cells was analyzed using proteomics approaches.

**Results:** SMAP1 activated one round HIV-1 infection and latent HIV-1 in chronically infected T-cells and monocytes. SMAP1 induces PP1 activity in vitro and increased expression of PP1 regulatory subunit Sds22 in cultured cells. Docking of SMAP1 to PP1 showed its binding to a pocket that overlaps with the predicted Sds22-binding site.

**Conclusions:** We developed a new compound, SMAP1, which targets PP1 and may affect the PP1 binding to its regulatory subunit Sds22 increasing HIV-1 Tat activated transcription. These compounds can be used for purpose of eradication of HIV-1 in combination with the anti-retroviral HIV-1 therapy.

**TUPEA080**

Discovery and anti-HIV-1 activity of a new class of diheteroarylamide-type anti-HIV-1 agents acting on HIV-1 alternative splicing

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**Background:** Our research, built upon an earlier observation that a tetracyclic indole compound (IDC16) inhibits HIV-1 pre-messenger RNA splicing, is aimed at identifying novel HIV-1 splicing inhibitors that are more readily accessible by synthesis than IDC16 and not cytoxic (devoid of DNA-intercalating properties). A diversity-driven library synthesis approach was used to design six different families of flexible diheteroarylamide compounds that mimic the essential features of the IDC16 structure. The most potent compound, C8, was selected for detailed analysis of its anti-HIV-1 activity against a comprehensive panel of HIV-1 mutant strains conferring resistance to all known anti-HIV-1 drugs. Further studies (Chabot et al) revealed that this molecule interferes with the activity of the splicing factor SRSF10.

**Methods:** Parallel synthesis strategies were used to prepare the library of 240 potential IDC16 mimics. The evaluation of the anti-HIV activity of this collection was determined by a T-cell reporter assay that expresses green fluorescent protein upon HIV-1 infection. The level of infection was monitored using flow cytometry. To investigate the adverse effect on cell viability, we employed Guava ViaCount Assay (Millipore) on the same reporter cells.

**Results:** Of the four structurally related diheteroarylamide compounds identified as active in the preliminary screen, the anti-HIV-1 profile of compound C8 was studied in detail. C8 was active against a broad range of wild-type and drug-resistant HIV-1 variants. C8 inhibits wild-type subtype A strain 97US354, and subtype B strain IIIB with IC50 of 1.5 µM, and 0.9 µM respectively. In addition, at 16 µM concentration, C8 elicited a modest protease inhibitors, integrase inhibitors, and CCR5 antagonist inhibitors with IC50's of 1.4 µM, and NNRTI with IC50 of 1.3 µM. Compound C8 was also active against viruses resistant to ARVs.

**Conclusion:** These results show that C8 remains active against the entire panel of HIV-1 mutants studied, and that it displays no cross-resistance to the above antiretroviral agents. Our findings also show that C8 most likely does not act on the traditional drug targets.

**TUPEA081**

Discovery of novel HIV-1 inhibitors from natural products


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**Background:** Rapid scale-up of antiretroviral (ART) treatment programs has significantly reduced morbidity and mortality due to HIV infection in resource-limited settings such as parts of sub-Saharan Africa. However, new HIV inhibitors are needed to minimize adverse effects and overcome potential resistance to existing drugs.

**Methods:** Natural products are a promising but undervalued resource for identifying new antiviral compounds that act via distinct mechanisms.

**Results:** We identified two compounds from the p-ANAPL, ixoratannin A-2 and boldine, that inhibited WT NL4.3 and displayed weaker activity against NL4.3ΔVpu (ioxoratannin A-2: EC50 = 34.4 and 52.0 µM; boldine: EC50 = 50.2 and >100 µM, for NL4.3 and NL4.3ΔVpu, respectively). Two crude plant extracts supported by traditional medicinal knowledge; and 3) A library of 255 pure marine natural products from Southeast Asia.

**Conclusions:** We have identified new sources of anti-HIV agents from pure natural products and crude extracts supported by traditional medicinal knowledge. Several compounds inhibited drug-resistant strains, suggesting mechanisms of action that are different from licensed ARVs.

**TUPEA082**

Development of efficient parallel synthesis strategies for the generation of compound libraries of anti-HIV-1 agents that alter HIV alternative splicing

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**Background:** Our research is directed toward the discovery of new classes of anti-HIV drugs that:

i) act through unexploited mechanisms of action,

ii) bypass the problem of drug resistance,

iii) display minimal, or no, toxicity,

iv) address the problem of activating the latent viral pool.

HIV produces over 40 distinct mRNAs by alternative splicing. In this context, targeting the expression or activity of splicing regulators using small molecules is being explored as a novel anti-HIV strategy, as the exquisite reliance of HIV on splicing may render it sensitive to even slight disturbances in splicing.

**Methods:** Based on the finding that a fused tetracyclic indole compound, IDC16 inhibits HIV replication by acting on HIV-1 pre-mRNA splicing, a diversity-driven library synthesis-screening program allowed the identification of four novel diheteroarylamide-compounds. C8, E5, C2 and D3, as anti-HIV agents. Preliminary data showed that C8 has the highest inhibitory effect in HIV-1 replication through interaction with SRSF10. In the subsequent SAR-driven phase of this program, highly efficient and environmentally clean strategies have been perfected for the synthesis of diheteroarylamide-type structures. Molecular modeling plays an important role in the study of the conformational properties of these library molecules.

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Preclinical microbiode development

TUPEA083
Antiviral activity of 5-Hydroxytyrosol, a microbicidal candidate against HIV-1 transmission

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Background: Microbicides are currently one of the main strategies to prevent HIV infection that is especially important in developing countries. The objective of this work is to study the anti-HIV in vitro activity and in vivo toxicity of 5-hydroxytyrosol (5-HT), an anti-inflammatory and antiviral natural compound, in order to develop an effective low-cost microbicide.

Methods: The antiviral activity of 5-HT was assessed against SIV and several HIV-1 strains including founder viruses, strains resistant to other antiretrovirals using different experimental models: cell lines, lymphocytes and monocytes from human peripheral blood, autologous co-culture of DC-SIGN expressing cells and lymphocytes and infection through epithelial layers. Anti-HIV activity of 5-HT was also assessed in combination with Tenofovir or Lamivudine. Synergism was analyzed according to T-C Chou and P. Talaya method. Mechanism of action was studied using VSV pseudotyped HIV-1, RT-PCR and transfection experiments. Toxicity was tested in vitro and in vivo, through evaluation of local tolerability at vaginal mucosa in New Zealand White rabbits (n=6) at three different concentrations (30, 100 y 200 mM or 4.8, 15.4 and 30.8 mg/l) during 14 consecutive days by topical route. Results: 5-HT was active against SIV and all the HIV-1 strains and scenarios tested with IC50 ranging between 20-60 µM. In vitro toxicity was only observed at doses greater than 250 µM. A strong synergistic effect was displayed by combination of 5-HT and Tenofovir (Combination index as low as 0.24) while an additive effect was observed with Lamivudine. The mechanism of action of 5-HT is not related to viral entry, retrotranscription or integration. 5-HT was able to diminish viral transcription through NF-kB and Sp-1 inhibition. Topical administration of 5-HT did not cause inflammatory responses or morphological alteration in the vaginal mucosa of rabbit.

Conclusions: 5-HT was active against SIV and different HIV-1 strains in a variety of scenarios in vitro. A strong synergistic activity with Tenofovir was found being viral transcription the main target of 5-HT through NF-κB and Sp-1 inhibition. In summary 5-Hydroxytyrosol is a new class of microbicide combining both anti-inflammatory and anti-HIV properties and represents a potential candidate for clinical trials.

TUPEA084
Protection from HIV-1 infection by S-layer mediated display of anti-HIV proteins on Caulobacter crescentus

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Background: Despite effective prevention options, more than 2.7 million new HIV-1 infections occur each year. Due to societal and biological factors, women are 2-4 times more likely to acquire HIV-1 through sexual transmission, suggesting that female controlled prevention options are urgently needed. We have previously proposed the development of an HIV-1 specific microbicide using the non-pathogenic freshwater bacterium Caulobacter crescentus.

Methods: C. crescentus has a Surface or S-layer, which is a repeating layer of the protein RaaA that coats the surface of the bacterium. We have developed a technique to insert foreign protein sequences into the RaaA protein, which leads to high-density display of recombinant proteins on the surface of C. crescentus. Recombiant C. crescentus have been tested for the ability to prevent HIV-1 infection in vitro using a virus blocking assay and in vivo with humanized mice.

Results: We have successfully expressed 17 different anti-HIV-1 proteins on the surface of C. crescentus including CD4, MIP1α, fusion inhibitors and anti-viral lectins. Using an in vivo viral blocking assay we have demonstrated that 12 of the recombination C. crescentus are able to provide significant protection from HIV-1 infection, with protection levels reaching 97% when recombinant C. crescentus are used in combination. Studies with immune-competent mice have demonstrated that C. crescentus does not induce the production of inflammatory cytokines or the recruitment of immune cells to the vaginal tract. We have continued in vivo experiments utilizing the humanized Bone marrow-Liver -Thymus (BLT) mouse model. The implantation of human liver and thymus tissue is combined with the intravenous injection of autologous human CD4+ cells into NOD-scid IL2rg−/− mice to create the BLT mice. The peripheral blood of these mice contains 40% human CD4+ cells including human CD4+ T cells, CD8+ T cells, B cells, NK cells and myeloid cells and the mice are susceptible to intravaginal infection with HIV-1. We have demonstrated significant protection from vaginal HIV-1 infection when recombinant C. crescentus is applied intravaginally at the time of HIV-1 infection.

Conclusions: Taken together these results suggest that a C. crescentus based microbicide could be a safe and effective method for HIV-1 prevention.

Targeting HIV persistence during ART (cure strategies)

TUPEA085
MG1 and VSVΔ51 viruses target and kill latently HIV-infected myeloid cells

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Background: Latent HIV reservoirs represent a major barrier to eradication. We propose a novel strategy to eliminate this reservoir using a class of oncolytic viruses (OV) that include Maraba (MG1) and Vescular Stomatitis Virus (VSVΔ51). These recombinant OV target cancer cells by exploiting defects in type I interferon (IFN)-signaling. Similar alterations in IFN-mediated antiviral responses are also seen in HIV-infected cells, providing a crucial link between cancer cells and the HIV reservoir. We hypothesize that MG1 and VSVΔ51 selectively target and kill latently HIV-infected cells.

Methods: Latently HIV-infected myeloid (U1 and OM10.1) cell lines, as well as their respective parental uninfected controls (U937 and HL60) were infected with GFP-expressing MG1 or VSVΔ51. Productive OV infection was quantified by flow cytometry. PI, MTT, and Alamar Blue assays were used to assess cell viability. Type I IFN response to OV infection was characterized by measuring IFNα secretion by ELISA, as well as PKR expression by Western blot. OV infection of primary monocytes, MDMs, and CD4+ T cells from HIV-infected donors was also assessed.

Results: U1 and OM10.1 cells were significantly more susceptible to MG1 and VSVΔ51 infection and killing than their respective HIV-uninfected U937 and HL60 parental controls. IFNα secretion significantly increased in response to OV infection in control cell lines, but not in the latently HIV-infected cells. In parallel, PKR expression in response to OV infection was significantly higher in the HIV-uninfected controls than in the latently HIV-infected cells. Primary monocytes, MDMs, and CD4+ T cells from HIV-infected individuals were relatively resistant to OV infection and killing.

Conclusions: Latently HIV-infected myeloid cells are preferentially targeted and killed by MG1 and VSVΔ51 when compared to their uninfected parent cells. Underlying defects in type I IFN-responses in latently HIV-infected cells may facilitate selective targeting by OV. Therefore, our results suggest that the use of OV may represent a novel and potentially safe approach to selective elimination of the latent HIV reservoir.
Background: Current guidelines recommend suppression of plasma human immunodeficiency virus type 1 (HIV-1) RNA viral load to below the limit of assay detection. Newer generations of viral load assays are now able to detect and quantify viral load at very low levels, but the significance of this very low-level viremia (VLV) remains unclear.

Methods: A retrospective cohort study was conducted to analyse the association between VLLV and virologic rebound in 820 HIV-1 infected patients on highly active antiretroviral therapy (HAART). Patients with viral load <50 copies/ml were stratified into “VLV” group (20-49 copies/ml) and “suppressed” group (<20 copies/ml) according to the viral load tested by Roche Molecular Systems COBAS Amplicor/COBAS Taqman HIV-1 Test version 2.0. Independent effects of viral load groups, demographic, clinical and laboratory variables on risk of virologic rebound at 104 weeks were investigated by a Cox proportional hazard model.

Results: There were 628 patients in the “suppressed” group and 194 patients in the “VLV” group. Median follow-up time was 96 weeks (interquartile range (IQR) 90-101 weeks), virologic rebound rate were 1.8% and 3.6% in the “suppressed” and “VLV” group respectively at 48 weeks and 3.2% and 7.2% at 104 weeks. Time to virologic rebound at 104 weeks is significantly shorter in the “VLV” group (log-rank test, p < 0.005). Cox proportional hazard model demonstrated that adjusted hazard ratio for virologic rebound for VLLV at 104 weeks was 3.351 (95% confidence interval, 1.411-7.567, p < 0.001), which is independent of adherence levels. Another independent predictor was suboptimal HAART adherence.

Conclusions: HIV-1 infected patients on HAART with very-low level viremia were associated with virologic rebound and this finding was independent of other recognized determinants. The clinical significance of VLV warrants further study.

Background: "Shock and kill" methods are being tested as a strategy to cure HIV infection. Various agents can reactivate latent proviruses; however, immune-mediated killing of these cells appears to be inefficient. To investigate whether this is due in part to poor antigen presentation. Various agents can reactivate latent proviruses; however, immune-mediated killing of these cells appears to be inefficient. To investigate whether this is due in part to poor antigen presentation.

Methods: A latent Jurkat-GFP (J-Lat) cell line stably expressing HLA-A*02+ was constructed and used as target cells. HIV was reactivated using anti-latency agents (TNFα and HDACi) and reactivated cells were obtained and used as target cells. HIV-1 infected patients on HAART with very-low level viremia were associated with virologic rebound and this finding was independent of other recognized determinants. The clinical significance of VLV warrants further study.

Results: Co-culture of TK10-pulsed J-Lat-A02 targets with TCR+ effectors cells as an increase in luciferase signal. Results: Co-culture of TK10-pulsed J-Lat-A02 targets with TCR+ effectors resulted in a dose-dependent increase in luciferase signal. Anti-latency agents reactivated ≤5% to 40% of live J-Lat cells, versus TNFα (30%) and DMSO (0%), and expression of Gag-p24 correlated with higher GFP fluorescence. Peptide presentation by HDACi-treated target cells, even in the presence of IFNγ and ATRA, suggests that these drugs further impaired peptide presentation. Altered antigen presentation intrinsic to latent cells/ cell lines or as a side-effect of anti-latency drugs should be considered as a potential barrier to HIV eradication.

TUPEA086
Risk of virologic rebound in HIV-infected patients on HAART with very low-level viremia
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TUPEA087
Minimal HIV-1 Gag epitope presentation in a T cell line during reactivation
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Background: “Shock and kill” methods are being tested as a strategy to cure HIV infection. Various agents can reactivate latent proviruses; however, immune-mediated killing of these cells appears to be inefficient. To investigate whether this is due in part to poor antigen presentation.

Methods: A latent Jurkat-GFP (J-Lat) cell line stably expressing HLA-A*02+ was constructed and used as target cells. HIV was reactivated using anti-latency agents (TNFα and HDACi) and reactivated cells were obtained and used as target cells. HIV-1 infected patients on HAART with very-low level viremia were associated with virologic rebound and this finding was independent of other recognized determinants. The clinical significance of VLV warrants further study.

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Conclusions: These results indicate that J-Lat cells present endogenous viral peptides poorly, but this activity could be enhanced by IFNγ and ATRA. Lack of TCR-mediated stimulation by HDACi-treated target cells, even in the presence of IFNγ and ATRA, suggests that these drugs further impaired peptide presentation. Altered antigen presentation intrinsic to latent cells/ cell lines or as a side-effect of anti-latency drugs should be considered as a potential barrier to HIV eradication.

TUPEA088
Vorinostat, panobinostat and romidepsin nonselectively activate transcription from quiescent HIV-1 proviruses in HIV-infected individuals on long-term suppressive antiretroviral therapy
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Background: Clinical trials in HIV-infected individuals on long-term anti-retroviral therapy (ART) using histone deacetylase inhibitors (HDACis) to reverse HIV latency have demonstrated a measurable increase in HIV transcription in CD4 T cells in blood. However, for effective viral clearance, it is important that these compounds activate transcription from a broad range of integrated proviruses.

In this study, we sequenced to determine whether vorinostat, panobinostat, and romidepsin selectively or nonselectively target HIV-1 proviruses.

Methods: CD4 T cells were obtained from 36 participants before, during, and after HDACi treatment using vorinostat (n=15), panobinostat (n=15), and romidepsin (n=6). We used single-proviral genome sequencing to characterize the genetic composition of the env region of cell-associated HIV-1 DNA and RNA to determine which HIV-1 proviruses were being transcribed in response to HDACi therapy within CD4 T cells. Additionally, for the panobinostat trial, we sequenced plasma HIV-1 RNA from samples collected during a post-HDACi ART interruption. Maximum-likelihood trees were constructed for each participant and the average-pairwise distance of the sequences was calculated using MEGA6.0.

Results: The average-pairwise distance of the cell-associated HIV-1 RNA that was detected following administration of the HDACis was not significantly different from that of the cell-associated HIV-1 DNA (2.9% vs. 3.1%, p=0.79). Furthermore, upon phylogenetic analysis, the HIV-1 RNA sequences intermingled with the HIV-1 DNA sequences throughout the phylogenetic trees, supporting a broad and nonselective activation of HIV-1 proviruses. The plasma-derived sequences from the ART interruption samples contained expansions of identical sequences, which in three cases were identical to cell-associated DNA sequences. Additionally, cell-associated HIV-1 RNA had a significantly higher percentage of dead-end virus (hypermutated and/or containing stop codons) than the cell-associated HIV-1 DNA (40.1% vs. 7.8%, p=0.0004).

Conclusions: We found that vorinostat, panobinostat, and romidepsin nonselectively induce transcription from HIV-1 proviruses in HIV-infected individuals on long-term suppressive therapy, which is promising for the development of future therapies that aim to activate quiescent HIV-1 proviruses as part of an eradication strategy. Although, a large amount of cell-associated HIV-1 RNA was replication incompetent, we did identify cell-associated HIV-1 DNA that contributed to rebound virus during a post-HDACi ART interruption.

TUPEA089
Combinatorial CRISPR/Cas9 approaches targeting different steps in the HIV life cycle efficiently limits viral reactivation and halts viral replication
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Background: Currently available combination antiretroviral therapy can successfully control HIV replication. However, conventional treatment lacks the ability to stop viral production and clear the latent reservoir, which remains the major obstacle towards a cure. Novel strategies are required to permanently disrupt the HIV genome in the latently infected cells. In this study we have investigated the potential of the CRISPR/Cas9 system to prevent HIV re-activation from latently infected cells and to target different steps in the viral lifecycle to halt viral replication.

Methods: The CRISPR/Cas9 system is comprised of a Cas9 protein, which in combination with a guideRNA (gRNA), is able to cleave a complementary dsDNA sequence. gRNAs were designed to target HIV LTR, protease, reverse transcriptase, integrase and the structural matrix protein. The CRISPR/Cas9 system was cloned in a lentivirus vector and used to transduce SupT1 and Jurkat cells. The latter contains full-length HIV and expresses GFP upon TNFα stimulation. SupT1 cells were transduced with the lentiviral constructs and subsequently infected with HIV using different MOIs and viral replication was monitored by HIV DNA quantification and HIV CA-p24 production. On and off targeting efficiency (three genes per CRISPR) were determined through deep sequencing.

Conclusions: These approaches are able to disrupt transcription from HIV-1 proviruses. These results indicate that J-Lat cells present endogenous viral peptides poorly, but this activity could be enhanced by IFNγ and ATRA. Lack of TCR-mediated stimulation by HDACi-treated target cells, even in the presence of IFNγ and ATRA, suggests that these drugs further impaired peptide presentation. Altered antigen presentation intrinsic to latent cells/ cell lines or as a side-effect of anti-latency drugs should be considered as a potential barrier to HIV eradication.
**Results:** Lentiviral transduction in SupT1 and Jurkat cells resulted in stable expression of the CRISPRCas9 system. Deep sequence analysis demonstrated efficient HIV genome editing (75-99%) and an off-target efficiency ranging between 0.1-1.7%. TNFα-induced HIV reactivation from latently infected T cells was significantly reduced after transduction with gRNAs. Single gRNA resulted in 90-95% HIV loss of expression and in cells and targets by combination of two LTR gRNAs >98% loss of expression was shown. Subsequently, we investigated the potential of gRNAs to inhibit viral replication. HIV DNA quantification demonstrated up to 40-fold reduction in intracellular HIV DNA and a significant reduction in virus production. Most combinations of two gRNAs resulted in complete abrogation of viral replication, which could not even be rescued after months of in vitro selection.

**Conclusions:** The newly discovered CRISPRCas9 system is able to target HIV efficiently in both primary infection and latency models and may provide a specific, efficacious prophylactic and therapeutic anti-viral approach.

**TUPEA090**

**Universal Tre-recombinase (uTre) specifically targets the majority of primary HIV-1 isolates**


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**Background:** HIV-1 integrates into the host chromosome and persists as a provirus, flanked by long terminal repeats (LTR). To date, treatment regimens primarily target virus uptake, -transcription, -viral fusion or the virus enzymes, but not the integrated provirus. Thus, current antiretroviral therapy (cART) cannot eradicate HIV-1, a fact that highlights the urgency of pursuing new strategies to find a cure for HIV/AIDS. Previously, we engineered an experimental HIV-1 LTR-specific recombinase (Tre-recombinase) that can efficiently excise integrated pro-viral DNA from infected human cell cultures. Subsequently, we demonstrated highly significant antiviral activity of this HIV-1 subtype A-specific Tre in humanized mice. Broad clinical application, however, requires availability of a Tre-recombinase that recognizes a majority of clinical HIV-1 isolates.

**Methods:** We employed substrate-linked protein evolution to engineer universal Tre-recombinase (uTre), recognizing the LTRs in a majority of clinical HIV-1 isolates (>94% of HIV-1 subtype A, B, and C). The activity of uTre was subsequently analyzed in cell lines and primary cell cultures, as well as in HIV-infected humanized mice.

**Results:** Here we demonstrate the absence of cytotoxic and off-target effects, as well as pronounced antiviral uTre activity. In particular, uTre expression resulted in decline of viral loads below the detection limit (<20 HIV-1 RNA copies/ml) in “personalized” mice, which were engrafted with CD4+ T cells from HIV-infected patients.

**Conclusions:** The presented data suggest that uTre technology may become a valuable component of future eradication strategies to reverse infection and thereby provide a cure for HIV/AIDS.

**TUPEA091**

**Polyvalent immune responses correlate with lower number of HIV-infected CD4 T cells in chronically infected subjects treated with autologous RNA pulsed DC therapy**

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**Background:** AGS-004 immunotherapy consists of autologous DCs electroporated with autologous amplified HIV RNAs (Gag, Vpr, Rev and Nef). AGS-004 was administered every four weeks to chronic HIV patients while on standard antiretroviral therapy (ART). At week 14, following two rounds of romidepsin, followed by CD8+ cell depletion. Two SIV/RdV-infected RMs spontaneously reactivated HIV, while none of the subjects treated with romidepsin showed significant virus rebound (up to 10^3 copies/ml) that was controlled upon administration of CD8+ T-cell recovery. Romidepsin toxicity was monitored clinically and biologically, T-cell apoptosis post-RMD was assessed flow-cytometrically and by LDH ELISA.

**Results:** Romidepsin administration resulted in significant virus rebounds (up to 10^3 copies/ml) for SIV/BRF5 and 10^4 copies/ml for SIV/Sab followed by gradual viral decline. Romidepsin was well-tolerated and induced a massive surge in T-cell activation and transient lymphopenia during the first week post-treatment. Lymphopenia resulted from cell redistribution and down-regulation of surface markers rather than T-cell destruction. CD8+ cell depletion resulted in robust viral rebound (up to 10^4 copies/ml) that was controlled upon administration of CD8+ T-cell recovery. Romidepsin did not significantly affect CTL antiviral functions in vivo. Using mathematical modeling, we showed that a small fraction of latently infected cells were at the origin of virus rebound.

**Conclusions:** Using two different in vivo models of SIV control, we demonstrated that romidepsin can reactivate the reservoir virus. The levels of virus replication, timing of virus re-bound and rapid control of virus replication after romidepsin administration suggest the reactivated virus is replication-competent and romidepsin does not persistently alter CTL function. CD8+ cell depletion resulted in higher viral rebound compared to romidepsin administration, suggesting that romidepsin does not completely ablate CTL function. Altogether, our results show romidepsin may effectively reverse HIV latency.
TUPEA093
Robust HIV-specific T cells in post-treatment controllers from the VISCONTI cohort

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HIV-1 was reactivated and HIV-specific CD4 T cells were isolated from PBMCs, naïve and memory sorted resting CD4 T cell subsets. The cell-associated HIV-specific IFN-γ, IL-2, TNFα, MIP1β or CD40L production was measured by flow cytometry. The background was subtracted: HIV-1-specific responses were considered positive.

Results: Background of patients was characterized by high with respect to reactivation and treatment. Within the CD4 T cell subset, the proportion of HIV-specific IFN-γ and IL-2 producing cells was determined. The results showed that patients had a high frequency of HIV-specific CD4 T cells. These results suggest that the reactivation of HIV-specific T cells is not affected by treatment and that the reactivation of HIV-specific T cells is not influenced by treatment.

Conclusion: The reactivation of HIV-specific T cells is not affected by treatment and that the reactivation of HIV-specific T cells is not influenced by treatment.
Results: one predominant fingerprinting pattern with frequency 55% was detected. The OD obtained from reaction of the antibody with the corresponding epitope was significantly higher than those of the corresponding anti-CD4i Fabs. These methods established assays to measure ADCC-mediated killing by modifying the LDH release assay and ADCC-induced NK cell activation following reactivation of latently infected cell lines. Results: ADCC-mediated killing and NK cell activation was detected following exposure of a chronically infected CD4+ T cell line or cell lines pulsed with the HIV envelope glycoprotein gp120. However, we found that reactivated latently infected T cell lines, although they elicited higher background levels of killing and NK cell activation, were not susceptible to ADCC-mediated killing and did not elicit HIV-specific antibody-mediated NK cell activation. The reactivated cells expressed high levels of gp120 (as high or higher than gp120 pulsed cells), but did not express CD4, likely due to down-modulation by the HIV accessory proteins Vpu and Nef.

Conclusions: These studies suggest the hypothesis that reduction in CD4-induced ADCC epitopes at least partially protects reactivated latently infected cells from ADCC recognition. These studies need to be confirmed in primary CD4+ T cell models of latency and will need to assess whether inhibition of Vpu and/or Nef can restore the susceptibility of reactivated latently infected cells to ADCC. Our results highlight a previously under-appreciated problem for the proposition that ADCC antibodies can assist in an HIV cure.

Conclusions: Taken together, the anti-CD4i scFvs are accessible to CD4i epitope hidden inside trimeric Env before binding to CD4, and effectively neutralize multi-clade HIV-1. The small fragment of anti-CD4i antibodies will be useful for a potent and broadly neutralizing HIV-1.

TUPEA099
A novel TLR-9 agonist (MGN1703) activates NK-cells and enhances NK-cell mediated viral killing of HIV-1 infected CD4+ T cells ex vivo
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Background: Toll-like receptor (TLR) agonists may have dual favorable effects in the context of ‘kick and kill’ HIV eradication approaches. First, as enhancers of anti-viral immunity via stimulation of immune effector cells and second as direct latency-reversing agents. To hasten the inclusion of a TLR agonist into an HIV cure strategy, we have performed extensive preclinical testing of a novel, specific and potent TLR-9 agonist, MGN1703. Classical TLR-9 agonists (e.g. CpG-ODN) exhibit toxicity and backbone-dependent activity associated with phosphorothioate modifications. In contrast, such chemical modifications are not required to maintain the structure of MGN1703, which greatly enhances the safety profile of this molecule. Methods: PBMCs from HIV-infected were stimulated with MGN1703 or media. Unspliced HIV-1 RNA (usHIV-RNA) in subsequently enriched CD4+ T cells was quantified using RT-qPCR. CR, NK-cell activation, intracellular IFN-gamma production and degranulation were assessed by flow cytometry. NK-mediated viral inhibition of HIV-1 (H9B2) infected, autologous CD4+ T cells was assessed using HIV-1 P24 ELISA and intracellular HIV-1 P24 staining of CD4+ T-cells. Supernatant cytokines were quantified by QuickPlex (MSD). Statistical analyses included one-sample and paired t-tests on log-transformed data.

Results: Regarding the ability of MGN1703 to improve antiviral immune responses, we found that MGN1703-stimulation led to: (i) increased CD69 expression on CD8+CD16+ ‘CD16’ NK-cells (47.5-fold; p=0.0014); (ii) a higher proportion of CD107a+ NK-cells (2.04-fold; p=0.0016); and (iii) a higher proportion of CD107a+ IFN-gamma+ NK-cells (2.43-fold; p=0.013). Furthermore, MGN1703-stimulated NK cells suppressed unspliced HIV-1 p24 levels by 76% versus 51% for unstimulated NK-cells (culture day 5; p=0.03). PBMCs stimulated with MGN1703 exhibited significant increases in cytokine production from (e.g. IP-10 increased 16.16-fold; p=0.024). Regarding the potential of MGN1703 to activate transcription of latent HIV-1, we found that MGN1703 increased transcription of usHIV-RNA in CD4+ T cells by 1.51-fold over media alone (p=0.38).

Conclusions: MGN1703 stimulation activated and enhanced the degranulation capacity of NK-cells. In addition, NK-cells stimulated with MGN1703 exhibited a significantly increased capacity to control HIV-1 replication in autologous CD4+ T-cells. These findings combined with the observation that MGN1703 induced an increase in usHIV-RNA transcription in CD4+ T-cells support the incorporation of the TLR9-agonist MGN1703 into HIV eradication trials.

HIV testing (including new algorithms, rapid/poin of care testing and strategies)

TUPEB216
What individual and contextual factors are associated with rapid HIV test utilization in the U.S.?
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Background: Rapid HIV tests (RT) can improve access to screening for high-risk populations. This is the first known nationwide U.S. study to explore correlates of RT utilization. Methods: This study includes 13,392 HIV-tested participants (ages 18-64) from the 2010 Behavioral Risk Factor Surveillance System with linked contextual data from the 2009 Area Health Education Resources file and state-level sources. Adjusted multilevel logistic models with scaled survey weights and clustered errors were estimated using GLLAMM to explore the association of RT receipt with individual, county and state fixed factors. Results: 25.98% of individuals received a RT for their last HIV test. RT users were significantly more likely to be young adults (age 18-24, AOR=1.68, 95% CI: 1.39, 2.03; Ref=25 to 34) or middle-aged (e.g. age 55-64, AOR=1.32, 95% CI: 1.11, 1.58); of minority race/ethnicity (e.g. Black/African American, AOR = 1.62, 95% CI: 1.37, 1.90; Ref=White); uninsured (AOR=1.41, 95% CI: 1.20, 1.67); of lower household income (e.g. income < $15,000, AOR: 1.49, 95% CI: 1.22, 1.80; Ref=$15,000 or more); and live in counties with above-average adult poverty rates.
High acceptability of rapid HIV test in Argentina: experience during a seroprevalence study in vulnerable groups

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Background: The Ministry of Health in Argentina recently updated the HIV diagnosis algorithm, incorporating the rapid HIV test (RHT) and the confirmation of reactive cases with viral load (bDNA Versant HIV RNA). CD4 cell count was also performed.

Methods: From September 2013 to May 2014, a cross-sectional HIV seroprevalence survey was conducted at different settings (non-governmental organizations, hospitals and field visits). Men who have sex with men (MSM), female transgender/travesties, drug users (DU) and female sex workers (FSW) were included in the study. HIV diagnosis was performed with Alere Determine HIV-1/2. All samples were also tested with Genescreen Ultra HIV Ag/Ab. Reactive cases were confirmed with viral load (DNAsy Versant HIV RNA), CD4 cell count was also performed.

Results: Between September 2013 and May 2014, 1517 individuals were tested. Regarding RHT acceptability, 99.5% of participants reported that proceedings had been “good” or “very good” and 91.2% preferred to know results in the same day. For 19% of the participants this was the first time they tested for HIV. Prevalence of HIV infection was 11.5% ([95% CI: 9.5-13.5]) for MSM, 31.5% ([95% CI: 24.1-38.9]) for female transgender/travesties, 3.5% ([95% CI: 1.5-6.9]) for DU and 5.1% ([95% CI: 3.4-7.8]) for FSW. Comparison of RHT with standard laboratory diagnosis showed 10 discordant observations (0.66%). RHT sensitivity and specificity was 97.3% and 99.6%, respectively (PPV: 96.7%, NPV: 99.7%). Acute HIV infection was detected in the laboratory in four MSM with a negative RHT. Fifty eight percent of HIV positive individuals had less than 500 CD4/µl at diagnosis.

Conclusions: Implementation of RHT was successful, revealing that its implementation could be a useful tool to facilitate access to diagnosis in vulnerable groups, where prevalence of HIV remains extremely high. RHT expansion, improving early diagnosis, would diminish the frequency of individuals that are diagnosed at advanced stages of the infection.

TUPEB218

Novel diagnostic peptide epitope biomarkers for detection and identification of recent and longstanding HIV infection using the Europium Nanoparticle Immuno Assay (ENIA)

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Background: Accurate and early detection of HIV infection is critical for timely initiation of therapy and help prevent transmission. Estimation of HIV incidence is necessary to evaluate impact of HIV prevention measures, and to identify populations for recruitment into clinical trials designed to prevent infection or treat early infection. Many incidence tests have been developed in the last decade but several limitations exist and improved tests are needed. We sought to evaluate disease-stage specific viral immune responses using a peptide epitope screening method to identify diagnostic biomarkers that distinguish recent and chronic infection.

Methods: We synthesized 20-mer peptides for consensus sequences for HIV-1 p24, gp41 and gp120 proteins using overlapping by 15 amino acids. Peptides were evaluated for binding of antibodies using plasma samples from 40 recent and 40 longstanding HIV-infected patients. Peptides were coated onto microtiter plate wells to capture anti-p24, anti-gp41 and anti-gp120 antibodies followed by binding to an anti-human antibody labeled with biotin molecules and streptavidin (SA)-conjugated Eu3+ nanoparticles (NPs) through biotin-SA interaction.

Results: We have identified three gp41 peptides which elicit strong reactivity with samples from chronically infected patients and very low or no reactivity with samples from recently infected patients. These gp41 peptides showed consistent positive reactivity in chronically infected patient samples and negative or very low response in recently infected plasma. We also have identified three gp120 peptides which showed strong reactivity with samples from recently infected plasma but negative response in chronic patients.

Conclusions: We have identified novel peptide epitopes in gp120 and gp41 proteins that could serve as diagnostic biomarkers for recent or longstanding infection. Together with HIV p24 antigen, the inclusion of appropriate peptide epitopes could enhance accuracy and specificity of identifying recent HIV infection cases. The Europium Nanoparticle Immunoassay platform eliminates background fluorescence thus enhancing sensitivity. It will be useful to evaluate other HIV epitopes to improve assay sensitivity for identification of recent infection and develop suitable testing format for use in a variety of settings. This work will contribute to development of new assays for distinguishing recent vs. chronic infection, improving current status of assays in this field.

TUPEB219

Performance of the determine HIV 1/2 Ag/Ab combo rapid test for detecting acute HIV infection: a systematic review and Bayesian meta-analysis

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Background: Fourth generation HIV point of care assays (Ag/Ab combo) offer a huge potential for timely detection of acute HIV infection, which is important for test and treat initiatives, but data on their field performance has not been synthesized to date. To fill this gap, we synthesized evidence on the diagnostic performance of the only FDA-approved fourth generation rapid test (the Determine HIV 1/2 Ag/Ab Combo) in adults, using Bayesian methods for meta-analysis.

Methods: Two reviewers searched seven databases (Medline, Embase, Pubmed, BIOSIS, The Cochrane Library, ULACS, and African Index Medicus) and gray literature, independently extracted data, and assessed study quality with QUADAS-2. Included studies evaluated the rapid test in adults, against a reference standard. From 17 studies, data on sensitivity and specificity of assay components (i.e., antigen, antibody, overall) were pooled using a Bayesian hierarchical random effects meta-analysis model. Subgroup analyses by blood sample and study design was performed.

Results: The pooled sensitivity of the antigen component was 12.3%, 95% credible interval (CrI) [1.1 - 44.2], while pooled antigen specificity was 99.7%, 95% CrI [96.8 - 100]. Pooled sensitivity of the antibody component was 97.3%, 95% CrI [96.7 - 99.9], while pooled antibody specificity was 99.6%, 95% CrI [99.0 - 99.9]. The overall pooled sensitivity for the device was 88.5%, 95% (CrI [80.1 - 93.4], and overall pooled specificity was 99.1%, 95% CrI [97.3 - 99.8].
Conclusions: Although the specifics of the antigen and antibody components of the Determine Combo rapid test were high; the antigen sensitivity calls for an improvement. Future research with improvements in study designs, patient sampling, and case mixes (to avoid bias), is pertinent. The Determine Combo assay has potential for timely and affordable detection of HIV post-seroconversion at point of care, but accuracy parameters need improvement for widespread global use.

TUPEB220
Roll-out of a national early infant diagnosis program in Papua New Guinea, 2008-2013

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Background: In 2007, Papua New Guinea (PNG) had an HIV vertical transmission rate of 30% with a national prevention of parent to child transmission (PPTCT) coverage less than 3% and no local method to confirm infant HIV status, a prerequisite for early infant treatment (EIT). With support from Clinton Health Access Initiative, the Central Public Health Laboratory implemented HIV DNA PCR testing, and, in collaboration with the PPTCT program, rolled out an Early Infant Diagnosis (EID) program to 158 sites in 21 provinces with 396 health care workers trained to collect dried blood spots (DBS). Here, we report the EID program data on accuracy.

Results: Receiving a virological test for HIV within 2 months of birth was calculated. Age (refer to Table 1; Figure 1). Individual study limitations included weak study designs, poor patient case mixes, and variable reference standards. Detection bias, selection bias (selecting patients or samples based on HIV status), verification bias, and incorporation bias limited further analyses. Data limitations prevented statistical exploration of the effect of patient case-mix on accuracy.

Conclusions: The sensitivity and specificity of the Determine Combo rapid test were high; the antigen sensitivity calls for a future study.

TUPEB221
Performance of the Trinity Biotech Uni-Gold HIV 1/2 rapid test as a first-line screening assay for gay and bisexual men compared with 4th generation immunoassays

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Background: There is a strong public health need to increase HIV testing in gay and bisexual men (GBM). Rapid testing is preferred by the majority of GBM over conventional testing. The Trinity Uni-Gold HIV 1/2 rapid test (Uni-Gold) is an antibody-only test used in some countries for HIV screening but not yet approved in Australia. Most evaluations of the Uni-Gold have compared its performance to 3rd generation antibody-only immunoassays (EIA) and/or nucleic acid tests, however 4th generation combination antigen/antibody EIA are increasingly used in laboratory HIV testing algorithms. We evaluated the operational performance of the Uni-Gold test as a first-line screening assay in GBM in NSW compared to 4th generation EIAs.

Methods: GBM attending any of 17 clinical and community sites were offered the Uni-Gold test. We assessed the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of Uni-Gold compared with conventional laboratory serology including 4th generation EIA. Individuals were classified as having acute HIV infection if they had reactive 4th generation EIA and negative or indeterminate western blot (WB) pattern, AND positive p24 antigen OR HIV-1 RNA tests OR a previous HIV-negative test in the past 3 months. Established infections were defined by a positive 4th generation EIA and WB.

Results: Of 9277 specimens tested with Uni-Gold and conventional serology, 82 (0.9%) were confirmed as HIV-positive by conventional serology and 67 were Uni-Gold reactive (sensitivity=81.7%, 95%CI:71.6-91.4%). Of these, 30 (36.8%) were acute infections, of which 16 were Uni-Gold reactive (sensitivity=53.2%, 95%CI:34.7-72.7%) and 72 (83.2%) were established infections, of which 51 were Uni-Gold reactive (sensitivity=81.9%, 95%CI:66.2-94.0%). Of 195 specimens confirmed as HIV-negative, 918 were Uni-Gold negative (specificity=99.9%, 95%CI:99.5-100.0%). PPV overall was 98.5% (95%CI:98.0-99.1%) and NPV was 99.7% (95%CI:99.6-100.0%).

Conclusions: The sensitivity of Uni-Gold in acute and established HIV infection versus results on 4th generation EIAs appears comparable to other rapid tests used in the same population and setting, though PPV and specificity of Uni-Gold is higher. When using any rapid test for screening, we recommend men at risk of acute HIV infection also have conventional serology including 4th generation EIA or direct detection (p24 or nucleic acid) performed.
**TUPEB222**

Evaluation of SD bioline HIV Ag/Ab assay for detection acute HIV infection (AHI)

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**Background:** Early detection of acute HIV infection (AHI) among pregnant and postpartum women can enable timely initiation of antiretrovirals and prevent mother-to-child HIV transmission (PMTCT). Rapid HIV tests used for antenatal screening only detect antibody and fail to detect AHI in the "window period." We evaluated a 4th generation assay for detecting AHI during pregnancy and postpartum.

**Methods:** HIV-negative women seeking antenatal care in Nairobi, Kenya were enrolled in a cohort study of HIV acquisition during pregnancy and postpartum. Blood samples were collected for nucleic acid amplification testing (NAT) at enrollment, 28, and 36 weeks gestation; and at 6, 14, 24, and 36 weeks postpartum. Women with positive NAT results were classified as AHI. The Abbott Determine HIV-1/2 Test and SD Bioline HIV Ag/Ab Combo Rapid Test (4th generation) were conducted on blood specimens at time of first HIV RNA detection. Median time to HIV detection was calculated for women who were non-reactive Determine but had positive NATs and had samples available at subsequent visits.

**Results:** Among 27 women with AHI detected by NAT, 19 (70%) were reactive by Determine and 21 (78%) were reactive by Bioline. Among 27 women with initial Determine non-reactive results, 6 (75%) were also Bioline non-reactive. Four of 6 AHI initially Determine reactive were also reactive by Bioline. Rapid and inexpensive assays are needed to reliably detect AHI in PMTCT programs.

**Conclusions:** We detected a median of 6 days earlier with Bioline than Determine (IQR:0-13). Among 5 AHI detected first by Bioline, AHI were detected 1 (13%) AHI not detected by Bioline. Half (n=2) of Bioline reactive samples were reactive results, 6 (75%) were also Bioline non-reactive. Four of 6 AHI initially Determine reactive were also reactive by Bioline. Rapid and inexpensive assays are needed to reliably detect AHI in PMTCT programs.

**CD4 measurement (including point of care diagnostics)**

**TUPEB223**

A meta-analysis of the performance of the Pima™ CD4 for point of care testing

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**Background:** The Alere point-of-care (POC) Pima™ CD4 analyzer allows for decentralized testing and expansion to testing antiretroviral therapy (ART) eligibility. A consortium conducted a pooled multi-data technical performance analysis of the Pima CD4.

**Methods:** The study used primary data (11,803 paired observations) comprised from 22 independent studies between 2009-2012 from the Caribbean, Asia, Sub-Saharan Africa, USA, and Europe, using 6 laboratory-based reference technologies. Data was analyzed as categorial (including binary) and numerical (absolute) observations using a bivariate and/or univariate random effects model when appropriate.

**Results:** At a median reference range of 383 cells/µL the mean Pima CD4 bias is -2.3 cells/µL (average bias across all CD4 ranges is 10% for venous and 15% for capillary testing). Sensitivity of the Pima CD4 is 93% (95% confidence interval [CI] 91.4%-94.9%) at 350 cells/µL and 96% (CI 95.2%-98.9%) at 500 cells/µL, with no significant difference between venous and capillary testing. Specificity reduced to 86% (CI 82%-89%) at 100 cells/µL (for Cryptococcal antigen screening), with significant difference between venous (88%, CI 85%-91%) and capillary (79%, CI 73%-84%) testing. Total CD4 misclassification is 2.3% cases at 100 cells/µL, 11.5% at 350 cells/µL and 9.5% at 500 cells/µL, due to higher false positive rates resulting in more patients identified for treatment. Misclassification increased by 1.2%, 2.6% and 1.8% respectively for capillary testing. There was no difference in misclassification between the full dataset and a population subset of HIV+ ART naive individuals, nor in misclassification among operator cadres. The Pima CD4 was most similar to Beckman Coulter PAnLeuOCegated CD4, Becton Dickinson FACSCalibur and FACScan, and less similar to Partec CyFlow reference technologies.

**Conclusions:** The Pima CD4 can be recommended using venous-derived specimens for screening (100 cells/µL) for reflex CrAg screening; and for HIV ART eligibility at 350 cells/µL and 500 cells/µL thresholds using both capillary and venous derived specimens. These meta-analysis findings add to the knowledge of acceptance criteria of the Pima CD4 and future POC tests, but implementation will require full costing analysis.

**Viral load measurement (including point of care diagnostics)**

**TUPEB224**

Assessment of new technology for the scale up of HIV viral load monitoring in South Africa

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**Background:** To reduce the global HIV incidence, scale up efforts are required to diagnose and treat patients in order to suppress the virus and reduce transmission, in line with the UNAIDS effort to increase access to viral load monitoring. South Africa has a centralized HIV-1 viral load (VL) testing model that supports scale up initiatives which relies on the laboratory to manage the increasing demand. New tools are required to be able to address this demand, handle reduced input volume without compromising performance and provide comprehensive coverage of diverse HIV-1 variants.

Here, we present data using a new high throughput system designed to detect and quantify HIV-1.

**Methods:** The cobas® HIV-1 test (CE-IVD) evaluation was performed on the fully automated cobas® 8800 System (CE-IVD) for method correlation to the COBAS® Amplicor® COBAS®/TaqMan® HIV-1, version 2.0 (TaqMan® HIV-1 v2) using 168 residual clinical samples from routine testing at NHPs. Subtype inclusivity and two input volumes (200uL & 500uL) were assessed. Reproducibility (> 50 samples) and throughput capability of the system were analysed. The dynamic range and analytical sensitivity were also defined.

**Results:** The new assay compared well with the TaqMan® HIV-1 v2 (mean titre difference of -0.05 log10, with a 95% CI of 0.11 to -0.01 log10). Accurate quantification of HIV-1 group M subtypes, HIV-1 group N and O isolates in EDTA plasma was demonstrated. Input volume of 200 uL correlated well (R2 = 0.9) to 500 uL. The new platform released the first 96 tests in 3.5 hours followed by additional 96 results every 30 minutes achieving a total of 960 results in 8 h. The cobas® HIV-1 test is reproducible over the dynamic range (20-10,000,000 cp/mL) with an improved sensitivity of 13.2 cp/mL. At a 200 uL sample input volume, the dynamic range was 50,000,000 cp/mL.

**Conclusions:** The new HIV-1 test and system are well suited to support centralized laboratory model for HIV-1 VL monitoring which is key to enable rapid scale up efforts in Sub-Saharan Africa. The availability of two lower sample input volumes optimizes the sample utilization and reduces the blood draws in patients where sample volume is a limiting factor.

**TUPEB225**

Alere™ q HIV-1/2 POC assay on plasma rather than whole blood, yields adequate viral load results

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**Background:** For HIV viral load tests has increased globally in response to the UNAIDS call for universal access to HIV treatment. The centralised HIV viral load testing model in South Africa can result in prolonged turnaround times at remote ARV clinics which may adversely affect patient management. These clinics may benefit from access to onsite viral load tests as well as specialised centres of care where a prompt viral load result may improve adherence. We assessed the performance of Alere™ q HIV-1/2 assay on plasma rather than whole blood against the local standard; Roche CAP/CTM HIV-1 V2 assay.
TUPEB227
Alarming levels of drug resistance in HIV-1-infected patients failing treatment in Cuba
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Background: By the end of 2013, Cuba had 16,479 patients living with HIV-1 of whom 9,662 (58.6%) were receiving antiretroviral therapy (ART). The objectives of this study were to analyze the levels and patterns of drug resistance in HIV-1 patients failing ART.
Methods: Demographic, clinical and laboratory data were collected from 588 ART-experienced HIV-1 patients attending a clinical center in Havana from January 2008 to September 2013. HIV-1 drug resistance genotyping was performed using Sanger sequencing of the pol gene. Drug resistance mutations and levels were determined using Reva version 8.0.2. Full-class resistance was defined as no antiviral drug fully susceptible in a respective drug class. Multidrug resistance was scored if the virus strain was interpreted as susceptible to at most one drug belonging to the 3 commonly available drug classes in Cuba.
Results: The majority of patients were male (76.5%), men who have sex with men (68.5%) with a median age of 40.4 years and 67.2% of the patients were from La Habana province. The median CD4 cell count and viral load at genotyping were 205 cells/mm3 and 24,713 RNA copies/mL, respectively. The median of ART exposure was 2.9 years and patients had median of ART duration of 1-13 ART regimens. Sequencing revealed the highest drug resistance levels against 3TC/FTC (79.3%), NVP (73.0%) and EFV (72.6%). The most frequent NNRTI and NNRTI mutations were M184VsI (79.3%), NVP (73.0%) and EFV (72.6%). The most frequent NRTI and NNRTI mutations were 3TC/FTC (82.3%), EFV (79.3%), V1081Q (0%) and YM1 (0%). After 6 months of ART, patients who had primary HIVDR had lower median CD4 cell counts (205 vs. 295 cells/mm3, p<0.001) and lower proportion of HIV RNA < 50 copies/mL after 6 months of ART were having M184VsI [odds ratio (OR) 0.11; 95% confidence interval (CI) 0.04-0.29].
Conclusions: Our study reveals a high level of drug resistance in HIV-1 patients failing ART and supports the need for appropriate laboratory monitoring in clinical practice, as infrequent viral load monitoring and limited access to drug resistance testing might have contributed to this high prevalence. Additionally, there is an urgent need for potent drug regimens that can be prescribed upon virological failure.

TUPEB228
Prevalence of primary drug resistance by high throughput reverse transcriptase genotypic resistance assay in Thailand
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Background: The emergence and transmission of HIV drug resistance (HIVDR) has raised concern after rapid scaling up of antiretroviral therapy (ART). Currently HIVDR testing prior to ART is not routinely recommended in Thailand due to cost, effectiveness and low reported prevalence.
Methods: A prospective cohort study was conducted in naive HIV-infected patients. Blood samples were tested for drug resistance (DR) by detection of codon 95-191 on the RT gene. We selected this region to cover 8 major mutations which were K120N, V106A/M, V108I, G151M, Y181C/I, M184VsI, L180I/M and G190S/A for lowering the cost of testing to approximately 35 USD. The HIVdb program of Stanford HIV database was used to classify the DR mutations. The association between the presence of primary HIVDR and HIV RNA < 50 copies/mL after 6 months of ART was determined by logistic regression.
Results: A total of 265 HIV-infected patients were included with median age of 35.2 (range, 16-72) years and 76.5% males. Risk of HIV infection included heterosexual (63.4%) and homosexual (30.2%). Median [interquartile range (IQR)] CD4 count was 292 (87-498) cells/mm3 and median HIV RNA (IQR) was 65,700 (17,306-211,256) copies/mL. The overall prevalence of primary HIVDR was 7.9%. The prevalence of each mutation were K120N (6.0%), V106A/M (1.1%), V108I (0.4%), Q151M (0%), Y181C (3.4%), M184VsI (4.5%), L180I/M (0%) and G190S/A (2.3%). After 6 months of ART, patients who had primary HIVDR had lower median CD4 cell counts (76 vs. 232 cells/mm3, p=0.010) and lower proportion of HIV RNA < 50 copies/mL (46.1% vs. 53.8%, p=0.077). By multivariate logistic regression, factors associated with HIV RNA < 50 copies/mL after 6 month of ART were having M184VsI [odds ratio (OR) 0.11, 95% con-
TUPEB229
Establishment of an Illumina MiSeq-based HIV drug resistance testing platform

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Background: Accountable HIV drug resistance (DR) testing represents a key component in effective HIV/AIDS management. We had previously developed a tagged pooled pyrosequencing (TPP)-based HIV DR testing method which offers improved sensitivity, data throughput and cost-efficiency as compared to conventional Sanger sequencing (SS). However, the limited TPP accountability in detecting mutation residing in homopolymeric regions, such as K103N, remains unresolved due to its intrinsic technical limitation. Here we present a fully validated, Illumina MiSeq-based platform that addresses SS and TPP limitations including homopolymeric issue.

Methods: MiSeq-based DR testing starts with HIV RNA extraction followed by two rounds of PCR amplifications of the HIV protease and partial RT genes. The derived amplicons are then indexed and sequenced using Illumina MiSeq sequencer. A proprietary web-based HIV drug resistance testing platform (Hydra2Seq) was used for MiSeq data processing and all HIV DRMs were inferred based on the Stanford DR database. The accuracy, sensitivity, precision and HIV subtype coverage of this platform was assessed using 6 pediatric pedigrees, 15 EQA controls and a cohort of clinical specimens.

Results: The protocol performs well on all examined HIV-1 subtypes including A1, B, C, D, F2, G, CRF01_AE and CRF02_AG. The overall error rate was determined as 0.0042 (0.0021 and 0.0085) for homopolymeric and non-homopolymeric areas respectively. The analytical sensitivity varied amongst HIV subtypes in range of 200–500 copies/ml. MiSeq reliably detects minor variants at frequencies as low as 1%. MiSeq consensus sequences with a mixed-base identification threshold at 20% (MBIT20) showed high identity with matching SS sequences (99.62% and 99.77% for nucleotide and amino acid respectively). All examined HIV DRMs were consistently detected among all replicates at comparable frequency readouts. All DRMs identifiable by SS were readily and quantitatively detected by MiSeq while low abundance DRMs were consistently detected among all replicates at comparable frequency readouts. All DRMs identifiable by SS were readily and quantitatively detected by MiSeq while low abundance DRMs were consistently detected among all replicates at comparable frequency readouts. All DRMs identifiable by SS were readily and quantitatively detected by MiSeq while low abundance DRMs were consistently detected among all replicates at comparable frequency readouts. All DRMs identifiable by SS were readily and quantitatively detected by MiSeq while low abundance DRMs were consistently detected among all replicates at comparable frequency readouts.

Conclusions: MiSeq platform offers considerably enhanced sensitivity, accountability and accessibility of HIV DR monitoring for either patient care or surveillance purposes. It not only deciphers intra-host HIV diversity with high resolution, but also renders fully packaged, customizable HIV drug resistance testing platform with ease. The MiSeq platform holds the promise of becoming a new standard HIV DR testing in this NGS era.

TUPEB230
Validating the World Health Organization HIV drug resistance early warning indicators

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Background: In 2006, the WHO released the HIV Drug Resistance (HIV/DR) Early Warning Indicator (EWI) Monitoring system as a part of the WHO Global Strategy for the Surveillance and Monitoring of HIV/DR. EWIs measure ART side effects associated with HIV/DR prevention, without the use of HIV/DR laboratory testing. However, there is a dearth of published studies validating EWIs. Thus, we validated WHO EWIs (from the April 2010 update) using data from British Columbia, Canada, a high-income setting with universal access to HIV treatment and acquiring: i) any class of HIVDR (either a non-nucleoside reverse-transcriptase inhibitor (NNRTI), or protease inhibitor resistance), ii) NNRTI, and iii) 3TC/FTC resistance, during follow-up. A predictive logistic regression model was built to assess whether the EWI Score predicted acquiring any class of HIVDR (yes/no).

Results: We included 3,082 individuals (82% males, median age: 42 years (25–75% percentiles: 34–46)) in our analysis. All explored EWIs, except for EW1 (ART prescribing practices) were associated with having any class of HIVDR or a NNRTI resistance during follow-up. All EWIs except for EW1 and EW2 (patients lost to follow-up 12 months post-ART initiation) were associated with a 3TC/FTC or any other NNRTI resistance (Table 1).

Conclusions: Several EWIs were found to be associated with and predictive of HIVDR. Also, failing to meet the target of ≥1 EWI (except for EW1) was predictive of acquiring any class of HIVDR.

TUPEB231
High prevalence of NNRTI HIV drug resistance in children under 18 months of age recently diagnosed with HIV: results from a national survey in South Africa

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Background: The number of children infected with HIV in 2013 was 240 000, notably less than previous periods. The decline is attributed to the success of PMTCT programs. With the expansion of maternal and infant prophylaxis regimens, the early vertical transmission rate in South Africa has decreased to ≤0.2% however, HIV-infected infants are at risk of harbouring resistant HIV-1 strains prior to initiation of ART. This study aimed to assess the prevalence of resistance profiles in infants under 18 months of age across South Africa.

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TUPEB233
Prevalence of HIV-1 cross-resistance against dolutegravir and elvitegravir in raltegravir-experienced patients in Germany over the past five years
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Background: This evaluation focussed on the prevalence of cross-resistance against RAL, EVG and/or DTG in RAL-experienced patients with detectable HIV viremia between 2009 and 2015.

Methods: 202 RAL-experienced patients from Germany (76% with subtype B) were tested for resistance mutations in HIV-1 integrate between 2009 and 2014 (33 pts. in 2009-2010 / 49 pts. in 2011-2012 / 120 pts. in 2014). Data of mutations within the integrate, reverse transcriptase and protease were analyzed in relation to prescribed therapy regimens. Resistance interpretation results were assessed by using the HIV-Grade, ANRS, Rega and Stanford interpretation algorithms and results were compared concerning the degree of concordance.

Results: The rate of patients tested positive for integrate inhibitor resistance decreased from 2009 to 2014 from 45% -51% between 2009 and 2012 to 19.2% in 2014. N155H, Q148HR and T87A were the most frequent mutations. Q148HR was less frequently detected in 2014 (13.0%) as compared to 2009-2010 (26.8%) and 2011-2012 (20.0%) while the prevalence of N155H increased over the time from 16.7% (2009), 22.2% (2010), 33.6% (2011), 56.2% (2012) to 47.8% in 2014. There was a high degree of concordance between the interpretation systems concerning EVG and RAL cross-resistance. However, prediction of DTG resistance showed a higher discrepancy. HIV-Grade predicted 67%/88%/85% to show at least intermediate resistance 2009-2010, 2011-2012 and 2014. ANRS predicted resistance in 33%/20%/13% of cases and the Stanford interpretation system predicted 53%/78%/52% and REGA predicted 33%/24%/9% to be at least partly resistant.

Conclusions: Interpretation resistance analysis is now part of the routine testing. This has changed since the approval of raltegravir where resistance analysis was performed later in the process of viral breakthrough due to difficult reimbursement procedures. This might explain the decrease of total detected resistance mutations over the years. It also might explain an increase of observed early N155H substitutions as compared to the Q148H mutation, which represents a later event in resistance pathways. There is a high concordance between the interpretation systems in EVG and RAL cross-resistance prediction. However, there is a higher discrepancy in predicting DTG resistance, which might make it difficult to decide about the use of DTG in ongoing therapies.

TUPEB232
Moderate levels of pre-treatment HIV-1 antiretroviral drug resistance observed in a national survey in South Africa
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Background: In order to assess the level of transmitted and/or pre-treatment drug resistance WHO recommends regular surveys to be conducted. This study assessed the frequency of HIV-1 antiretroviral drug resistance in patients initiating ART in South Africa.

Methods: A prospective cross-sectional survey was conducted between March 2013 and October 2014, using probability proportional to size sampling. This method ensured that samples, from all 9 South African provinces, were proportionally collected, based on the number of patients receiving ART in each region. Samples were collected from 45 health care facilities in 34 districts. Pol sequences were obtained using RT-PCR and Sanger sequencing and submitted to Stanford Calibrated Population Resistance tool v6.2 which uses 2009 WHO surveillance drug resistance mutation (SDRM) list. Pol subtyping was performed using Rega HIV subtyping tool v2.5. Statistical analyses were performed using GraphPad Prism 6.

Results: A total of 277 sequences were available for analysis and 98% were found to be subtype C. Most volunteers were female (58.8%) and the median age was 34 years (IQR: 29-42). The median baseline CD4-count was 149 cells/mm3 (IQR:26-349) and, based on self-reporting, volunteers had been diagnosed to be HIV-positive for a median of 44 days prior to sample collection (IQR: 23-179). Overall, 25 out of 277 patients presented with ≥1 SDRM (9.0%, 95% CI: 6.1-13.0%), NNRTI mutations were most often detected (n=23). Only two patients presented with a PI mutation. In four patients 3’ SDRMs were detected, which might indicate that they were not truly ART naıve, yet they presented at the clinic for ART initiation. All patients were tested positive for TDF-3TC-EFV-NVP. No tumors were detected at TDF-ITC-EFV/ENFV, as per national guidelines. 17 patients (6.1%) would receive a dual NRTI regimen; one patient (0.4%) would receive TDF against dolutegravir and elvitegravir.

Conclusions: These results show that the level of antiretroviral drug resistance in ART-naıve South Africans has reached the upper margin of moderate levels as per WHO classification. Therefore, regular assessment of pre-treatment drug resistance levels in all regions of South Africa are highly recommended to monitor changing levels of pre-treatment drug resistance.

TUPEB234
High frequency of genotypic resistance in HIV-1-infected patients on highly active antiretroviral therapy with persistent low viremia
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Background: Resistance is a major cause of virologic failure in HIV-1 infected patients: genotypic analyses optimize salvage therapy but technical constraints limit testing in plasma viral load (pVL) below 1000 copies/ml. Nevertheless a great amount of patients are failing therapy with persistent low viremia and virologic response after switching to genotype-guided salvage therapy is low. Therefore, genotypic resistance testing is not performed in routine care. Nevertheless, there is a growing interest in genotypic resistance testing to guide salvage therapy in patients with persistent low viremia.

Methods: Cohort prospective study in which eligible HIV infected patients were at least 18 years old, provided informed consent, were on ART for at least 12 months with two consecutive pVL between 50 - 999 copies/ml after achieving and maintaining viral suppression (less than 50 copies/ml). Modifications in genotype standard procedures included a larger volume of starting plasma, concentrating the sample by centrifugation and higher viral RNA input. Resistance was defined as the detection of any NRTI, NNRTI or PI major resistance mutations. Virologic response was assessed 8 weeks after salvage therapy.

Results: Hundred patients, 53% male, median age 49, median CD4 508 cells/mm³, median pVL 240 copies/ml, average number of previous regimens 5, 87% with successful genotype. Resistance mutations were detected in 63 patients (72.4%) 61% were receiving a PI-based regimen. All patients had NRTI mutations, 20% had NNRTI mutations and 45% had PI mutations, most common mutations were M41L, D67N, M184V, K103N, I47V, I54V and L90M. Of these 63 patients 81 started a genotype-guided salvage regimen and presented a pVL<50 copies/ml after 8 weeks of follow up. For seven patients there was previous genotypic information highlighting the selection and accumulation of resistance mutation during persistent low-level viremia.

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Diagnoses of co-infections (including syphilis, TB, Cryptococcus, hepatitis B, C and other)

TUPEB235
Global performance of GeneXpert (Xpert MTB/RIF, Cepheid) using standardized verification and external quality assessment material

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Background: The dried MTB culture spot (DCS) proficiency testing matrix has been endorsed by the WHO to verify GeneXpert instruments (Cepheid, Sunnyvale, CA) upon initial installation or relocation, module replacement and cartridge calibration when performing the Xpert MTB/RIF assay. DCS external quality assessment (EQA) program is available and has been expanded worldwide to 295 testing sites. We report the performance of this globally distributed matrix on Xpert MTB/RIF.

Methods: DCS material used for verification consisted of inactivated Mycobacterium tuberculosis (M. tuberculosis) susceptible to Rifampicin (rif). DCS for EQA consisted of 3 panels/year comprising 4 DCS of Mtb with rif susceptible, rif resistant and non-TB mycobacteria. Submission and reporting of results is managed through an in-house software program www.tbmonitor.com.

Results: Global participants (>1site) in the DCS quality program (verification and EQA) include: South Africa’s National Health Laboratory Service (207 sites), AIDS Clinical Trial Group (13 countries world-wide), Ghana National Tuberculosis Program, Walter Reed Army Institute of Research (4 countries), Namibia Institute of Pathology and Swaziland Health Laboratory Services. Sites using DCS verification material have increased rapidly from 66 (2011), 92 (2012), 143 (2013) and 2014. By the end of 2014, 4,317 verification DCS were performed globally. The total number of EQA panels distributed between 2012 and 2014 i.e. currently 392 devices in 18 countries (throughout Africa, Asia, Europe and the Caribbean). Timely submission of EQA panel results fluctuated from 68-100%, with 74% in 2012 to 295 in 2014 i.e. currently 392 devices in 18 countries (throughout Africa, Asia, Europe and the Caribbean). Timely submission of EQA panel results fluctuated from 68-100%, with 74% in 2012 to 295 in 2014 i.e. currently 392 devices in 18 countries (throughout Africa, Asia, Europe and the Caribbean).

Conclusions: The DCS quality program highlights the successful, rapid implementation of quality assured Xpert MTB/RIF testing globally. The standardization of testing material and minimal variation of testing sites illustrates stability and robustness of instruments. High quality assay performance over time as well as consistency among sites and users was demonstrated.

TUPEB236
Routine eye screening by an ophthalmologist is clinically useful for HIV-1-infected patients with CD4 count less than 200 /µL

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Background: The revised 2013 American CDC guidelines for opportunistic infections did not state recommendations for routine eye screening by ophthalmologists for patients with HIV-1 infection. This study aims to investigate clinical usefulness of routine ophthalmologic screening for HIV-1-infected patients.

Methods: We conducted a single-center observational study in Tokyo. HIV-1-infected patients with age over 17 who visited our clinic for the first time between January 2004 and December 2013 and underwent full ophthalmologic examination within one year from the first visit were enrolled. Patients who were already diagnosed of ophthalmologic diseases at the time of referral to our clinic were excluded. At our clinic, ophthalmologic examination, including dilated retinal examination by indirect ophthalmoscopy was routinely conducted by ophthalmologists on the first visit. The prevalence of ophthalmologic diseases and associated factors including the existence of ocular symptoms were analyzed. Diagnosis of CMV retinitis (CMR) was based on “confirmed CMV retinitis” of the ACTG criteria.

Results: The 1,515 study patients were mostly Asian men who have sex with men, with the median CD4 count and HIV-1 load of 210 /µL (IQR 66-353 /µL) and 4.76 log10_copies/mL (IQR 4.04-5.28 log10_copies/mL), respectively. 87% were treatment-naïve for HIV-1 infection. CMR was diagnosed in 24 (2%) patients. HIV retinopathy (HR) in 127 (8%), cataract in 31 (2%), ocular syphilis in 4 (0.3%), uveitis with unknown cause in 8 (0.5%). Other ocular diseases were diagnosed in 14 patients. All CMR cases and 87% of HIV-1 were with CD4 count <200 /µL. The prevalence of any ocular diseases, CMR, and HIV in patients with CD4 <200 /µL were 22%, 3%, and 15%, respectively, whereas for those with CD4 ≥200 /µL, they were 5%, 0%, and 2%.

Conclusions: Routine ophthalmologic screening is recommended for HIV-1-infected patients with CD4 <200 /µL in resource-rich settings based on the high prevalence of ocular diseases within this CD4 count category and most patients with ocular diseases, including those with CMR, were free of ocular symptoms.

TUPEB237
Association between transient elastography (TE) scores and AST to platelet ratio index (APRI) among HIV/HCV co-infected patients

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Background: Hepatic fibrosis is one of the complications in patients with chronic hepatitis C (HCV) due to HCV co-infection. Routine transient elastography (TE) is used to assess liver fibrosis. TE evaluates the stiffness of the liver and provides an estimate of the stage of fibrosis. APRI is an easily available, non-invasive index used to detect the presence of liver fibrosis. APRI is the ratio of AST to platelet count. This ratio is considered to be a good indicator of liver fibrosis.

Methods: This is a retrospective study of patients with HIV/HCV co-infection under treatment with antiretroviral therapy between January 2010 and December 2013 at the University of British Columbia Hospital. Of the 1,979 patients who met the inclusion criteria, 852 patients had adequate data to be included in the study. A total of 1,979 patients were included in the analysis. The data was collected from the electronic medical record database. The AST was measured in units of IU/L and the platelet count was measured in units of 10^9/µL. APRI was calculated by dividing the AST by the platelet count and expressing the result as a percentage. The difference in APRI between those with CD4 > 200 /µL and ≤ 200 /µL was compared using the t test. The difference in APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL was compared using the t test. The difference in APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL was compared using the t test. The difference in APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL was compared using the t test. The difference in APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL was compared using the t test.

Results: No statistically significant differences were found in the APRI between those with CD4 > 200 /µL and ≤ 200 /µL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL. No statistically significant differences were found in the APRI between those with HCV-RNA ≥ 40 copies/mL and < 40 copies/mL.
Conclusions: Where TE is not available, an APR of >1.0 could be considered suggestive of cirrhosis in HIV/HCV co-infected patients.

Hepatitis C

TUPEB238
Decreasing prevalence of HCV-HIV co-infection (2004-2013) in Madrid, Spain

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Background: Since HIV and HCV share common routes of transmission, HIV/HCV co-infection has traditionally been frequent. Nevertheless, whereas HCV can be highly contagious by sexual contact, the efficiency of HIV by this route is low. While HIV co-infection seems to be expanding among HIV-infected men who have sex with men (MSM), the rate of coinfection in intravenous drug users (IDU) is assumed to remain constant. We evaluated the serial prevalence of HIV/HCV coinfection across at risk groups for HIV infection at our Healthcare Area in Madrid (Spain).

Methods: We examined the serial prevalence of HCV infection in HIV-infected/uninfected subjects using data from the Microbiology Department registry of our tertiary hospital (HCV antibodies samples sent between 2004 and 2013). Risk factors for HIV/HCV coinfection were analyzed in 676 newly HIV-positive diagnosed subjects at our centre during the study period by logistic regression analysis. We further examined tendencies in anti-HCV treatment use and community HCV RNA.

Results: The prevalence of HIV/HCV coinfection at our Healthcare Area decreased from 13.04% (95%CI, 11.54-15.65) in 2004-05 to 5.39% (95%CI, 4.51-6.38) in 2012-13, P<0.001. The prevalence of HIV coinfection among HIV-negative subjects decreased from 6.90% (95%CI, 6.63-7.17) in 2004-05 to 3.47% (95%CI, 3.29-3.64) in 2012-13, P<0.001. Among HIV-infected subjects the trend from 2004 to 2013 among each risk group was: IDU, 85.72% to 100%, P<0.001; heterosexual, 8.91% to 4.17%, P<0.001; born 1971-80 (OR, 0.18, 95%CI, 0.07-0.44), birth decade >1980 (OR, 0.07, 95%CI, 0.01-0.39), and high educational level (OR, 0.65, 95%CI, 0.46-0.95). During the same period no association was observed between HCV prevalence and the use of treatment for HIV or community HCV RNA load.

Conclusions: The prevalence of HCV/HIV coinfection decreased in Madrid between 2004 and 2013. This decline was not consistently observed across any risk group and is likely to be explained by a declining burden of HCV in the general population.

TUPEB239
No difference in safety profiles comparing 12- and 24-week HCV treatment durations in HCV genotype 1 and HIV-1 co-infected patients: results from TURQUOISE-I

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Background: The 3 direct-acting antiviral (3D) regimen of obtaivir (OBV), paritaprevir (identified by AbbVie and Enanta; co-dosed with ritonavir; PTVr), and dasuvir (DSV) with ribavirin (RBV) is approved to treat HCV infection in patients with H1-V1 co-infection. In the TURQUOISE-I trial, response rates were 91 and 94% in this population when treated for 24 or 12 weeks, respectively. We report the safety profiles of the two treatment durations.

Methods: Patients were randomized to receive OBV/PTVr/DS + RBV for 12 (N=31) or 24 weeks (N=32). Eligible patients in this open-label study were treatment-naive or pegIFN RBV-experienced patients, with or without cirrhosis, who had CD4+ count ≥200 cells/mm³ and CD4+ % ≥14%, and plasma HIV-1 RNA suppression while receiving a stable azanavir- or raltegravin-inclusive antiretroviral (ART) regimen. Treatment-emergent adverse events (AEs) from the time of study drug administration until 30 days after last dose for all patients who received ≥1 dose of study drug are reported.

Results: The percentage of patients experiencing any AE, severe, or serious AEs were similar in both arms. The majority of AEs were mild or moderate, and no serious AE or discontinuation due to an AE was reported. The most common AEs in the 12- and 24-week arms respectively, were fatigue (55 vs 38%), insomnia (15 vs 22%), and nausea (16 vs 15%). Seven patients experienced an anemia-related AE, all deemed RBV-related, though no patient interrupted study drugs. Among patients receiving azanavir or raltegravin-inclusive ART, 55% and 6% experienced grade 3+ total bilirubin elevations, respectively. Median declines in CD4+ T-cell counts of 47 and 62 cells/mm³ were observed at the end of 12 and 24 weeks of treatment, respectively, and returned to above baseline levels by post-treatment week 4. Mean CD4+ per centages remained stable throughout the study. No patient had a confirmed HIV-1 breakthrough ≥200 copies/mL during treatment or experienced an AIDS-related opportunistic infection.

Conclusions: In GT1 HCV/H1-1 co-infected patients, treatment duration did not appear to influence the rate or severity of AEs or laboratory abnormalities and no patient discontinued HCV treatment due to AE. HIV-1 suppression remained stable throughout the course of HCV treatment.

TUPEB240
Low incidence of reinfection with hepatitis C virus after successful treatment in Montreal

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Background: The incidence rate of HCV infection is estimated at 26/100 py among Montreal IDU. Though HCV reinfection has been reported in IDU and MSM patients, the extent to which it occurs is unknown. Given the high treatment costs, HCV reinfection in cured patients may limit future access to treatment. We therefore aimed to evaluate the incidence of reinfection in a clinical cohort of HCV treated patients.

Methods: HCV patients with a sustained virological response (SVR) were included. Centrally collected data were used to estimate the number of person-years of observation after the end of treatment (EoT). Time from SVR to reinfection was estimated using Kaplan-Meier analyses.

Conclusions: Reinfection was defined as detectable HCV RNA. The rate of reinfection was calculated using the number of person-years of observation after the end of treatment (EoT). Time from SVR to reinfection was estimated using Kaplan-Meier analyses.
Results: 338 patients were included. The sample was 77% male; mean age was 46 years; and the main risk factor for HCV infection was IDU (n=275, 82%). Patients were followed for a median of 2.7 years after EOT (IQR=1.7-4.8); for a total of 1175 person-years. 716 (34%) patients remained HCV-negative, while 22 (9%) became reinjected during follow-up with an overall reinfection rate of 1.7/100py [95% CI 1.07-2.58]. Median time to reinfection was 14.7 years [95% CI 13.6-15.7]. Cumulative incidence of seroconversion within 2 years of SVR was 4% [92/210] and 11% [10/98] within 5 years. When controlling for drug use, the incidence rate of HCV reinfection was 0.43/100py [95% CI 0.20-0.71] for non-SVR, 1.9/100py [95% CI 1.13-3.14] for past IDU and 3.0/100py [95% CI 1.14-7.39] for present IDU.

Conclusions: HCV reinfection after successful treatment in our cohort is low. Although the rate of HCV reinfection is higher in IDU than non-IDU, it is much lower than the overall incidence rate of the first HCV infection among IDU in Montreal.

TUPEB241
Fibrosis regression is possible after a successful treatment of hepatitis C even with cirrhosis
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Background: Liver fibrosis was considered a long-term, irreversible damage. Despite the scaling up of HCV treatment and evidence of an HCV cure, there have been few encouraging results showing fibrosis regression. The aim of this study was to determine the factors associated with fibrosis regression.

Methods: Patients treated for HCV from a single-site clinical cohort with pre-treatment METAVIR score ≥ F2 and available post-treatment measures, were included. Liver fibrosis staging was assessed using elastometry (fibroscan) or biopsy. Clinical and laboratory data were routinely collected. Fibrosis regression and progression were defined as reduction and augmentation of ≥ 1 METAVIR score during follow-up. The determinants of fibrosis regression were analysed by multiple logistic regression using SPSS17.0.1©.

Results: A total of 92 patients were included with baseline METAVIR scores of F2 (28%), F3 (19%), F4 (55%), 21 (23%) patients were HCV co-infected, 12 (13%) were diabetics. 71 (77%) were infected with HCV-genotype 1a, 1b (20%) with HCV-genotype 3, and 3% had multiple genotypes. 32 patients (35%) were treated with DAA and 59 (65%) with peginterferon/ribavirin. Overall, 56 (61%) had a sustained virologic response (SVR) to treatment, while 36 (39%) were non-responders/relapsers. Overall, fibrosis regression was observed in 45 (49%) patients, which was greater when SVR was achieved (68% vs. 19% in non-SVR; p< 0.001). In SVR patients, fibrosis regression occurred regardless of baseline METAVIR score: 67% in patients with METAVIR=F2, 83% in F3 and 66% in F4 (p=0.219). Based on logistic regression analyses, controlling for drug use, the incidence rate of fibrosis regression was greater when SVR was achieved (68% vs. 19% in non-SVR; p< 0.001). In SVR patients, fibrosis regression was equally observed in HCV mono-infected and HIV-HCV co-infected patients.

Conclusions: Our results show that despite high HCV prevalence, hardly any of FSWs with HCV accessed treatment. Further, almost half of self-reported HCV-seronegative FSWs did not receive a recent test. These findings likely reflect a combination of structural and individual barriers to healthcare. In a setting with universal access to healthcare and increasing availability of safer and more efficacious HCV drugs, these findings highlight the need for comprehensive interventions to facilitate and sustain access to HCV testing and care, including harm reduction and addiction management, among FSWs. This will be critical to the success of an HCV Treatment as Prevention strategy.

TUPEB243
Pro-inflammatory gene expression remains altered after successful HCV treatment
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Background: Inflammatory gene expression in peripheral blood mononuclear cells (PBMC) is altered in chronic Hepatitis C Virus (HCV) infection. However duration of these changes after pegylated-interferon (peg-IFN) based HCV treatment is unclear. We investigated PBMC gene expression in treated patients to determine if differences persisted despite successful treatment.

Methods: PBMC Gene expression of 184 genes involved in inflammatory response pathways were assayed using the nCounter GX Human Inflammation Kit (Nanostring). HCV or HCV/HIV infected patients were categorized as treatment non-responders (NR, n=17), sustained virologic responders (SVR, n=52) and spontaneous downers (HC, n=23). Patients in NR and SVR groups had received peg-IFN-based regimens in the preceding 5 years. Pair-wise analyses were performed to assess differences.

Results: There were no differences in race or gender between groups. Mean time from last treatment was 2.6 and 3 years in SVR, NR respectively (p=0.47). SC mean age was 5 years younger than SVR or NR (p=0.02). Of 184 genes assessed, 120 had expression levels above background (mean counts greater than 50). Using a significance threshold of p <.01, mRNA counts were significantly different for 43 genes comparing SVR vs SC patients, 54 genes comparing NR vs SC, and 12 genes comparing SVR to NR. Differential expression of 45 genes was significantly different in both SVR and NR groups when compared to SC. Of note, IL-8 gene expression was 10 and 8-fold higher in SVR and NR vs SC (p<0.016 and p=0.02 respectively). CCL3 gene expression was similarly upregulated (3-fold higher in both SVR and NR vs SC, p<0.01 for both) as were AP-1 components Fox (3.5 fold higher in both SVR and NR vs SC, p<0.001 for both) and Jun (2.5 fold higher in both SVR and NR vs SC, p=0.007 and 0.003 respectively) [Fig 1].
Gene Name | LRT p-value | 5% Significance Threshold | LRT p-value (controlled for HIV status) | 5% Significance Threshold (controlled for HIV status)
--- | --- | --- | --- | ---
HLA-DBQ1 | 0.000076 | 0.0526 | 0.000019 | 0.0025
IL-6 | 0.00077 | 0.0117 | 0.0008 | 0.0110
IL-28B | 0.1700 | 0.0347 | 0.1600 | 0.0324

[Figure 1. Linkage Disequilibrium Maps of Significant Genes]

40 and 42 SNPs were examined and linkage mapped for HLA-DBQ1 and IL-6, respectively [fig. 1].

No individual SNP surpassed the multiple-testing correction in the broader genome-wide analysis.

Conclusions: Our whole-gene analytic strategy identified a previously unreported association of IL-6 with spontaneous clearance of HCV infection. We also confirmed an earlier finding that HLA-DBQ1 is associated with spontaneous resolution of HCV infection.

TUPEB245

Favourable IFNL3 genotypes and liver fibrosis in HIV-hepatitis C (HCV) co-infected individuals from the Canadian Co-infection Cohort

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Background: Liver fibrosis progression is faster in HIV/HCV co-infected individuals due to an elevated inflammatory profile. Interferon Lambda-3 (IFN3-), encoded by the IFNL3 gene (formerly IL28B), has antiviral and pro-inflammatory properties, though reports of its association with liver fibrosis is inconsistent. Homozygous recessive single nucleotide polymorphisms (SNPs) rs912976GCCCC, rs9999177 in this gene are linked to spontaneous HCV clearance and better treatment response, possibly via functional variant rs8103142, which causes a lysine-arginine substitution at position 70 (K70R).

We examined the relationship between IFNL3 genotypes and significant liver fibrosis (AST-to-platelet ratio index (APRI) ≥1.5) in HIV-HCV co-infected Canadians.

Methods: HCV RNA-positive participants free of fibrosis, end-stage liver disease and chronic Hepatitis B at baseline (n=612) were included from the prospective Canadian Co-infection Cohort (n=1176). Cases developed an APRI≥1.5 over follow-up. Cox proportional hazards was used, adjusting for sex, ethnicity, alcohol use, age, CD4 count (≤350 vs. >350), year of birth, age at HIV diagnosis, baseline AST, ALT, HIV RNA, HCV RNA, HCV genotype 1 vs non-1, baseline and endpoint AST and ALT, HHV8, and baseline apolipoprotein B. Haplotype analysis was performed, adjusting for ethnicity.

Results: Overall 69% were male with median HCV duration=17 years; 126 participants developed liver fibrosis over 1346 person-years of risk (9.40/100 person-years, 95% CI: 7.90-11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y). Homozygous recessive genotype at rs8099177 and rs8103142 individually increased the risk of significant liver fibrosis, HR (95% CI) 1.96 (1.18, 3.26) and 3.51 (1.15, 11.20/100 p-y).

Conclusions: Our results suggest that rs8099177 and rs8103142 are individually linked to a higher rate of liver fibrosis among HIV-HCV co-infected Canadians. When present together, these SNPs reduce fibrosis risk, possibly via enhanced HCV clearance. Functional studies are needed to examine any potential biological interactions.

TUPEB246

The risk of cardiovascular disease and death over 10 years in HIV/HCV co-infected patients with and without steatosis

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Background: Co-infection with HIV/HCV is associated with more severe liver disease including increased frequency of steatosis and significant fibrosis compared to patients mono-infected with HIV or HCV. Hepatic steatosis has been associated with greater fibrosis in cross sectional studies. We sought to explore the impact of steatosis on fibrosis progression, cardiovascular (CV) disease, and survival over time.

Methods: An IRB-approved, single-center retrospective cohort study was undertaken to analyze 10-year clinical outcomes in patients co-infected with HIV and HCV previously studied by Marks et al in 2005. Patients included underwent liver biopsy between 1998-2003 for the evaluation of HCV disease. Biopsy samples were assessed by a study pathologist (blinded) for fibrosis and steatosis. Clinical outcomes including cardiac events, liver function, and survival were collected over 10 years. Liver fibrosis progression was assessed using FIB-4 and APRI scoring systems.

Results: 105 patients met criteria for this study. At cohort entry, mean age 45 +/- 7 yrs, 70% male, 88% on ARVs, 61% had undetectable HIV VL, median CD4+ count was 410 and 12 patients had CD4 < 200, mean BMI was 26.3, 10% had diabetes, and 20% had HTN. 10-year
TUPEB247
Implications of baseline HCV RNA level and intrapatient viral load variability on
OBV/PTV/r + DSV 12-week treatment outcomes
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Background: High levels of pretreatment HCV RNA may impact the risk of virologic relapse post-treatment. Within theombitasvir/paritaprevir/ritonavir and daabostip (3D) development program, we examined the effect of viral load on the risk of virologic relapse within various HCV viral strata.

Methods: Non-cirrhotic treatment-naïve HCV-infected patients who received 12 weeks of 3D (GT1b) or 3D+RBV (GT1a) were included in the analysis. Post-treatment relapse rates were summarized by pretreatment HCV RNA thresholds. Intrapatient HCV RNA measurement variability was assessed by evaluating differences in HCV RNA levels between screening and baseline (median interval=3 weeks). Plasma samples were analyzed at a central laboratory using the Roche COBAS® TaqMan® RT-PCR assay v2.0.

Results: Among 618 patients, median baseline HCV RNA was 6.56 log10 IU/mL (3.6 million [M] IU/mL); 7/618 (1.1%) had post-treatment relapse. There was no association between baseline HCV RNA and relapse rate for any threshold (Table), with relapse rates of 1.2% at all thresholds. In patients who achieved SVR2 or relapsed, the median baseline HCV RNA was 6.55 and 6.68 log10 IU/mL, respectively (p=0.2). No relapses were observed for any patient with viral load < 2.5M IU/mL.

Conclusions: In this multi-targeted regimen, we did not identify any viral threshold for risk of relapse. suggesting that 12 weeks of therapy is optimal for minimizing the risk of relapse in naive, non-cirrhotic patients, regardless of underlying host or viral factors. Intrapatient variability in HCV RNA measurements was common, suggesting that a subset of patients may be misclassified if viral thresholds are important for clinical decision-making. *Partiprevir was identified by AbbVie, Enanta, and the National Institute of Allergy and Infectious Diseases.

<table>
<thead>
<tr>
<th>Threshold</th>
<th>Below threshold</th>
<th>Above threshold</th>
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<tbody>
<tr>
<td>1 million IU/mL</td>
<td>0/157 (0%)</td>
<td>7/744 (0.9%)</td>
</tr>
<tr>
<td>1.5 million IU/mL</td>
<td>0/201 (0%)</td>
<td>7/747 (0.9%)</td>
</tr>
<tr>
<td>2 million IU/mL</td>
<td>0/223 (0%)</td>
<td>7/730 (0.9%)</td>
</tr>
<tr>
<td>2.5 million IU/mL</td>
<td>0/248 (0%)</td>
<td>7/730 (0.9%)</td>
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<td>3 million IU/mL</td>
<td>1/260 (0.4%)</td>
<td>6/739 (0.8%)</td>
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<td>3.5 million IU/mL</td>
<td>1/302 (0.3%)</td>
<td>6/736 (0.8%)</td>
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<td>4 million IU/mL</td>
<td>2/254 (0.6%)</td>
<td>5/729 (0.7%)</td>
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<td>5 million IU/mL</td>
<td>4/273 (1.1%)</td>
<td>3/732 (0.4%)</td>
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<td>4/410 (1.0%)</td>
<td>3/729 (0.4%)</td>
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<td>7 million IU/mL</td>
<td>5/443 (1.1%)</td>
<td>2/719 (0.3%)</td>
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<tr>
<td>8 million IU/mL</td>
<td>5/487 (1.1%)</td>
<td>2/715 (0.3%)</td>
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<td>5/489 (1.0%)</td>
<td>2/720 (0.3%)</td>
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<td>6/502 (1.2%)</td>
<td>1/1/16 (0.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>7/741 (1.1%)</td>
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</table>

[Table. Relapse rates according to baseline HCV RNA thresholds chosen based on recent FDA analysis]

TUPEB248
National trend and characteristics of acute hepatitis C among HIV-infected individuals: a matched case-control study - Taiwan, June 2001 - December 2014
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Background: Hepatitis C virus (HCV) infection has been recognized as an emerging sexually transmitted disease among HIV-infected men who have sex with men (MSM) in Europe, North America, and Australia. In Taiwan, a hospital-based study demonstrated increasing incidence of HCV infection among individuals with behavior consistent with HIV infection and MSM from 1995 to 2004. We determined the national trend and associated characteristics of acute hepatitis C (AHC) among HIV-infected individuals.

Methods: The National Disease Surveillance System collects characteristics of notifiable disease cases including HCV infection, syphilis, and gonorrhea through mandatory physician and patient interviews. Information on HCV seroconversion has been collected since June 2001. We defined an HIV/AHC case as AHC reported during June 1, 2001-December 31, 2014 in a previously reported HIV-infected individual with a positive HCV antibody test (HCV) or ≥ 12 months after the test. Each HIV/AHC case was matched to two HIV-infected, non-AHC controls on age (+/-5 years), sex, mode of transmission, date of diagnosis (+/-30 days), and county of resident. Logistic regression was used to identify characteristics associated with AHC among HIV-infected individuals in Taiwan.

Results: During the study period, 93 (1.4%) of 6,624 AHC reports met the HCV/AHC case definition; the case counts during 2001-2004, 2005-2008, 2009-2011, and 2012-2014 were 6, 11, 7, and 7, respectively. A total of 8 million IU/mL 5/467 (1.1%) 2/151 (1.3%) 7 million IU/mL 5/443 (1.1%) 2/175 (1.1%) 5 million IU/mL 4/373 (1.1%) 3/245 (1.2%) 4 million IU/mL 2/324 (0.6%) 5/294 (1.2%) 3.5 million IU/mL 1/302 (0.3%) 6/316 (1.7%) 3 million IU/mL 1/269 (0.4%) 6/349 (1.9%) 2.5 million IU/mL 1/248 (0.4%) 7/730 (0.9%) 2 million IU/mL 1/223 (0.4%) 7/730 (0.9%) 1.5 million IU/mL 0/201 (0%) 7/747 (0.9%) 1 million IU/mL 0/157 (0%) 7/744 (0.9%)

Conclusions: AHC has been increasingly reported among HIV-infected men nationwide, predominantly among MSM in the metropolitan area. Physicians should suspect and monitor AHC in HIV-infected MSM with a diagnosis of recent syphilis or gonorrhea. We recommend continued surveillance and identification of behavioral and virologic characteristics contributing to AHC among HIV-infected individuals in Taiwan.

TUPEB249
High efficacy and low relapse rates observed with 8 or 12 weeks of LDV/SOF STR in GT1 HCV infected treatment-naïve, non-cirrhotic patients with pretreatment HCV RNA <6 million IU/mL
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Background: A shortened duration of ledipasvir/sofosbuvir (LDV/SOF) for 8 weeks (+/−RBV) was compared to 12 weeks LDV/SOF in genotype 1 (GT1) treatment-naïve, non-cirrhotic patients in the ION-3a, a Phase 3, randomized, open label study (N=947). Overall sustained virologic response (SVR) rates were non-inferior between the 8 and 12 week LDV/SOF arms (94% and 96%, respectively) however relapse was numerically higher in those treated for 8 weeks (5.1%) compared to 12 weeks (1.4%). Addition of RBV did not improve SVR. A post-hoc analysis of the ION-3 trial was conducted to evaluate baseline factors that might be responsible for the difference in relapse rates between the 8 and 12 weeks arms of LDV/SOF.

Methods: Baseline historical negative predictors were evaluated in subjects who relapsed, including: age, gender, race, GT1 subtype, METAVIR fibrosis stage, BMI, IL28B status, and baseline HCV RNA. For baseline viral load, pre-defined cut-off of 80,000 IU/mL and subsequently up to 10 million IU/mL were assessed.

Results: In the ION-3 trial, approximately 60% of treatment-naïve, non-cirrhotic subjects had baseline HCV RNA <6 million IU/mL. For these subjects, there was no difference in SVR rates (97% and 96%) nor relapse rates (1.6% and 1.5%) between 8 and 12 weeks of LDV/SOF treatment. SVR rates were identical for the 8 week and 12 week arms (96%) in patients with pretreatment HCV RNA < 10 million IU/mL, and relapse occurred in 3.1% vs 1.2%, respectively. The majority of failures in ION-3 who were treated for 8 weeks had a baseline HCV RNA greater than the 6 million IU/mL threshold.
TUPEB250

The impact of serosorting on hepatitis C and HIV co-infection amongst men who have sex with men: a modelling analysis

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Background: Recent observations highlight a sexually driven emerging Hepatitis C (HCV) epidemic within HIV positive men who have sex with men (MSM). We use transmission modelling to explore the potential role of soring (modifying of behaviours based on perceived HIV status between sexual partners) on both infections’ prevalence within MSM.

Methods: We developed a deterministic HIV and HCV sexual transmission model amongst MSM parameterized to the UK. We used the European MSM Internet Survey (EMIS) 2010 UK dataset to parameterise soring behaviours, condom usage and frequency of sexual partners. Two soring behaviours were considered: firstly individuals preferring sexual partners of concomitant HIV status, and secondly condom use being governed by the perceived HIV status of each partner. A parameter was included denoting the accuracy with which MSM decide an individual’s HIV status. Consistent with UK data, the baseline model running from 2000-2010 was fit to a steady HIV prevalence of 4.7% among MSM and HCV prevalence increases from 0.3% to 7.7% amongst HIV-infected MSM while incorporating soring, run between 2000-2010. We examined the effect of soring and biological interactions (HIV increasing the susceptibility and infectiousness of HCV) on the observed patterns in disease prevalence.

Results:

- In the absence of biological interactions between HIV and HCV, the model could fit the observed pattern but not magnitude of observed Hiv and HCV prevalence data. If HCV-positive MSM are more (2.8 fold) infective and (2-3 fold) susceptible to HCV, the degree to which soring elevates HCV prevalence amongst HIV-positive individuals is amplified, producing accurate fits to observed prevalence data. Compared to a model with no soring, accurate HIV soring (Figure) leads to moderate decreases in HIV prevalence (from 6.0% to 4.7%), but large increases in HCV prevalence among HIV-positive MSM (from 1.5% to 7.7%), and small increases in HIV among HIV negative MSM (from 0.8% to 0.83%). As soring becomes less accurate, HIV prevalence increases whereas HCV prevalence decreases in HIV-negative MSM but increases in HIV-negative MSM.

Conclusions: Soring practices decrease HIV prevalence regardless of errors in judgement, but can increase HCV among HIV-positive MSM. Discouraging soring could reduce HIV prevalence but increase HCV prevalence.

TUPEB251

Pending availability and affordability of new HCV regimens in resource-limited settings, should HIV-HCV co-infected patients start receive peg-interferon and ribavirin which just started to be affordable?

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Background: In many limited resource settings, HIV/HCV co-infected patients with advanced fibrosis have not yet benefited from any HCV treatment. In Thailand, peg-interferon/ribavirin combination therapy, which remained unaffordable until 2013, has never been evaluated in real life for HIV-HCV co-infected patients. We initiated a peg-interferon/ribavirin-based treatment program for co-infected patients in four HIV clinics in Thailand.

Methods: Population is composed of HIV infected adults with chronic HCV infection, fibrosis stage of F2/F3/4 by transient elastography, well controlled for their HIV infection, with no contra-indications. Treatment is prescribed by internists, with hepatologist advice as necessary; peg-interferon alpha-2a (1.5 microgram/kg once a week) and ribavirin (dosing according to HCV genotype and bodyweight) for 40 weeks. Monitoring for safety is done at 2, 4, 6, 8, 12, 24, 36, 48 weeks (dosing adapted as needed). HCV RNA is assessed at 12, 24, 48 and 72 weeks (Abbott 2000) with complete early virological response (EVR) defined as undetectable HCV RNA (threshold 12 IU/mL) after 12 weeks and partial EVR as dose 2>log IU.

Results: Of the first 16 patients enrolled, 11 were males. At enrollment, median (interquartile range) age was 44.3 (40-51) years and HCV RNA 5.95 (5.53-6.75) log IU/mL. Eleven patients had fibrosis stage F4, 4 F3 and 1 F2. Two had HCV genotype (GT) 1a, 7 GT1b, 5 GT3a, and 2 GT6. Thirteen had IL28b CC and 3 CT. One patient discontinued treatment for intolerance after first peg-interferon injection. During the first 24 weeks, 4 patients experienced anemia (1 Grade 3 and 3 Grade 1), 5 neutropenia (1 Grade 4, 3 Grade 3 and 1 Grade 1) and 3 thrombocytopenia (all Grade 2) but none discontinued treatment. 9/15 patients had complete EVR, 4 had partial EVR and 2 did not respond.

Conclusions: In these HIV-HCV co-infected patients with favorable IL28b but advanced fibrosis, this therapy appeared effective and relatively well tolerated. Hepatologists and HIV specialists collaboration is essential for patients with HCV co-infection. This treatment remains the only option for a significant number of patients who cannot wait longer for the availability and affordability of all oral HCV treatment regimens.

TUPEB252

Prevalence of HIV, HBV and HCV infections in Nigeria

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Background: Nigeria has the world’s second highest number of HIV/AIDS related deaths after South Africa and is highly endemic for viral hepatitis. Co-infection of HIV-1 positive individuals with HBV or HCV has previously been shown to lead to rapid decline of CD4, progression of HIV disease, increased risk of antiretroviral drug associated toxicity, and increased mortality

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More than 10 million IUs/mL. Although higher overall rates of relapse were observed for males and subjects who were IL28b non-CC, sex and IL28b status had no effect on outcome among those with a pretreatment HCV RNA < 6 million IUs/mL.

Conclusions: A baseline HCV RNA < 6 million IUs/mL in treatment-naive, non-cirrhotic GT1 patients correlated with similar SVR and relapse rates with 8 weeks or 12 weeks of LDV-SOF single tablet regimen regardless of other patient characteristics. This shortened duration could improve adherence and affordability of HCV treatment.
and morbidity. A study was conducted to estimate the prevalence and distribution of HIV-1, HBV and HCV infections at selected sites throughout Nigeria as part of evaluation of populations for HIV vaccine cohort development. Participants included workers in “Mammy Markets” adjacent to military barracks and general markets (Makurdi, Abuja, Enugu, Kaduna), as well as bar, hotel, restaurant and brothel workers in highway settlements (Tafa, Ojo Lagos), regarded as locations of increased risk for HIV infection.

**Methods**

Plasma samples from a total of 3,229 subjects from the six study sites were tested for HIV, HBV and HCV infection by standard laboratory tests: Bio-Rad GS HIV-1/2/O EIA, Ortho HCV v3.0 ELISA, Bio-Rad MONOLISA Anti-Hbc EIA, and Bio-Rad GS HBsAg EIA 3.0. HIV repeat reactive samples were confirmed by Bio-Rad GS HIV-1 Western Blot, while HCV repeat reactive were confirmed by either Ortho HCV RIBA (sites 1-4) or INNO-LIA HCV Score (sites 5-6).

**Results**

Site-specific and aggregate proportion of HIV, HCV, and HBV infections are shown in Fig 1. The prevalence of HIV-1 and HCV ranged from 3.1 to 23.0%, and 1.0 to 4.8%, respectively. Prevalence of HCV, based on anti-Hbc and HbsAg testing, ranged from 23.6 to 40.8%, and 9.9 to 13.2%, respectively. Infection with HIV did not correlate with HBV or HCV suggesting independent factors.

**TUPEB253**

**PegIFN-α 2a dose-dependent reduction in HIV-DNA levels during the first 4 weeks of treatment in HIV-1/HCV co-infected patients**

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**Background:** IFN-α has been shown to exert active antiviral activity against HIV-1, and its administration has been shown to reduce HIV-1 viraemia in untreated patients up to 5-10 fold. However, scarce data is available about the effects of exogenous IFN-α in the HIV reservoir of HAART treated patients. The aim of this study is to investigate whether or not there is a dose-dependent effect of IFN on the levels of HIV-DNA in a cohort of HIV/HCV co-infected patients.

**Methods:** Retrospective and longitudinal study that recruited HIV-infected patients who started a pegIFN-α 2a (either 180 or 360 mg week) plus ribavirin-based (600-800 mg BID) anti-HCV therapy. PBMCs and plasma samples were obtained at baseline, weeks 4, 12, 24, 26 and 48 of bi-therapy and after 6-12 months after the end of the bi-therapy. All patients were HIV suppressed for the entire follow-up. Isolated PBMCs were digested to extract cellular DNA and total HIV DNA levels were quantified by real time-PCR.

**Results:** Forty-seven patients were recruited due to sample availability; 33 patients treated with 180 mg week and 14 receiving 360 mg week of pegIFN-α 2a. Patients showed similar characteristics at baseline. Similar baseline HIV-DNA levels were found in both groups of patients (single-dose: 3.37 vs. double-dose: 3.42 log HIV-DNA copies/10⁶ PBMCs; p-value=0.551). Overall, HIV-DNA levels were significant higher at week 4 among patients with single-dose compared to those receiving double-dose of IFN (2.01 vs. 2.16 log HIV-DNA Copies/10⁶ PBMCs; p-value=0.041). Comparing both dosages, the decrease on the HIV reservoir size was significantly higher in patients with the 360 mg dosage (single-dose:1.38 vs. double-dose: 0.583 log HIV-DNA copies/10⁶ PBMCs; p-value=0.037). However, no differences between both dosages were found at week 48 of the follow-up (single-dose: 1.85 vs. double-dose: 1.68 log HIV-DNA copies/10⁶ PBMCs; p-value=0.045). Moreover, after the end of the bi-therapy, HIV-DNA levels raised significantly compared to when IFN was administered (single-dose: 2.23 vs. double-dose: 2.54 log HIV-DNA copies/10⁶ PBMCs; p-value=0.031), though without differences between both groups (p-value=0.539).

**Conclusions:** HIV reservoir decrease is affected upon pegIFN-α 2a administration during the first 4 weeks of treatment in a dose-dependent manner. After treatment interruption, a significant replenishment is observed with both doses.
TUPEB255
Safety of ledipasvir/sofosbuvir with and without ribavirin for the treatment of patients with chronic HCV genotype 1 infection: an analysis of the phase 3 ION trials

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Background: The once-daily fixed-dose combination tablet of ledipasvir/sofosbuvir (LDV/SOF) was evaluated with and without ribavirin (RBV) for the treatment of HCV genotype 1 infection in three phase 3 studies (ION-1, ION-2, and ION-3). Overall, SVR rates were high (97%) regardless of RBV use. The purpose of this analysis was to characterize the safety profile of RBV in an interferon-free regimen.

Methods: Treatment-naive and -experienced patients with HCV genotype 1 infection, including those with compensated cirrhosis, were randomized to 8, 12, and 24 weeks of LDV/SOF ± RBV in the ION-1, ION-2, and ION-3 studies. Treatment-emergent adverse events (AEs) and laboratory abnormalities were assessed.

Results: 1952 patients (No RBV, n=1080; RBV, n=872) were treated in the phase 3 studies: 308 (16%) were African American, 224 (11%) had compensated cirrhosis, 501 (26%) had a BMI ≥30 kg/m², and 440 (23%) were treatment-experienced. Overall, 97% of all patients achieved SVR12. Treatment-related AEs occurred in 71% and 45% of patients treated with and without RBV (Table 1). For both groups, treatment-related serious AEs (≤0.4%) and treatment-related deaths were uncommon. More patients taking RBV than LDV/SOF alone required dose modification or interruptions of study treatment due to AEs (13.5% vs. 11.2%) and other medications during treatment (63% vs. 53%) including topical corticosteroids. For both groups, treatment-related serious AEs (≤0.4%) and treatment-related deaths were uncommon. More patients taking RBV than LDV/SOF alone required dose modification or interruptions of study treatment due to AEs (13.5% vs. 11.2%) and other medications during treatment (63% vs. 53%) including topical corticosteroids. For both groups, treatment-related serious AEs (≤0.4%) and treatment-related deaths were uncommon. More patients taking RBV than LDV/SOF alone required dose modification or interruptions of study treatment due to AEs (13.5% vs. 11.2%) and other medications during treatment (63% v 53%) including topical corticosteroids

Conclusions: The addition of RBV did not increase the rate of treatment discontinuation or treatment-related serious AEs, but was associated with greater incidence of AEs including fatigue, insomnia, irritability and rash/pruritus, and concomitant medication use. RBV use did not impact the efficacy of LDV/SOF.

<table>
<thead>
<tr>
<th>Adverse event N (%)</th>
<th>% Difference</th>
<th>SOF/LDV 8, 12, or 24 weeks N=1080</th>
<th>SOF/LDV + RBV 8, 12, or 24 weeks N=872</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>-16</td>
<td>240 (22)</td>
<td>331 (38)</td>
</tr>
<tr>
<td>Headache</td>
<td>-5</td>
<td>222 (21)</td>
<td>228 (25)</td>
</tr>
<tr>
<td>Nausea</td>
<td>-7</td>
<td>112 (10)</td>
<td>152 (17)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>-10</td>
<td>82 (8)</td>
<td>155 (18)</td>
</tr>
<tr>
<td>Irritability</td>
<td>-7</td>
<td>46 (4)</td>
<td>95 (11)</td>
</tr>
<tr>
<td>Rash</td>
<td>-7</td>
<td>47 (4)</td>
<td>94 (11)</td>
</tr>
<tr>
<td>Cough</td>
<td>-6</td>
<td>42 (4)</td>
<td>90 (10)</td>
</tr>
<tr>
<td>Pruritus</td>
<td>-6</td>
<td>33 (3)</td>
<td>78 (9)</td>
</tr>
<tr>
<td>Mean change in hemoglobin from baseline at end of treatment (Bek / 12wk / 24 wk) (g/dL)</td>
<td>N/A</td>
<td>-0.2 / -0.4 / -0.3</td>
<td>-1.9 / -2.3 / -2.0</td>
</tr>
</tbody>
</table>

[Table 1]

Other adverse reactions and complications of ART

TUPEB256
Adverse drug reactions associated with integrase strand transfer inhibitors (INSTI) in clinical practice: post-marketing experience with raltegravir, elvitegravir-cobicistat and dolutegravir

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Presenting abstract author email: klepik@cfenet.ubc.ca

Background: The integrase strand transfer inhibitors (INSTI) raltegravir, elvitegravir-cobicistat and dolutegravir have demonstrated safety and efficacy in clinical trials. This post-marketing, observational study describes and compares the incidence and type of INSTI adverse drug reactions (ADR) reported during routine clinical use in British Columbia (BC) Canada.

Methods: HIV-1-infected persons age ≥19 years were included if their first prescription for raltegravir, elvitegravir-cobicistat or dolutegravir was dispensed between 01-Jan-2012 and 31-Aug-2014 through the BC Centre for Excellence in HIV/AIDS (BC-CIE) Drug Treatment Program. Patients could contribute data for more than one INSTI. All patients had ≥4 months follow-up opportunity until 31-Dec-2014. Clinical and demographic variables and ADR reports were abstracted from BC-CIE databases and summarized by descriptive statistics. The primary outcome was any ADR resulting in therapy discontinuation. ADR incidence density rates and 95% confidence intervals (CI95) were estimated by Poisson regression, adjusted for covariates. Adjusted relative ADR rates (RR) were calculated using raltegravir as the reference.

Results: The cohort included 1044 INSTI-treated patients, 75 (7.2%) of whom contributed data for 22 INSTIs, providing 1122 distinct patient-INSTI records: 522 raltegravir-treated, 301 elvitegravir-cobicistat-treated and 299 dolutegravir-treated patients. Table 1 summarizes patient and INSTI regimen characteristics.

Variable | Raltegravir N=522 | Elvitegravir-Cobicistat N=301 | Dolutegravir N=299
--- | --- | --- | ---
Age, median (IQR) yr | 50 (43,56) | 53 (48, 50) | 49 (41,55)
Sex (%) | | | |
| male | 420 (80%) | 225 (75%) | 237 (79%)
| female | 102 (20%) | 78 (25%) | 62 (21%)
CD4 median (IQR) cell/mm³ | 440 (230, 650) | 470 (280, 650) | 550 (390, 710)
Suppressed viral load <50 copies/mL (%) | 288 (55%) | 126 (42%) | 201 (67%)
Hepatitis C co-infection (%) | 239 (46%) | 106 (35%) | 74 (25%)
Previous ART, n(%): | | | |
| treatment naive | 67 (13%) | 63 (22%) | 41 (13%)
| treatment experienced | 126 (42%) | 149 (60%) | 255 (87%)
Concurrent ARVs: | | | |
| 2 NRTI: ABC+3TC | 185 (36%) | 266 (87%) | 61 (20%)
| 2 NRTI: ABC+3TC | 111 (21%) | 95 (31%) | 179 (60%)
| Other ARV combination | 226 (43%) | 71 (20%) | 39 (20%)
INSTI treatment duration: median (IQR) yr | 1.15 (0.65, 1.79) | 0.75 (0.44, 1.13) | 0.50 (0.38, 0.63)
Cumulative person-year exposure | 635 person-year | 233 person-year | 150 person-year

[Table 1: Patient and Treatment Characteristics]

Abbreviations: IQR: interquartile range; ARV: antiretroviral; ART: ARV therapy; INSTI: integrase strand transfer inhibitor; ABC: abacavir; 3TC: lamivudine; FTC: emtricitabine; TDF: tenofovir; NNRTI: Non-nucleoside reverse transcriptase inhibitor

[Figure 1. INSTI adverse drug reactions by symptom category]

Abstract Book  I  www.ias2015.org
For each INSTI, the proportion of patients with an ADR leading to discontinuation was: Raltegravir 1.88 (0.72-4.93), elvitegravir-cobicistat 5.76 (2.14-15.49), and dolutegravir 3.34 (1.19-9.40). The adjusted RR (CIs) of ADR relative to raltegravir was 3.08 (2.97-14.14) for elvitegravir-cobicistat and 1.78 (1.65-1.91) for dolutegravir.

Conclusions: All INSTIs were generally well tolerated. The newer INSTIs elvitegravir-cobicistat and dolutegravir had shorter follow-up times than raltegravir, but had relatively higher rates of ADRs resulting in therapy discontinuation. Follow-up of this cohort is ongoing.

TUPEB257
Physiological concentrations of combination antiretroviral therapy drugs affect mitochondrial DNA (mtDNA) quantity and quality in cell culture models

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Background: NNRTIs inhibit mitochondrial polynucleotide gamma, which can deplete mtDNA. However, mitochondrial dysfunction is not always associated with mtDNA depletion. PIs and NNRTIs can induce oxidative stress and mtDNA damage that can stimulate compensatory mitochondrial biogenesis. We evaluated the effects of individual ARVs and two cART regimens on mtDNA quantity and quality in cultured cells.

Methods: Immortalized human placental (JEG-3) and T lymphoblast (CEM) cells were cultured in the presence of NNRTIs: ABC, ATZ, FTC, TDF, 3TC, D4T (control), NNRTIs: EFV, NVP, and PIs: LPV, NFV, all at 1x, 10x and 20x Cmax for 3 days, then harvested. The JEG-3 cells were also exposed to similar (0.5x and 1x Cmax) concentrations of cART regimens used in HIV pregnancy: AZT/3TC/LPV and 3TC/TDF/EFV. After 21 days, the cells were returned to ARV-free medium for 10 days, to allow recovery. Cells were collected every 3 days. Growth rate, viability, mtDNA content and mtDNA apparent oxidative damage (AOD) were measured. Somatic mtDNA mutation burden was also quantified in a subset using an ultra-deep sequencing strategy.

Results: Both cells showed similar trends in response to ARVs. MtDNA content increased at 1x but depleted at 10x and 20x Cmax atT1 while mtDNA content and AOD both increased in cells exposed to ABC, LPV and NVP. These effects were concurrent with substantially reduced growth rates. In cells exposed to EFV, a mixed effect was seen whereby mtDNA increased at 1x and 20x Cmax but decreased at 10x Cmax. Among all ARVs tested, EFV exerted the largest effect on growth rate, mtDNA content and AOD. Somatic mtDNA mutation burden was also quantified in a subset using an ultra-deep sequencing strategy.

Conclusions: The opposite effects of ARVs on mtDNA content illustrate the need to evaluate ARVs alone and in combinations, using multiple mtDNA measures, as various mtDNA alterations could affect mitochondrial function, cellular metabolism and aging. The mtDNA effects seen here with EFV, LPV and ABC warrant further research given their increasing use in pregnancy.

TUPEB258
Hearing loss in HIV-infected children in Lilongwe, Malawi

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Background: With improved access to pediatric antiretroviral therapy (ART), HIV infection has become a chronic illness. Preliminary data suggest that HIV-infected children have a higher risk of disabilities such as hearing impairment. This study aimed to estimate the prevalence and types of hearing loss in HIV-infected children in Lilongwe, Malawi.

Methods: This was a cross-sectional survey of 380 HIV-infected children aged 4-14 years attending ART clinic in Lilongwe, December 2013-March 2014. Data was collected through pediatric quality of life (PedsQL™) and sociodemographic questionnaires that were translated into Chichewa and reviewed with a research assistant, review of the electronic medical record, and audiologic testing for all participants. Hearing loss was defined as hearing loss >20 dB in either ear. Predictors of hearing loss were explored by multiple regression analysis generating age- and sex-adjusted odds ratios. Children with significant hearing impairment were fitted with hearing aids.

Results: Of the 380 recruited patients, 24% of patients had hearing loss in either ear. 82% of the hearing loss was conductive, 14% was sensorineural, and 3% was mixed. Twenty-one patients (23% of those with hearing loss) were referred by audiologists for hearing aid fitting. There was a higher prevalence of hearing loss in children with history of frequent ear infections (OR 7.4, 4.2-13.0) and ear drainage (OR 6.4, 3.6-11.6). Hearing loss was linked to history of WHO Stage 3 (OR 2.4, 1.2-4.5) or Stage 4 (OR 4.6, 2.7-15.2) and history of malnutrition (OR 2.1, 1.3-3.5), but not to duration of ART or measures of CD4. Only 40% of caregivers accurately perceived that their child had hearing loss. Children with hearing loss were less likely to attend school and had poorer emotional (p = 0.02) and school functioning (p < 0.04).

Conclusions: Hearing loss was common among children with HIV, and can affect schooling and quality of life. Many children with hearing loss qualified for hearing aids. Caregivers were not reliable at identifying hearing loss. There is therefore an urgent need for improved screening and identification of hearing problems in HIV-infected children to treat this disability, especially in resource-limited settings.

TUPEB259
Serious non-AIDS events and biomarker changes in HIV-1-infected individuals

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Background: HIV-1-infected individuals may experience serious non-AIDS events (SNAEs) despite suppressive antiretroviral therapy (ART), possibly from ongoing immune activation. Increased circulating levels of soluble CD14 (sCD14), soluble CD163 (sCD163) and interleukin-6 (IL-6) at a single time point have been associated with SNAEs. However, it is unknown if trends in these biomarker levels can predict the SNAEs.

Methods: We retrospectively reviewed 284 HIV-infected individuals with prospectively collected plasma samples from a single center. We identified 39 SNAEs (14 major cardiovascular events, 4 end stage renal disease, 3 compensated cirrhosis, 12 non-AIDS-defining malignancies and 8 death of unknown cause) and 39 age- and gender-match controls. sCD14, sCD163 and IL-6 were analyzed at baseline (T1) and proximal (T2) to the event (or equivalent duration in matched controls). Biomarker changes between T1 and T2 within each group and the differences in changes between two groups were tested using Wilcoxon signed rank test.

Results: Median age of cases and controls was 56 and 57 years, respectively, 79% were male. Median time between T1 and T2 of cases and controls were 34 and 35 months, respectively. 74% and 67% of cases and controls were respectively co-infected with HCV. At T2, 87% and 97% of cases and controls were on ART, and 59% and 72% of cases and controls had undetectable plasma HIV RNA levels, respectively. Table 1 shows median sCD14, sCD163 and IL-6 levels, median change between T1 and T2 in cases and controls; and the median difference in change from T1 to T2 for each case-control pair (change in case minus change in control). Similar results were obtained when evaluating the changes normalized for the time between T1 and T2. HCV co-infection status had no significant association with biomarker levels.

Conclusions: Overall, the biomarkers significantly decreased in both cases and controls during follow up, likely from ongoing ART. The decreases in sCD14, sCD163 and IL-6 were attenuated in the cases compared to controls and were statistically significant for sCD14 and IL-6 but not sCD163. Thus, both the absolute levels of inflammatory biomarkers and their rate of change over time may be relevant for predicting SNAEs.

Table 1

<table>
<thead>
<tr>
<th>Marker</th>
<th>Cases T1 (μg/mL)</th>
<th>T2 (μg/mL)</th>
<th>Change from T1 (μg/mL)</th>
<th>Controls T1 (μg/mL)</th>
<th>T2 (μg/mL)</th>
<th>Change from T1 (μg/mL)</th>
<th>Median (case-control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>sCD14</td>
<td>1.20 (0.3-3.18)</td>
<td>0.79 (0.54-3.29)</td>
<td>-0.12 (1.82-0.78)</td>
<td>P&lt;0.01</td>
<td>1.93 (1.13-3.50)</td>
<td>0.52 (2.62-2.61)</td>
<td>-0.47 (2.9-2.91)</td>
</tr>
<tr>
<td>sCD163</td>
<td>1.76 (221-466)</td>
<td>1.76 (194-443)</td>
<td>-0.01 (5.59-6.1)</td>
<td>P&lt;0.05</td>
<td>1.76 (154-338)</td>
<td>1.17 (394-404)</td>
<td>-0.39 (259-340)</td>
</tr>
<tr>
<td>IL-6</td>
<td>2.83 (0.47-7.78)</td>
<td>0.84 (0.79-12.19)</td>
<td>-0.19 (5.59-6.1)</td>
<td>P&lt;0.05</td>
<td>2.59 (0.54-12.1)</td>
<td>1.92 (0.82-7.59)</td>
<td>-0.13 (2.98-3.4)</td>
</tr>
</tbody>
</table>

[Table 1]

Conclusions: Overall, the biomarkers significantly decreased in both cases and controls during follow up, likely from ongoing ART. The decreases in sCD14, sCD163 and IL-6 were attenuated in the cases compared to controls and were statistically significant for sCD14 and IL-6 but not sCD163. Thus, both the absolute levels of inflammatory biomarkers and their rate of change over time may be relevant for predicting SNAE.
TUPEB260
Heterogeneity of preferences for antiretroviral drug regimens from the perspective of people living with HIV

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Presenting author email: ahmed.bayoumi@utoronto.ca

Background: Antiretroviral drug regimens vary in terms of efficacy, toxicity, and the potential for future cross-resistance. We conducted a discrete choice experiment and elicited preferences from people living with HIV to determine the relative importance of attributes of antiretroviral drug regimens and the degree of heterogeneity in participants’ responses.

Methods: Participants completed a survey consisting of 16 choices sets; for each set, participants selected 1 of 3 hypothetical regimens, each characterized by one of four levels of the following six attributes: efficacy in suppressing viral load, cardiovascular risk, fracture risk, mood effects, pill burden, and the potential for future resistance. Participants also completed a consistency test and demographic and clinical questionnaires. We recruited a convenience sample from clinics and AIDS service organizations, with oversampling of women and black participants. We used generalized multinomial (random parameter) logit analysis and focused on two firsts. First, we analyzed whether participants have heterogeneous variance (scale sensitivity) in their responses and whether gender and ethnicity explained this variation. Second, we report the random parameters (regimen attribute levels) with the greatest standard deviations as an indication of preference heterogeneity.

Results: We analyzed data from 123 of 135 participants. Participants were willing to accept some inefficacy (risk of virologic failure) to avoid less convenient dosing, viral resistance, and all toxicities except wrist fracture. Participants exhibited significantly heterogeneous variance in their responses (scale parameter p-value < 0.001). Neither ethnicity nor gender explained this variance. The greatest preference heterogeneity of responses was for the attributes “greatly increase my chances of having a heart attack” and the potential for “resistance to other similar drugs is very high.” The least preference heterogeneity was for the attributes related to moderately increased risks of hip and wrist fractures and for taking two pills once daily.

Conclusions: People living with HIV have heterogeneous preferences about antiretroviral therapy, particularly concerning severe cardiovascular toxicity and the potential for future resistance. In contrast, preferences for avoiding severe fractures and about pill burden are more homogeneous. Our results underscore the need to address a range of toxicities while maintaining convenient dosing regimens to meet patient-centered preferences for antiretroviral medications.

Clinical trials: phase III

TUPEB261
Safety and efficacy of DTG by age, race and gender: subgroup analysis of 96-week results from treatment-naive patients in phase III trials [SPRING-2 (ING113086), SINGLE (ING114467) and FLAMINGO (ING114915)]

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Background: DTG once daily (QD) was well tolerated in ART-naïve studies and has demonstrated comparable efficacy versus RAL (SPRING-2), favorable efficacy versus DRV (FLA) and efficacy versus EFV/FTC/TDF QD. Analyses of 96-week safety and efficacy data by age, race and gender - shown comparable efficacy versus RAL (SPRING-2), favorable efficacy versus DRV (FLA) and efficacy versus EFV/FTC/TDF QD. Adverse event (AE) and response rates by FDA-Snapshot at 96 weeks were summarized in subgroups: age (< vs ≥ 50 years), race (white vs non-white) and gender (male vs female).

Results: There were 1067 patients treated with DTG in the three clinical studies. Efficacy rates at 96 weeks remained high across subgroups and are described in Table 1. Additionally, safety summaries showed comparable grade 2-4 drug related AE’s across subgroups. The rates of AEs leading to withdrawals were low across all DTG subgroups. There was some numerical variability in treatment differences in the smaller subgroups evaluated which was inconsistent across studies.

<table>
<thead>
<tr>
<th>Proportion of Subjects with Plasma HIV-1 RNA &lt;50 c/mL at Week 96 In Snapshot (Prima) Analysis: n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPRING-2</td>
</tr>
<tr>
<td>DTG</td>
</tr>
<tr>
<td>Overall</td>
</tr>
<tr>
<td>Age &lt;50yr</td>
</tr>
<tr>
<td>Age ≥50yr</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Non-White</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
</tbody>
</table>

(Table 1: Results by Demographic Subgroup)

Conclusions: In the three treatment naive clinical trials DTG once daily was seen to be effective and well tolerated treatment option across age, race and gender subgroups evaluated.

Timing of therapy initiation

TUPEB262
Short course versus deferred therapy for the treatment of HIV primary infection: a meta-analysis

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Background: In recent years three randomised trials have been undertaken to ascertain whether short course antiretroviral therapy (ART) has benefit for persons with primary HIV infection. Each trial used varying definitions of “benefit” relating to CD4+ T-cell counts (CD4+), viral load (VL) and long term ART initiation (ltART). We determined common estimates of effect across the three trials.

Methods: Available online listing data on participant follow up, CD4, VL and ART use were extracted from the Primo-ShM, SETPOINT (ACTG5217), and SPARTRAC trials in 2013. We summarised CD4+ decline and ltART initiation using a common methodology across trials. The primary endpoint was time from randomisation to first of two consecutive CD4+ < 350 cells/mm³ or ltART summarised as a between arm hazard ratio. Participants in the immediate arm who did not interrupt therapy as mandated by protocol were assigned to have reached endpoint at the scheduled end of the immediate phase. Results were meta-analysed for comparisons between the deferred arm and the longest immediate treatment arm in each trial (weeks 60, 36 and 48 respectively). Data were combined using fixed effects methods.

Results: Time to primary endpoint was significantly increased in the immediate treatment arm (Table) compared to deferred ART. Of the 395 participants across all trial arms with CD4+ >350 cells/mm³ at trial entry, 100 (18.5%) commenced ART prior to CD4 decline < 350 cells/mm³.

Timing of therapy initiation

<table>
<thead>
<tr>
<th>Trial</th>
<th>Arm</th>
<th>N</th>
<th>Events</th>
<th>Rate/1000 person weeks</th>
<th>95% CI</th>
<th>Median time to event/weeks</th>
<th>Hazard Ratio</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primo-ShM</td>
<td>Deferred</td>
<td>36</td>
<td>31</td>
<td>12.8 &gt;350 cells/mm³, 60.4 0.6 0.3, 0.6 &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>60 weeks</td>
<td>39</td>
<td>23</td>
<td>4.6 10.3 0.9, 18.2 110.5 0.3 0.2, 0.6 &lt;0.01</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SETPOINT</td>
<td>Deferred</td>
<td>64</td>
<td>24</td>
<td>7.2 4.9, 10.8 38.6 0.6 0.3, 0.6 0.00</td>
<td></td>
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<tr>
<td></td>
<td>56 weeks</td>
<td>63</td>
<td>21</td>
<td>4.2 2.8, 6.5 72.0 0.6 0.3, 0.6 0.00</td>
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<tr>
<td></td>
<td>SPARTRAC</td>
<td>Deferred</td>
<td>123</td>
<td>75</td>
<td>4.4 3.3, 5.5 73.3 0.6 0.3, 0.6 0.00</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>48 weeks</td>
<td>118</td>
<td>61</td>
<td>3.3 2.5, 4.2 179.0 0.7 0.5, 1.0 0.08</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Table. Time to first of two consecutive CD4+ < 350 cells/mm³ or commencement of long term ART)
Conclusions: Across all three trials immediate short term ART delayed disease progression or commencement of IART. However the duration of immediate therapy accounted for much of the delay in this analysis. The high proportion of participants continuing or commencing IART without reaching CD4 criteria likely reflects the current setting of guidelines promoting early treatment and at higher CD4 thresholds. As such an ART treatment strategy that requires interruption may be untenable.

TUPEB263
CD4 reconstitution is related to CD4 at effective antiretroviral treatment initiation

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1Johns Hopkins School of Public Health, Epidemiology, Baltimore, United States, 2University of North Carolina, Chapel Hill, United States, 3US Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention, Atlanta, United States, 4Kaiser Permanente Mid-Atlantic States, Rockville, United States, 5Yale University School of Medicine, New Haven, United States, 6Harvard School of Public Health, Boston, United States
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Background: Despite almost 20 years of effective antiretroviral therapy (ART), the CD4 cell count (CD4) asymptote (i.e. maximum level of CD4 reconstitution) after treatment remains poorly characterized. Prior analyses examined the CD4 treatment response curve but not typical range of response or asymptote. We sought to better characterize CD4 reconstitution among individuals with optimal response to treatment.

Methods: HIV-infected individuals starting ART between 1996 and 2012 in NA-ACCORD were analyzed. Individuals that did not achieve viral suppression (< 50 copies/ml) within 1 year were censored. Those achieving initial viral suppression were censored at virologic failure (>500 copies/ml) or ART discontinuation. A natural cubic splines linear quantile mixed model was used to predict the typical CD4 response to ART (10th, 50th, and 90th percentiles) stratified by CD4 prior to treatment (<50, 51-200, 201-350, 351-500, and >500 cells/mm^3). Baseline information on the 75,281 HIV-infected adults in the population is included in the table. Results: Baseline information on the 75,281 HIV-infected adults in the population is included in the table. The estimated individual level intercept and asymptote from the negative exponential model was strongly correlated (0.60 [0.59-0.62]) providing evidence that the maximum level of CD4 reconstitution is tied to an individual’s CD4 at initiation of ART. The typical CD4 response (80% of individuals fall within curves) for each strata of CD4 prior to treatment was better with higher CD4 at ART initiation (Figure 1). However, the asymptote random effects suggest that a large proportion of individuals in each stratum reached CD4=500 cells/mm^3 (45%, 58%, 69%, and 76% for CD4 strata below 500).

Conclusions: The maximum level of CD4 reconstitution was determined in part by the CD4 level at ART initiation. CD4 counts above 500 cells/mm^3 were achievable even when initial CD4 was low; however likelihood of reaching this threshold decreased with lower CD4 at ART initiation.

First-line therapy
TUPEB264
Comparison of the effectiveness, tolerability and efficiency (cost-effectiveness) of an antiretroviral regimen administered as a single tablet regimen (STR) vs. multiple tablet regimens (MTR) in antiretroviral naive HIV patients

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Background: STR are generally recommended by guidelines. Despite higher direct cost, efficiency may be better when compared with MTR with same or different components.

Methods: All HIV antiretroviral naive patients of 6 centers who initiated STR-Atripla®, with their components (Tenofovir+Lamivudine+Etritrocabine+Efavirenz; MTR-Atripla®-Components) or with a different multiple tablet regimen (MTR-Other) after June-2008 and before December-2011 were eligible. Effectiveness was measured as percent of patients < 50 copies/ml at 48 weeks by ITT (Missing or NC=Failure). Costs included the direct cost of antiretrovirals plus those related with outpatient visits, hospital admissions and resistance tests. Efficiency was the ratio between costs and effectiveness for the base case scenario and for the most and less favorable scenarios as a sensitivity analysis.

Results: 3736 patients (933 STR-Atripla®, 796 MTR-Atripla®-Components and 2007 MTR-Other) were included. Median age was 37 years, 82% were males, 14% were co-infected with HCV, 23% had a CD4+ cell count < 200 and 23% had viral load>100,000copies/ml. Median duration of assigned regimen was 2.2, 2.9 and 1.6 years for the STR-Atripla®, MTR-Atripla®-Components and MTR-Other respectively. Percentage of patients completing at least one year of follow-up was 95%, 94% and 91% in the STR-Atripla®, MTR-Atripla®-Components and MTR-Other respectively (p < 0.0001 for comparison of STR-Atripla® with the other two arms). Virological failure and interruptions for tolerance problems were 5% and 9% in the STR-Atripla®, 9% and 5% in the MDR-Atripla®-Components and 13% and 16% in the MTR-Other respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively. Cost per responder at 48 weeks (effectiveness) was 11,703 Euros in the STR-Atripla®, 11,210 Euros (0.95 times higher) in the MTR-Atripla®-Components and 17,484 Euros respectively.
TUPEB265

Treatment outcomes among older HIV-infected adults in Jos, Nigeria

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Background: The proportion of older patients living with HIV in sub-Saharan Africa is increasing, despite inadequate prevention interventions targeted at this group. Our objectives were to compare baseline characteristics and outcomes to cART between older and younger patients in our clinical cohort in Jos, Nigeria.

Methods: Treatment-naïve patients aged 15 years and above enrolled in care between 2004-2012 and commencing first-line cART were included in this analysis. We used descriptive statistics to compare baseline and treatment differences between older (50 years or older) and younger (15-49years) and Cox proportional hazard models to determine factors associated with all-cause mortality and loss to follow-up (LTFU) at 24 months.

Results: There were 10,991 patients with (7.8%) aged 50 years or older. Older patients were more likely to be male (p < 0.001), married (p < 0.001), have no formal education (p < 0.001), and be unemployed (p = 0.001) with a mean age of 55 ± 5 years. Older patients had higher rates of viral suppression (< 400 copies/mL) at 6 (p = 0.007), 18 (p = 0.007) and 24 (p = 0.006) months with comparable suppression at 12 (p = 0.14) months. Older patients had significantly lower median CD4+ cell counts at most time points on cART except at 18 months (p = 0.09) despite having higher counts at baseline. In Cox proportional models stratified by age and adjusting for baseline and treatment variables, older age (aHR = 1.81, CI 1.02-3.21) and advanced clinical disease (aHR = 1.63, CI 1.28-2.07) were associated with mortality. Similarly, only advanced clinical disease (aHR = 1.90, CI 1.01-1.18) and male sex (aHR = 1.12, CI 1.03-1.22) were associated with LTFU.

Conclusions: Older patients in our cohort have poorer immunological response and higher risk of mortality compared to younger patients despite having better viral suppression over 24 months. Age-appropriate interventions are encouraged to optimize outcomes among older patients in our setting.

TUPEB266

ANRS 12168 - DynaM-O; a 48 weeks-prospective study to compare the immuno-virological and clinical responses to HAART between HIV-1 group O and group M-infected patients

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Background: The divergent HIV-1 group O strains (HIV-1/O) are endemic in Cameroon and naturally resistant to NNRTI, largely used as first-line therapy in this country. Alternative therapeutic strategies are thus needed. DynaM-O is a prospective open-label study comparing the immuno-virological response to HAART, including two NRTI and one PI in HIV-1 group O (HIV-1/O) and HIV-1 group M (HIV-1/M) infected-naïve patients. Secondary objectives are to compare the kinetic of viral load responses, the CD4 restoration and the clinical events.

Methods: HAART was initiated in naïve patients with CD4 < 350/mm3; HIV-1/O and HIV-1/M patients were matched on sex, age, CD4, HB level and HBV status with ratio of 1:2. The primary endpoint was the percentage of patients having an undetectable viral load (VL < 60 cp/mL) at 48 weeks.

Results: 47 Cameroonian patients HIV-1/O and 94 HIV-1/M were included; results were available for 128 patients (13 died or were lost-to follow-up). At baseline, VL was significantly lower (p < 0.0001) in HIV-1/O with a median at 4.3 log cp/mL versus 5.1 in HIV-1/M. At 48 weeks, 86% of HIV-1/O samples were < 60 cp/mL vs 84% of HIV-1/M in per protocol analysis (p = 0.52). In ITT analysis (missing/failure), the result was similar (79% vs 76% for HIV-1/O and HIV-1/M respectively, p = 0.65). At baseline, median CD4 counts were well balanced between the two groups (227 vs 215 in HIV-1/O and HIV-1/M respectively, p = 0.68); at 48 weeks, a 58% CD4 gain compared to baseline was observed for 60% vs 78% of the HIV-1/O and HIV-1/M patients respectively (p = 0.03).

Conclusions: DynaM-O is the first and unique study analyzing the HAART responses in HIV-1/O infected patients compared to HIV-1/M patients. Data at week 48 showed good efficacy of the regimens in both groups, but viral load was significantly lower at baseline in HIV-1/O. In contrast, the CD4 restoration was lower in HIV-1/O than that observed for HIV-1/M patients.

Studying the mechanisms underlying these differences in response to HAART between these highly divergent HIV-1 strains are of importance in our understanding of the HIV natural history and to provide recommendations for HIV-1/O treatment and monitoring.

TUPEB267

“CD4 explorers” and “CD4 peak achievers” under ART in a large Italian cohort of HIV-infected subjects

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Background: cART treated PLHIV gaining a large amount of CD4+ T-cells over a short time (“CD4 explorers”, CD4%) or reaching a very high absolute CD4 count (“CD4 peak achievers”, CD4pa) have been recently described. We aimed to characterize these subjects and investigate whether the rate of morbidity/mortality of CD4% or CD4pa may differ from patients who have not present this peculiar CD4 ART responses.

Methods: We included naïve patients from Icona cohort who have undergone viral load test only starting ART. Individuals who gained CD4 >600 cells/mm3 above pre-ART and maintained it for ≥2 consecutive analysis were defined as CD4% those who achieved a CD4 >1000 cells/mm3 were defined as CD4pa. We estimated the frequency of CD4% and CD4pa by 3 years of suppressive cART and identified factors independently associated with the chance of CD4% and CD4pa using standard survival analysis (Kaplan-Meier curves, Cox model). Participants were further classified according to whether by 3 years of cART they belonged to CD4% or CD4pa and survival analysis was used to compare their risk of sNAE/death.

Results: 5,795 subjects were included: by 3 years, the cumulative incidence of CD4% and CD4pa was 12% (95% CI 10.8-13.1) and 10% (8.9-1.9). In multivariable analysis, older age (HR=0.79 per 10 years, 95% CI 0.71-0.86) and HCV (HR=0.73, 95% CI 0.54-1.00) were associated with lower chance of CD4% profile. Inflation with PI-based therapy increased the probability of an exploding CD4 response (HR=1.52, 95% CI 1.28-1.82). Factors independently associated with greater chance of CD4pa were younger age, without HCV, having started a PI-based regime and a higher CD4 nadir (HR=1.53 per 100 cells/mm3, 95% CI 1.47-1.59). Compared to others, subjects with CD4pa had a reduced risk of sNAE/deaths (p =0.03) while little difference was observed for CD4% (p=0.15).

Conclusions: By 3 years of effective cART approximately 10% of patients present an extreme CD4 count recovery. Such a CD4 count response is more likely in younger, without HCV and who started a PI-based therapy. People CD4% tended to have a subsequent lower risk of sNAE/death, suggesting that a fast kinetic of immune recovery might be more important than the absolute number achieved.

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### Table 1. Hazard ratios of SNAE/death from fitting a Cox regression model

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Unadjusted</th>
<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 explorer</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>No</td>
<td>0.41 (0.18, 0.95)</td>
<td>0.038</td>
</tr>
<tr>
<td>0.40 (0.14, 1.16)</td>
<td>0.080</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>CD4 peak achiever</td>
<td>1.38 (0.47, 4.04)</td>
<td>0.563</td>
</tr>
<tr>
<td>No</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>1.39 (0.46, 4.21)</td>
<td>0.565</td>
<td></td>
</tr>
</tbody>
</table>

*Adjusted for gender, age, mode of HIV transmission, time since HIV diagnosis, type of cART started (PI vs. NNRTI-based), HIV co-infection, CD4 nadir, HBV and CMV co-infection and CD4CD8 ratio
Second-line therapy

TUPEB268
HIV-1+ patients submitted to second line therapy display a comparable immunological biosignature to HIV+ untreated patients while first line therapy partially recovers immune response to a non-infected status

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Background: Successful highly active antiretroviral therapy (HAART) has changed the outcome of AIDS worldwide. The complete suppression of viremia improves health and prolongs life expectancy of HIV+ patients. Few highlights are given to immunological profile of patients under distinct HAART regimens. This work aims to clarify the differences in the immune outcome of AIDS worldwide. The complete suppression of viremia improves health and prolongs life expectancy of HIV-1+ patients. Few highlights are given to immunological profile of patients under first line or second line HAART.

Methods: A systems biology approach was used to compare Brazilian Non-infected (NI) (n=65), HIV-1+ untreated (HIV+1)(n=45), HIV+1 treated with NRTIs+NNRTIs (HAART1)(n=15) or NRTIs+IP patients (HAART2)(n=15). Plasma biomarkers levels of MCP-1, RANTES, IL-10, IL-4, IL-5 and IL-10 were measured using a multiplex platform and sCD14 and sCD163 by ELISA. To correlate disease progression with immunological profile, HIV+1 patients were classified into slow or rapid progressors and radar charts were constructed using the frequency (%) of high producers. Changes above 50% were considered relevant. Spearman correlation was used to define the biomarkers networks. A heatmap showing the Z-score of each biomarker was produced to verify the distance between the four groups.

Results: Considering disease progression, we found that the immunological biosignature of HIV-1+ patients is characterized by exacerbated inflammation among rapid progressors, as seen by increased frequency (above 75%) of biomarkers even producers, and moderate among slow progressors. HAART reduces exacerbated inflammation even in rapid progressors, however, biosignature of HAART1 is closer to NI individuals especially in slow progressors, while the use of HAART2 induces a moderate inflammation in rapid progressors that remains in the slow progressors, which approximates HAART2 pattern to HIV+1.

Conclusions: By using a systems biology approach, we concluded that patients in different HAART regimens develop distinct immunological biosignatures, giving rise to a novel perspective into disease outcome and scientific analysis, considering HAART patients as a heterogeneous group.

TUPEB269
Regimen switching and virological response in treatment experienced HIV+ patients receiving an integrase inhibitor based regimen: an Australian cohort study

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Background: Integrase inhibitors (II) offer a new option for treatment experienced patients as they reduce viral replication more rapidly than other drug classes. The aim of this study is to describe treatment durability and virological outcomes using II regimens in treatment experienced HIV+ patients receiving care outside of clinical trials.

Methods: We included patients from the Australian HIV Observational Database who have been on an II regimen for longer than 14 days and had previous treatments regimens (n=588). Patient follow-up was to March 2014. There were two groups of patient treatment experience: 2nd line patients and highly experienced patients. Highly experienced patients were those who had experienced all 3 main ARV classes (NRTI, NNRTI and PI) while all other patients were considered 2nd line patients. Survival methods were used to determine time to viral suppression and time to regimen switching, stratified by patient treatment experience. Factors evaluated as associated with regimen switching included age, gender, hepatitis B co-infection, hepatitis C co-infection, previous time on ART, patient treatment experience and baseline viral load.

Results: Time to viral suppression from II initiation was similar for 2nd line and highly experienced patients, with a 6% probability of regimen switching after 12 months for 2nd line patients and 70% for highly experienced patients. There were 60 occurrences of regimen switching, stratified by patient treatment experience. Factors evaluated as associated with regimen switching included age, gender, hepatitis B co-infection, hepatitis C co-infection, previous time on ART, patient treatment experience and baseline viral load.

Conclusions: We found that II regimens were potent and durable in experienced HIV+ patients receiving treatment outside clinical trials. These results confirm the role of II regimens as a robust treatment option.
Simplification (with one- or two-agent regimens) and switch studies

TUPEB270
Switch from PI/rtv +2 nucleos(t)ides to RPV+DRV/rtv maintains HIV suppression and is well tolerated
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Backgrounds: A nucleos(t)ides (NRTI) free regimen may be useful in selected patients who developed NRTI-related toxicity. We report the week 24 results of a pilot, prospective, randomized, ongoing trial of switch to a dual regimen ritonavir + raltegravir-boosted darunavir (RPV+DRV/r).

Methods: Virologically suppressed subjects on PI+/FTC/TDF or 3TC/ABC for > 6 months were randomized (1:1) to switch to RPV+DRV/r or remain on their baseline 3 drugs regimen (control). Eligibility criteria included no documented resistance to RPV and no HIV co-infection. The primary endpoint was the proportion of subjects who maintained HIV-RNA < 50 copies/ml at W24 by FDA snapshot algorithm (12% noninferiority margin).

Results: Sixty subjects (80% male, 22% with a previous diagnosis of AIDS, mean age 48 years) were randomized and treated (30 RPV+DRV/r; 30 controls). At randomization FTC/TDF was used in 83% of subjects and the most commonly used PIs were ritonavir-boosted atazanavir (57%) and ritonavir-boosted darunavir (35%). Median time since first ART use was 6.2 and median number of regimens 3. The mean CD4 count was 623 cells/ml and baseline characteristics were similar between the groups. At W24 100% of subjects who switched to RPV+DRV/r maintained HIV-RNA < 50 copies/ml compared to 86.7% of controls (difference 13.3%, 95% CI -1.1% to +25.4%). There was no confirmed virologic failure and, at W24, HIV-RNA was < 3 copies/ml in 50% of subjects in either group. Compared to controls, subjects on RPV+DRV/r experienced a greater CD4+ increment (mean +87 vs +17 cells/ml/mC), CD8+ decrement (mean -4 vs -17 cells/ml/mC) and CD4+CD8+HLA*DR+ decrement (mean -3.3 vs +1.2%). There was no AE leading to drug discontinuation. At W24 there was a lower increment in fasting triglycerides for RPV+DRV/rtv (+0.78 mg/dL vs +2.34 mg/dL) and a larger increment in both total (+4.1 mg/dL vs -0.7 mg/dL) and HDL cholesterol (+0.6 mg/dL vs -4.2 mg/dL).

Conclusions: Switching to RPV+DRV/r compared to continuing a PI+/FTC/TDF or 3TC/ABC demonstrated virologic non inferiority. RPV+DRV/r presented slight immunologic advantages and was well tolerated with a favorable safety profile. Switching to this NRTI free regimen may be an option for patients experiencing NRTI related toxicity.

Pharmacology / pharmacokinetics / pharmacogenomics / role of therapeutic drug monitoring

TUPEB271
Renal safety of tenofovir and amphotericin co-administration in treatment of cryptococcal meningitis
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Backgrounds: Tenofovir (TDF) and Amphotericin B deoxycholate (Amphotericin) are associated with kidney impairment, although the effect of TDF and Amphotericin co-administration on renal function is poorly characterized. We assessed kidney function during cryptococcal meningitis treatment and at 4-weeks post-diagnosis in patients receiving concomitant Amphotericin and TDF.

Methods: Serum creatinine was measured in 160 patients enrolled in a clinical trial investigating the survival benefit of adjunctive setraline compared with standard antifungal therapy for the treatment of cryptococcal meningitis in Uganda. At diagnosis, participants were classified as not receiving antiretroviral therapy (ART), receiving non-TDF ART, or receiving ART including TDF. Creatinine concentrations were measured on days 1, 3, 7, 10, 14, and 28 of follow-up, and kidney function was classified per the DAIDS Adverse Events grading system. Non-parametric tests and competing-risks regression evaluated differences across ART groups.

Results:

<table>
<thead>
<tr>
<th></th>
<th>No ART (n=91)</th>
<th>ART no TDF (n=27)</th>
<th>ART with TDF (n=42)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median [IQR] Creatinine Concentrations, mg/dL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>73 (65-80)</td>
<td>66 (59-85)</td>
<td>70 (60-80)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>14 Days</td>
<td>60 (51-70)</td>
<td>62 (53-71)</td>
<td>0.63</td>
<td></td>
</tr>
<tr>
<td>28 Days</td>
<td>43 (37-50)</td>
<td>43 (37-50)</td>
<td>0.67</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: At meningitis diagnosis, 17% (27/160) of patients were receiving non-TDF ART, 26% (42/160) were receiving ART with TDF, and 57% (91/160) were not receiving ART. Renal-related adverse event incidence was similar across ART groups (Table 1). After 14 days of amphotericin therapy, median creatinine concentrations (mg/dL) were also similar across groups: 1.11 (IQR: 0.87-1.34) among no ART, 0.83 (IQR: 0.80-1.51) among ART without TDF, and 0.97 (IQR: 0.78-1.50) among ART with TDF (p=0.83). At 4 weeks post-diagnosis, creatinine concentrations were approximately 0.3 mg/dL higher than at diagnosis but similar across groups, with medians of 0.89 (IQR: 0.89-1.10) without ART, 0.92 (IQR: 0.75-1.10) among ART without TDF, 1.02 (IQR: 0.84-1.15) among ART with TDF (p=0.07). During induction amphotericin therapy, ART was discontinued in 4.7% (2/42) of patients receiving TDF at diagnosis, and no patients receiving ART without TDF.

Conclusions: In persons with cryptococcal meningitis receiving amphotericin-based therapy, no differences in kidney-related adverse events or median serum creatinine were observed up to 4 weeks after amphotericin initiation, based on receipt of ART with or without TDF. TDF and Amphotericin co-administration did not substantially increase the risk of renal dysfunction. Among persons on ART presenting with cryptococcal meningitis, further study of patient management and their outcomes is necessary.

TUPEB272
The pharmacokinetic profiles of dolutegravir in Japanese HIV-1-infected patients
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Background: Dolutegravir is a second-generation HIV-1 integrase inhibitor that is high potent against both wild-type and drug-resistant HIV-1 strains. The quantification of dolutegravir in human plasma is important to support clinical studies. Dolutegravir was just approved at April 2014 in Japan. Therefore, pharmacokinetic study of dolutegravir for Japanese is still not clear. We intended to develop a conventional method for determining plasma dolutegravir concentrations and compare plasma dolutegravir concentrations of Japanese HIV-1-infected patients with that of foreign patients.

Methods: We used a Waters Alliance 2695 HPLC and a Micromass ZQ-2000 MS, controlled with MassLynx version 4.0 software. Our method involves rapid liquid-liquid drug extraction from plasma and use of gradient elution on a reversed-phase C18 column. We recruited 31 Japanese HIV-1-infected patients who were treated with dolutegravir containing regimen in Japan. All patients had been administered with 50mg dolutegravir once daily in combination with other antiretrovirals.

Results: The established LC-MS method was validated by estimating the precision and accuracy for inter- and intra-day analysis in the concentration range of 7.9-4012 ng/ml. The calibration curve was linear in this range. Relative standard deviations of both inter- and intra-assays were less than 4.3 %. In this study, mean dolutegravir plasma concentration for Japanese patients at trough was 0.54±0.38 µg/ml. Mean dolutegravir concentration at peak was 3.32±0.62 µg/ml. A calculated elimination half-life was 12 hours and AUC was 40.7 µg·h/ml. These values were similar with dolutegravir concentrations seen in foreign HIV-1-infected patients' trials.

Conclusions: Our LC-MS method can be used conveniently in clinical routine application and enables the study on the pharmacokinetics of dolutegravir in conventional hospital laboratories. In this study, the pharmacokinetic profile of dolutegravir in Japanese was similar with that of foreigner. In general, body build of Japanese is poor in comparison with Caucasian. As a result, high plasma dolutegravir concentrations may result in dose reduction for Japanese. However, our data showed that the dose adjustment of dolutegravir is not also required for Japanese HIV-1-infected patients.
TUPEB273

Composite CYPB2/CYP2A6 genotype and risk for suicidality among HIV-infected individuals randomly assigned to initiate efavirenz-containing regimens in AIDS Clinical Trials Group studies

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Background: Efavirenz (EFV)-containing regimens were associated with increased hazard of suicidality in a pooled analysis of four AIDS Clinical Trials Group (ACTG) studies wherein antiretroviral-naive individuals were randomly assigned to initial antiretroviral regimens. Here we examined relationships between composite CYPB2/CYP2A6 genotypes, which predict higher plasma EFV levels, and suicidality among individuals who initiated EFV-containing regimens.

Methods: Analyses included White, Black, and Hispanic participants in the United States from ACTG studies A5959, A5142, A5175, and A5202. Suicidality was defined as reported suicidal ideation, attempted, or completed suicide. Composite genotypes that predict 12 increasing plasma EFV exposure levels were defined by CYPB2 (15582C→T, 516G→T, 937C→T), and CYP2A6 (48T→G). Levels were also collapsed into extensive (levels 1-2), intermediate (3-7), and slow (8-12) metabolizer groups. Association between genotype and time to suicidality was evaluated with a Cox proportional hazards model stratified by race/ethnicity. Separate analyses were performed for EFV exposure (both follow-up after initiation) and EFV on-treatment (OT, follow-up from initiation to permanent discontinuation +28 days).

Results: Genotypes were available for 1656 (74%) of 2239 EFV recipients, including 41 (8%) of 493 EFV recipients, and 128 (25%) of 513 EFV recipients who developed a ‘backbone’ fixed-dose combination (FDC) with emtricitabine (FTC) for the treatment of HIV-1 infection in combination with 3’ agents. Co-administration of TAF within a regimen containing ritonavir (RTV) or cobicistat (Cobicistat, C) as a ‘booster’ results in a ~2.5-fold increase in EFV exposure via Pgp inhibition; TAF dosage strengths 10 mg and 25 mg target equivalent exposures in the boosted and unboosted states, respectively. Studies were conducted to determine the bioequivalence (BE) of the 2 dosage strengths of TAF/FDC (200/10 and 200/25 mg) to the extrelvir (EVG), Cobicistat, FTC, TAF/Cobicistat/150/200(20/10) mg FDC, which established the safety and efficacy of TAF in Phase 3 studies.

Methods: Two randomized, open-label, single-dose, 2-way, crossover studies were conducted in healthy adult subjects. Single-dose PK of TAF and FTC were compared between F/TAF FDC (200/25 mg Study 1 and F/TAF 200/10 mg + EVG + Cobicistat in Study 2) and E/C/F/TAF 150/150/200(20/10) mg FDC, the established safety and efficacy of TAF in Phase 3 studies.

Results: TAF and FTC exposures from F/TAF 200/25 mg (Study 1; N=116) and F/TAF 200/10 mg (Study 2; N=100) were comparable vs E/C/F/TAF, and in both studies, the 90% CI for GLSMR of AUC0-∞, AUC0-24h, and Cmax for TAF and FTC were contained within the pre-specified BE bounds. (Table 1) in both studies, TAF and FTC were generally well tolerated. There were no deaths or adverse events (AEs) leading to study drug discontinuation; one subject in Study 2 experienced a serious AE following FTC administration, which was not related to study drug.

Conclusions: The two dosage strengths of TAF/FDC are both bioequivalent to E/C/F/TAF FDC.

TUPEB275

Bioequivalence of two dosage strength fixed-dose combination formulations of F/TAF

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Background: Tenofovir alafenamide (TAF) is a novel prodrug of tenofovir (TFV) being developed as a ‘backbone’ fixed-dose combination (FDC) with emtricitabine (FTC) for the treatment of HIV-1 infection in combination with 3’ agents. Co-administration of TAF within a regimen containing ritonavir (RTV) or cobicistat (Cobicistat, C) as a ‘booster’ results in a ~2.5-fold increase in TAF exposure via Pgp inhibition; TAF dosage strengths 10 mg and 25 mg target equivalent exposures in the boosted and unboosted states, respectively. Studies were conducted to determine the bioequivalence (BE) of the 2 dosage strengths of TAF/FDC (200/10 and 200/25 mg) to the extrelvir (EVG), Cobicistat, FTC, TAF/Cobicistat/150/200(20/10) mg FDC, which established the safety and efficacy of TAF in Phase 3 studies.

Methods: Two randomized, open-label, single-dose, 2-way, crossover studies were conducted in healthy adult subjects. Single-dose PK of TAF and FTC were compared between F/TAF FDC (200/25 mg Study 1 and F/TAF 200/10 mg + EVG + Cobicistat in Study 2) and E/C/F/TAF 150/150/200(20/10) mg FDC, the established safety and efficacy of TAF in Phase 3 studies.

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Conclusions: The two dosage strengths of TAF/FDC are both bioequivalent to E/C/F/TAF FDC.

TUPEB274

Frequency of tablet remnants of nevirapine extended-release in stools and its impact on virological outcome in HIV-infected Taiwanese: a prospective cohort study

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Background: Presence of tablet remnants of nevirapine extended-release (NVP XR) in stools has been reported to occur in 1-3% of the subjects enrolled in clinical trials. The incidence may have been underestimated due to the information obtained by self-reporting.

Methods: Using a face-to-face questionnaire interview of the HIV-infected patients with switch to NVP XR plus 2 NRTIs between April to December 2014, we inquired about the frequency of noticing tablet remnants of NVP XR in stools. Clinical information was collected using a computerized data collection form. Patients were invited to participate in therapeutic drug monitoring (TDM) of plasma concentrations of NVP with the use of high-performance liquid chromatography (HPLC) 12 or 24 hours after the previous dose.

Results: During the 8-month study period, 244 patients switched to NVP XR plus 2 NRTIs and 69 patients (20.0%) noticed tablet remnants of NVP XR in stools. Compared with patients who did not notice tablet remnants, those who noticed tablet remnants in stools had a similar exposure duration to NVP XR before study was conducted (162 vs 155 days), were younger (34.4 vs 38.0 years), and had a higher mean CD4 count before switch to NVP XR (612 vs 495 cells/μL), but a similar plasma HIV RNA load (PVL) (1.55 vs 1.66 log10 copies/mL). After switch to NVP XR, the patients noticing tablet remnants tended to have a lower plasma HIV RNA load (1.39 vs 1.55 log10 copies/mL, P=0.07) and higher CD4 count (626 vs 547 cells/μL, P=0.05) than those without noticing tablet remnants within a mean interval of 3 months, despite the finding that the 20 patients in the former group who underwent TDM had a lower median NVP plasma concentration at 12 hours of dosing than the 17 patients in the latter group (3.55 vs 5.7 ng/mL).

Conclusions: We found that presence of tablet remnants of NVP XR is not infequent in HIV-infected Taiwanese and was associated with a lower NVP plasma concentrations, which did not have an adverse impact on the virological and immunological responses.
Drug interactions

TUPEB276
Rifabutin for treating tuberculosis in HIV-infected adult patients receiving boosted protease inhibitor containing ART regimen: experiences of neuropenia from an urban clinic

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Background: Rifabutin dosing during ritonavir co-administration remains a matter of debate due to the drug interaction between these medicines. While some studies have demonstrated that rifabutin 150 mg thrice weekly is inadequate, other studies in healthy subjects suggest that rifabutin 150 mg on alternate days, thrice weekly or every 4 days is adequate when administered with ritonavir. Several international guidelines now recommend administration of rifabutin 150mg once daily when co-administered with a ritonavir boosted protease inhibitor (PI). However there is still limited safety data with this combination for rifabutin-related toxicities. We evaluate the effect of once daily rifabutin dosing when co-administered with a ritonavir boosted PI on neuropenia.

Methods: This was a retrospective cohort study in 22 patients on an antiretroviral regimen containing a boosted PI and rifabutin 150mg once daily from Newlands Clinic in Harare, Zimbabwe. Patients had an absolute neutrophil count test prior to commencement of rifabutin 150mg and post commencement of rifabutin. Participants were also receiving either lopinavir/ritonavir or azatavir/ritonavir as part of their antiretroviral regimen. Data was analyzed with Stata version 12 to determine survival of patients and to identify the impact of co-administration on absolute neutrophil counts.

Results: Twenty-two participants with a median age of 24.3 (range = 15.8 - 45.1) years participated, with 68% being female. Seventeen (77.3%) participants had reductions in absolute neutrophil counts after commencing rifabutin. The median decline in neutrophil count for all participants was 1,150 cells/µL (IQR = 700 - 2,000 cells/µL). A Kaplan-Meier survival estimate of the time to neutropenia is shown below.

Conclusions: Co-administration of a ritonavir-PI containing antiretroviral regimen with rifabutin led to a decline in absolute neutrophil counts in the majority of patients. More than half the participants were neutropenic when co-administered once daily rifabutin with a ritonavir-PI antiretroviral containing regimen.

TUPEB277
HIV-1 attachment inhibitor prodrug BMS-663068: interactions with rifabutin, with or without ritonavir, in healthy subjects

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Background: BMS-663068 is a prodrug of BMS-626529, a first-in-class attachment inhibitor that binds directly to HIV-1 gp120, preventing initial viral attachment and entry into host CD4+ T cells. BMS-626529 is metabolized in part by CYP3A4. Rifabutin, a CYP3A4 inducer, is used to treat mycobacterium infections in HIV-1-infected patients and decreases BMS-626529 exposures. Ritonavir (RTV), a CYP3A4 inhibitor, is used as a protease inhibitor-boosting agent and increases BMS-626529 exposure. This study assessed the effects of combining rifabutin/RTV on BMS-626529 systemic exposures.

Methods: In this open-label, single-sequence, multiple-dose, two-cohort study, 46 healthy subjects received BMS-63068 600mg BID on Days 1-4. On Day 5, subjects were randomized 1:1 to receive BMS-63068 600mg BID+Rifabutin 300mg QD (Cohort 1) or BMS-63068 600mg BID+Rifabutin 150mg QD+RTV 100mg QD (Cohort 2) on Days 5-15. Pharmacokinetic parameters for BMS-626529 on Days 4 and 15 were derived using non-compartmental methods. Geometric mean ratios and 90% confidence intervals were calculated from log-transformed Cmax, AUC0-24, and C12 using a linear, mixed-effect model.

Results: Forty-five subjects (11 [22%] and 22 [43%]) had evaluable pharmacodynamic data (Table). Compared to BMS-63068 administration alone, coadministration with rifabutin (Cohort 1) decreased BMS-626529 Cmax, AUC0-24 and C12 by 27%, 30% and 41%, respectively; coadministration with rifabutin+RTV increased BMS-626529 Cmax, AUC0-24 and C12 by 50%, 66% and 158%, respectively. Systemic exposure changes in BMS-626529 in both cohorts were not considered as clinically meaningful based on efficacy results from a wide range of BMS-63068 doses in a Phase 2b study. All adverse events (AEs) were mild or moderate; the most frequent were headache (34.8%), chromaturia (26.1%), influenza-like illness (23.5%), and nausea (21.7%). Three (13.6%) and six (26.1%) subjects discontinued due to treatment-emergent AEs in Cohorts 1 and 2, respectively. One subject discontinued treatment before randomization. No deaths or serious AEs were reported.

Conclusions: Dose modification is not required when coadministering BMS-63068 600mg BID with rifabutin or RTV, and the combination was safe with acceptable tolerability.

<table>
<thead>
<tr>
<th>Treatment and comparison [h]</th>
<th>Pharmacokinetic parameter, adjusted geometric means</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMS-63068 600mg BID [22]</td>
<td>Cmax [ng/mL (90% CI)]</td>
</tr>
<tr>
<td>2398 (2199, 2614)</td>
<td>14736 (12171, 16363)</td>
</tr>
<tr>
<td>BMS-63068 600mg BID + Rif 300mg QD [16]</td>
<td>Cmax [ng/mL (90% CI)]</td>
</tr>
<tr>
<td>1796 (1496, 2061)</td>
<td>10292 (9108, 11563)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>230 (177, 299)</td>
</tr>
<tr>
<td>BMS-63068 600mg BID + Rif 300mg QD vs. BMS-63068 600mg BID</td>
<td>AUC0-24 [ng.h/mL (90% CI)]</td>
</tr>
<tr>
<td>0.732 (0.647, 0.829)</td>
<td>0.698 (0.642, 0.760)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>0.594 (0.441, 0.796)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>Cmax [ng/mL (90% CI)]</td>
</tr>
<tr>
<td>2419 (2150, 2767)</td>
<td>228 (12266, 16201)</td>
</tr>
<tr>
<td>BMS-63068 600mg BID [23]</td>
<td>2419 (2150, 2767)</td>
</tr>
<tr>
<td>BMS-63068 600mg BID + Rif 150mg QD + RTV 100mg QD [16]</td>
<td>AUC0-24 [ng.h/mL (90% CI)]</td>
</tr>
<tr>
<td>3633 (3166, 4164)</td>
<td>23428 (19888, 27574)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>346 (665, 1077)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>Cmax [ng/mL (90% CI)]</td>
</tr>
<tr>
<td>1.501 (1.378, 1.635)</td>
<td>1.692 (1.521, 1.813)</td>
</tr>
<tr>
<td>Cmax [ng/mL (90% CI)]</td>
<td>2.354 (1.954, 3.417)</td>
</tr>
</tbody>
</table>

[Table] CI, confidence interval; BID, twice daily; QD, once daily; GMT, geometric means ratio; Rif, rifabutin; RTV, ritonavir

Kaplan-Meier survival estimate of neutropenia
**TUPEB278**

Drug interactions between psychiatric drugs and antiretroviral therapy, adherence and clinical outcomes

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**Background:** Patients infected with HIV have a high prevalence of mental illnesses. Drug interactions (DI) between antiretroviral therapies (ART) and psychiatric drugs (PD) should be considered. The aim of the study was to describe the frequency and severity of DI between ART and PD; another objective was to compare adherence and the clinical outcomes between patients with or without PD.

**Methods:** A cross-sectional study in HIV-infected patients was carried out during 2014. A structured interview was conducted to detect any type of drug, frequency and grade of DI. Data collected: demographics, current ART, adherence measured by patients’ self-report, last viral load (VL), DI was evaluated by using the University of Liverpool database. Chi-square test was used to compare adherence and outcomes between patients with or without PD.

**Results:** Patients included 761; 179 (22.6%) with PD; 135 (75.4%) men, 48 ±10 years; 158 (88.2%) Caucasian; 128 (70.4%) smokers; 25 (14.5%) alcoholics; 47 (26.3%) drug users. Total PD prescriptions: 380 (2.1 PD/patient). Type of PD: 63 (16.6%) methadone and opioid drugs; 100 (26.3%) antidepressants; 148 (38.9%) anxiolytics; 69 (18.2%) antipsychotics. At least one relevant interaction was detected in 156 (87.2%) patients. Seventeen (9.5%) interactions were considered contraindicated: quetiapine (15), trazodone (1) and midazolam (1), in these cases a switch in ART or PD was recommended. In addition, it was recommended to change the dose, switch PD or ART in 26 (14.5%) patients. Relevant interactions were found in 156 (87.2%) and in 178 (30.6%) of patients with and without PD respectively. Table 1 shows the comparison of type of ART, adherence, interruption of ART and HIV-RNA< 20 copies/mL between patients with or without PD.

<table>
<thead>
<tr>
<th>Patients with Psychiatric drugs N=179</th>
<th>Patients without Psychiatric drugs N=582</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease inhibitors use</td>
<td>110 (61.8%)</td>
<td>224 (38.5%)</td>
</tr>
<tr>
<td>Non-nucleoside use</td>
<td>63 (35.2%)</td>
<td>319 (54.8%)</td>
</tr>
<tr>
<td>Raltegravir use</td>
<td>23 (12.8%)</td>
<td>56 (9.6%)</td>
</tr>
<tr>
<td>Adherence &gt;90%</td>
<td>154 (86%)</td>
<td>529 (90.2%)</td>
</tr>
<tr>
<td>Interruption of ART</td>
<td>22 (12.3%)</td>
<td>15 (2.6%)</td>
</tr>
<tr>
<td>HIV-RNA&lt;20 copies/mL</td>
<td>509 (89.8%)</td>
<td>509 (89.8%)</td>
</tr>
</tbody>
</table>

Table 1

**Conclusions:** A fifth of HIV patients are taking psychiatric drugs. Among them, 87% had at least one drug interaction. Contraindicated interactions were detected in almost 10% of psychiatric patients. In the group of patients taking psychiatric drugs, protease inhibitors were more frequently prescribed. Interruption of antiretroviral treatment was more common and the effectiveness of antiretroviral treatment was slightly lower.

**TUPEB279**

Pharmacokinetics and drug interaction potential of multiple-dose tenofovir alafenamide and rilpivirine

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**Background:** Tenofovir alafenamide (TAF), a novel tenofovir (TFV) prodrug, cofomulated in a fixed-dose combination (FDC) tablet with rilpivirine (RPV) and entecavir (ETV). FDC is a new class of antiretroviral therapy. This pilot study was conducted in support of the FDC development program to evaluate TAF and RPV exhibit a drug interaction upon multiple-dose co-administration.

**Methods:** In this fixed-sequence, open-label, 2-cohort, 2-period study, healthy subjects (N=34) were randomized to receive either: TAF alone, followed by TAF + RPV, each for 14 days (Cohort 1) or RPV alone, followed by TAF + RPV, each for 14 days (Cohort 2). Intensive pharmacokinetic assessments were performed on the final day of each treatment. Primary pharmacokinetic parameters of TAF and RPV, alone or in combination, were compared via geometric least-squares mean (GLSM) ratios and associated 90% confidence intervals (CI). Safety was assessed throughout the study.

**Results:** Thirty-two subjects completed the study. Following co-administration of TAF + RPV, exposures of TAF, TFV and RPV were comparable to administration of TAF or RPV alone: AUC<sub>24</sub> and C<sub>24</sub> GLSM(90%) CI for TAF were 101(93.8, 109) and 101(84.2, 122), respectively, AUC<sub>24</sub> and C<sub>24</sub> GLSM(90%) CI for TFV were 111(107, 113), 112(104, 123), and 119(113, 123) respectively and for RPV were 101(66.4,106), 92.9(87.4,98.7) and 113(104,123) respectively.

**Conclusions:** All treatments were well tolerated; no deaths, serious adverse events (AE), or Grade 3 or 4 AEs occurred. One subject discontinued the study due to a drug-related Grade 2 AE of increased hepatic enzymes.

**TUPEB280**

High rate of transmitted drug resistance in treatment-naive HIV-infected VCT clients in southern Taiwan, 2007-2014

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**Background:** The transmission of drug-resistant HIV-1 strains might compromise the efficacy of antiretroviral treatment. Rate of transmitted drug resistance (TDR) strains was influenced by duration of infection, selection of study populations and government policy of treatment. The aim of this study was to monitor the prevalence of TDR in Taiwan, where free highly active antiretroviral therapy (HAART) was provided since 1997.

**Methods:** A prospective study on TDR was conducted in antiretroviral therapy -naive HIV-1-infected voluntary counseling and testing (VCT) clients from 2007 to 2014 in Southern Taiwan. Genotypic drug resistance mutations were determined by VirusSeq<sup>®</sup> system. Results: From 2007 to 2014, a total of 20119 clients received a VCT. The positive rate for HIV-1 infection was ranged from 2.9% to 5.4% in every year. Sequences were obtained from 301 individuals, of whom 88% were infected by MSM, and 12% were infected by heterosexually. Subtype B HIV-1 strains were found in 98% of the individuals, subtype CRF01_AE in 1.7% and subtype C in 0.3%. Thirty-two (10.6 %) patients were found to harbor drug resistance strains. The rates of resistance to any three classes of antiretroviral drugs (NRTI, NNRTI and PI) were 6% in 2007, 9% in 2008, 8% in 2009, 6% in 2010, 6% in 2011, 7% in 2012, 13% in 2013 and 19% in 2014. The most common NRTI resistance associated mutation was M184V. The most common NNRTI resistance associated mutation was K103N and V179D. No PI resistance associated mutation was found in these 8 years.
TUPEB281
Ten year prevalence of HIV-1 drug resistance mutations in New South Wales, Australia

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Background: New South Wales (NSW) has the greatest burden of HIV in Australia with an estimated 46% (123,060/268,000) of all people living with HIV. Despite universal access to antiretrovirals from early in the epidemic and recommendation in 2008 of baseline genotypic antiretroviral testing (GART), rates of prevalent drug resistance in this state are not known. A statewide analysis of prevalent drug resistance was performed to determine changes in resistance mutations.

Methods: A retrospective study of protease (PR) and reverse transcriptase (RT) genes was performed at three reference laboratories covering all genotypic drug resistance tests in NSW from 2004-2013. Duplicates within calendar year were excluded. Treatment data was available for 26% (154,678/607,287), allowing estimates of prevalence in treatment naive and experienced subgroups. Genotyping was performed with Trugene, Viroseq and in house sequencing based assays. WHO 2009 Susceptibility database resistance mutations (SDRMs) were determined using Stanford Calibrated Population Resistance tool and overall frequency calculated per year.

Results: 7687 drug resistance tests were performed. Over ten years, we observed decreases in overall frequency of SDRM from 81.6% (321/391) to 22.2% (166/747). Similarly, decreases were observed in PR mutations from 28.5% (138/351) to 4.7% (35/747), NNRTI 56.3% (293/521) to 12.2% (91/747) and NNRTI 39.8% (207/521) to 12.9% (96/747). Similar declines were observed in dual class NNRTI and NNRTI resistance (35% to 5.8%) and triple class resistance (17.3% to 1.2%). In treatment experienced subgroup, most frequent NNRTI resistance mutations M184VI and T215YFISCDVE and PR mutation I54VTALMV were unchanged for the last five years, whereas G190AES has replaced Y181CIV as the second most frequent NNRTI mutation after K103NS. In treatment naive subgroup, there was no clear pattern of SDRMs, and protease mutations remain uncommon (< 0.6%). The overall rate of transmitted drug resistance (TDR) was stable at 10.0%.

Conclusions: There has been an apparent decrease in rate of prevalent SDRMs which is associated with the introduction of baseline routine genotypic testing. In a setting with universal access to antiretroviral therapy, rates of transmitted drug resistance have remained stable over time. This study provides baseline data before the implementation of statewide treatment strategies that target 95% coverage.

TUPEB282
Accuracy of WHO guidelines on management of adult patients on ART with unsuppressed viral load: a prospective multicenter study in rural Lesotho

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Background: The World Health Organization (WHO) 2013 Guidelines on antiretroviral therapy (ART) recommend routine viral load (VL) monitoring for all patients on ART. After a single VL ≥ 1000 copies/mL, enhanced adherence support is offered for 3-6 months and a second VL is obtained. In cases of sustained VL ≥ 1000 c/mL, an empiric switch to second-line ART consisting of a protease inhibitor (PI), lamivudine, and a new nuceloside reverse transcriptase inhibitor (NRTI) is recommended.

Methods: Adults on first-line ART ≥ 6 months attending routine care in 10 rural clinics in Lesotho received VL testing. Those with detectable VL (≥ 800 c/mL) underwent adherence support and a second VL was obtained after 3 months. Those with a detectable VL received genotypic resistance testing (GRT). Accuracy of WHO-recommendations was assessed at three levels: VL cut-off < 1000 c/mL to exclude failure due to resistance (1); two subsequent VL ≥ 1000 c/mL to confirm failure due to resistance (2); accuracy of the empiric second-line regimen (3).

GRT were classified as DR-0, DR-1, DR-2 - corresponding to the detection of genotypic mutations conferring resistance to none (DR-0), one (DR-1), or ≥ 2 drugs (DR-2) of the patients’ first-line regimen. A report of “low-level resistance” or higher according to the Stanford HIV Drug Resistance Database was used as cut-off for this classification. Empiric second-line regimen (ESLR) where defined as “accurate” when GRT revealed full susceptibility to PI and at least one NRTI in the ESLR. (study-registration: NCT02129696)

Results: Figure 1 displays results stratified by the level of viroemia, indicating distribution by gender.

Accuracy of VL<1000c/mL to exclude drug-resistance was 82.6% (95%CI: 74.0%-89.0%). Two subsequent VL ≥ 1000 c/mL confirmed drug-resistance with an accuracy of 88.9% (81.0%-95.6%). Overall ESLR were accurate for 51.9% (47.3%-68.6%). 6.8% (1.4%-13.5%) were inaccurate because GRT was DR-0 for failure and in 35% (24.3%-45.9%) GRT revealed at least low-level resistance against both NRTIs of the ESLR.

Conclusions: Application of 2013 WHO-guidelines accurately identified failure due to drug-resistance in most cases. However, switching to ESLR according to guidelines would have resulted in nearly one third being switched to a regimen where HIV is at least partially resistant against ≥ 2 drugs.

TUPEB283
Projecting the epidemiological effect, cost-effectiveness and transmission of HIV drug resistance in Vietnam associated with viral load monitoring strategies

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Background: Routine viral load (VL) monitoring is not available in Vietnam for people living with HIV (PLHIV) on antiretroviral therapy (ART). We investigated the potential epidemiological impact of VL monitoring and its cost-effectiveness in Vietnam.

Methods: We collated data on reported HIV diagnoses and HIV-related deaths, number of PLHIV on ART, clinical outcomes, HIV drug resistance, and HIV-treatment-related costs in Vietnam during 2005-2013. A population-based mathematical model, calibrated to reflect the structure of CD4+ cell count and clinical monitoring, was used to assess the impacts of viral load monitoring on transmitted drug resistance (TDR), acquired drug resistance (ADR), and HIV-related mortality. We simulated scenarios of various combinations of VL testing coverage, VL thresholds for second-line ART initiation, and availability of salvage therapies and HIV drug resistance tests. We assessed cost-effectiveness as cost per disability-adjusted life year (DALY) averted.

Results: Projecting expected ART scale-up levels, to approximately double the number of people on ART by 2030, will lead to an estimated 17,600 [95% confidence interval: 9,650-29,620] cases of TDR (prevalence, 16% [11%-23%]) and 50,620 [40,150-62,633] cases of ADR (prevalence, 18% [13%-25%]) in the absence of VL monitoring. VL monitoring with 30% coverage is expected to lead to a reduction of 13-32% of TDR (2,420-6,050 cases), 26-59% of ADR (prevalence, 18% [13%-25%]) in the absence of VL monitoring. We estimated to cost US$5,054-5,385 per DALY averted. Maintaining 30% VL testing coverage and providing HIV resistance testing for PLHIV with a VL<1,000 copies/mL every two years was the most cost-effective strategy for the ART programme in Vietnam. Sensitivity analysis revealed that the cost of second-line ART is the most influential factor of the cost-effectiveness ratios.

Acknowledgments: This work is supported by the Wellcome Trust and the US National Institutes of Health.
Conclusions: VL monitoring in Vietnam can have considerable benefits for individuals and lead to population health benefits. It may be marginally cost-effective according to common willingness-to-pay thresholds.

TUPEB284

HIV-1 attachment inhibitor prodrug BMS-663068 in antiretroviral-experienced subjects: analysis of emergent viral drug resistance through 48 weeks of follow-up

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Background: BMS-663068 is a prodrug of BMS-625529, a first-in-class attachment inhibitor that binds to HIV-1 gp120, preventing initial viral attachment to host CD4+ T-cells. A433B011 is an ongoing, Phase III, randomized, active-controlled, dose-blinded trial investigating the safety, efficacy and dose-response of BMS-663068 versus atazanavir/ritonavir (ATV/r) in treatment-experienced, HIV-1-infected subjects. We report emergent drug resistance through the Week 48 database lock.

Methods: 251 treatment-experienced (≥1 week exposure to ≥1 antiretroviral) subjects with baseline susceptibility to all study drugs (including a conservative BMS-626529 IC50 cutoff of < 100 nM determined by PhenoSense® Entry assay) were randomized 1:1:1:1:1 to receive BMS-663068 (400 or 800 mg, twice-daily; 600 or 1200 mg, once-daily) or ATV/r (300/100 mg once-daily) with tenofovir disoproxil fumarate (TDF) + raltegravir (RAL). Emergent viral drug resistance was assessed in subjects meeting resistance testing criteria through Week 48. A conservative cutoff (>3-fold increase) was used to assess changes in BMS-626529 IC50 from baseline.

Results: Through Week 48, 46/200 and 9/51 subjects across the BMS-663068 and AT/ral arms, respectively, met resistance-testing criteria. Of these, 44/46 and 9/9 were successfully tested using the PhenoSense® GT and Integrate assays. No subjects had emergent TDF resistance. Six subjects across the BMS-663068 arms developed emergent RAL resistance. No subjects developed ATV resistance. 41/46 subjects across the BMS-663068 arms had a viable evaluable phenotype using the PhenoSense® Entry assay. Of those, 15/41 exhibited a >3-fold increase in BMS-625529 IC50 from baseline. Population sequencing of gp120 was successful in 14/15 subjects, and 10/14 had emergent substitutions in gp120 at positions associated with reduced susceptibility to BMS-626529 (S375, M426 or M434). Of the 15 BMS-663068-treated subjects with an emergent >3-fold increase in BMS-625529 IC50 from baseline, 5 achieved further viral suppression to < 50 c/mL, whilst on study, prior to the Week 48 database lock.

Conclusions: The rate of emergent changes in viral susceptibility to BMS-625529, and known lack of in vitro cross-resistance with approved antiretrovirals support the upcoming Phase III trial evaluating BMS-663068 for use in heavily treatment-experienced adults. Further evaluation of the conservative >3-fold increase cutoff in BMS-625529 IC50 will be required in larger clinical trials to determine its relevance in this population.

TUPEB285

Analysis of HIV drug resistance in adults receiving early antiretroviral treatment for HIV prevention: results from the HIV prevention trials network (HPTN) 052 trial


Background: HPTN 052 demonstrated that early antiretroviral therapy (ART) prevented 96% of linked HIV infections in serodiscordant couples. Antiretroviral (ARV) drug resistance could potentially compromise the efficacy of ART for HIV prevention. Furthermore, factors associated with emergence of resistance may be different when ART is initiated at higher CD4 counts. We evaluated resistance in participants in the early ART arm of HPTN 052 who failed ART before May 2011 (trial unblinding).

Methods: Early ART arm participants reported no prior ART and initiated ART at CD4 counts of 350-550 cells/mm3 72% received zidovudine/lamivudine/abacavir (ZDV/3TC/EFV). 75% had NRTI+NNRTI resistance; 3 had non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance; 3 had non-nucleoside reverse transcriptase inhibitor (NNRTI) resistance; 3 had NRTI+NNRTI resistance. Thirty (35.3%) had resistance at failure. ART initiation was associated with new resistance at failure (odds ratio=1.62 [1.16, 2.25], p=0.005).

Conclusions: HIV drug resistance frequently emerged in individuals who initiated ART at higher CD4 counts and failed treatment. This could potentially compromise the long-term efficacy of ART for prevention. Higher baseline VL was associated with resistance at ART failure. Further studies are planned to evaluate the relationship between baseline VL and resistance in early and delayed ART.
TUPEB286
Viral blips were infrequent and similar in treatment-naive adults treated with rilpivirine/emtricitabine/tenofovir DF or efavirenz/emtricitabine/tenofovir DF in the STAR study

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Background: The clinical impact of transient episodes of viremia (viral blips) on virologic failure and resistance development is not fully understood. Here we investigate the association of viral blips with clinical outcome for treatment-naive subjects initiating therapy on rilpivirine/emtricitabine/tenofovir DF (RPV/FTC/TDF) or efavirenz/emtricitabine/tenofovir DF (EFV/FTC/TDF) through Week 96 in the STAR Study (GS-US-284-0110).

Methods: Subjects treated with ≥1 dose of study drug and with ≥1 post-baseline HIV RNA value were included in this analysis. All on-drug HIV-1 RNA data points and FDA snapshot outcome data through Week 96 were utilized. Plasma HIV-1 RNA was measured using the Roche COBAS AmpliPrep Monitor v1.5 test. A viral blip was defined as after achieving confirmed suppression (2 consecutive HIV-1 RNA values < 50 copies/mL), any HIV-1 RNA value ≥50 copies/mL preceded and followed by HIV-1 RNA < 50 copies/mL.

Results: Of the 767 subjects included in the analysis, 67 (8.7%) experienced ≥1 blip through Week 96. Of those, 62 had single blips (62/767, 8.1%) and were distributed similarly between treatment groups (36/392, 9.2% RPV/FTC/TDF; 26/375, 6.9% EFV/FTC/TDF). A greater proportion of subjects with baseline HIV-1 RNA > 100,000 copies/mL experienced blips compared to subjects with baseline HIV-1 RNA ≤100,000 copies/mL (both in groups 19/133, 14.3% vs. 20/2259, 0.7% RPV/FTC/TDF; 15/137, 10.9% vs. 13/238, 5.5% EFV/FTC/TDF). Five subjects experienced two each (3 RPV/FTC/TDF, 2 EFV/FTC/TDF). Of 72 total blip events, 81 (8.5%) were low-level ≤50 copies/mL, including all events experienced by subjects with multiple blips. Among subjects with blips, 53/67 (79%) were virologic successes at Week 96 (30/39, 77% RPV/FTC/TDF; 23/28, 82% EFV/FTC/TDF), similar to those subjects without blips (53/363, 14.4% overall; 275/315, 87% RPV/FTC/TDF; 258/316, 82% EFV/FTC/TDF). All 5 subjects with multiple blips were virologic successes. Among subjects with ≥1 blip through Week 96, 2/39 in the RPV/FTC/TDF group and 2/29 in the EFV/FTC/TDF group experienced virologic failure with resistance development.

Conclusions: Viral blips were infrequent and similar among subjects treated with RPV/FTC/TDF or EFV/FTC/TDF through Week 96 of the STAR study. Most blips were low-level (<200 copies/mL) and most subjects with blips remained suppressed through Week 96 without experiencing virologic failure or resistance development.

TUPEB287
Virological response and HIV drug resistance patterns in individuals on first-line therapy for at least 4 years without routine viral load measurements: implications for second line regimens

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Background: Public health approach to the provision of ART in resource-limited settings is characterized by standardized drug regimens, using simplified formularies and standardized treatment monitoring, which does not insist on viral load (VL) testing. However, many patients monitored without VL testing in resource-limited settings will continue on failing regimens for long periods of time before failure is detected and will likely accumulate large numbers of drug resistance mutations (DRMs). How these accumulated DRMs affect response to the second-line regimens with stavudine was a risk factor for having greater numbers of TAMs.

Methods: We enrolled patients from TASO clinic, Jinja, who had been on first-line ART regimens for >4 years. We collected plasma at study enrolment and assayed for HIV-1 VL. Those with a VL ≤1000 c/ml were sequenced in the pol region, a 1257bp fragment spanning protease and reverse transcriptase genes.

Results: A total of 1091 patients enrolled in the study, of whom 74.7 % were female with median age of 44years (Q1-Q3=39-50 years). The median CD4 cell count was 493 cells/µL (Q1-Q3=351-687) and the median time on ART at enrolment was 6.8 years (Q1-Q3= 5.3 - 7.6). Of the 1091 patients identified, 113 (10.4%) had HIV V L<1000 c/ml and we successfully genotyped 105 (93%) of these samples. Frequencies of mutations were highest within NRTIs 95.2% (n=100), NNRTIs 93.3% (n=98) and PI 1.0% (n=1). Mutation M184V 90.5% (n=95) followed by Y181C 40.0% (n=42) were most frequent. Mutation K65R was at 11.4%, 60 patients (6.6%) had at least one TAM and 53 (50.5%) had ≥2 TAMs. Having ≥2 TAMs was more common with lower education levels (p=0.0403), previous exposure to nevirapine and lamivudine (p=0.0018) and baseline viral loads ≥5000 c/ml (p=0.0064).

Conclusions: The prevalence of virologic failure in these patients was quite low despite more than six years of ART without VL monitoring. Among those with virologic failure, the presence of one or more TAMs as well as K65R and M184V has the potential to compromise NRTI backbones in second line regimens. Low education levels, high enrolment viral loads and previous TAMs with stavudine were a risk factor for having greater numbers of TAMs.
TUPEB289
Prevalence of protease inhibitor and triple-class resistance in patients failing 2nd-line ART: results from a national survey in South Africa

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Adherence to antiretroviral treatment (ART) plays a crucial role in determining virological response. However, few studies have investigated the relationship between the patterns of adherence and virological response over the long-term. The objective of this study was to assess the effects of early and late adherence to ART on stable virological response, even after adjusting for time-varying adherence.

Methods: The APROCO-COPILOTE cohort enrolled 1,281 individuals upon initiation of a protease-inhibitor (PI)-containing regimen between 1997-1999. Clinical and laboratory data were collected every 4 months. Standardized self-administered questionnaires collected data on psycho-social and behavioral characteristics, including adherence to ART, at enrolment (M0), at M4 and every 6 months thereafter over an 11-year period. At each follow-up visit a validated algorithm was used to build a three-level adherence score as follows: high, moderate and low adherence, reflecting patients who reported taking, respectively, 100%, 80-99.9%, or less than 80% of their prescribed ART doses in the previous 4 days. A stable virological response (SVR) was defined at each follow-up visit as having an undetectable viral load at all three most recent visits (current visit and previous visits 4 and 8 months beforehand). Patients who completed the adherence questionnaire at M4, and had at least one measure of both adherence and SVR during the ART maintenance period (M12-M132) were selected for the analysis. The association between early (M4) adherence and SVR was evaluated using a mixed logistic model, after adjusting for time-varying maintenance (after M12) adherence to ART.

Results: Among the 751 eligible patients, at baseline (M0) median (IQR) CD4 was 291 (141-435) cells/mm3, median (IQR) viral load was 26,000 (6,032-128,000) copies/ml, 149 (20%) patients had AIDS; at M4, 412 (55%) were highly adherent. High early adherence (OR 22.2, 95% CI 9.39-51.7) was associated with undetectable viral load at M4, and high late adherence (OR 3.83, 95% CI 1.49-9.68) with undetectable viral load at M12. The factor associated with attainment of undetectable viral load was high early adherence (OR 22.2, 95% CI 9.39-51.7) and high late adherence (OR 3.83, 95% CI 1.49-9.68). The association between adherence and undetectable viral load was significantly stronger among patients who had a PI-based regimen (OR 15.3, 95% CI 6.17-38.0) compared to those who had a non-PI regimen (OR 2.1, 95% CI 0.87-5.16).

Conclusions: Adherence to antiretroviral treatment (ART) plays a crucial role in determining virological response. However, few studies have investigated the relationship between the patterns of adherence and virological response over the long-term. The objective of this study was to assess the effects of early and late adherence to ART on stable virological response, even after adjusting for time-varying adherence. The association between early (M4) adherence and SVR was evaluated using a mixed logistic model, after adjusting for time-varying maintenance (after M12) adherence to ART.

Monday 20 July

TUPEB291
Persistent effect of early (M4) adherence to antiretroviral treatment on long-term virological response in HIV-infected patients: results from the 11-year follow-up of the ANRS C08 APROCO-COPILOTE cohort

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Adherence to antiretroviral treatment (ART) plays a crucial role in determining virological response. However, few studies have investigated the relationship between the patterns of adherence and virological response over the long-term. The objective of this study was to assess the effects of early and late adherence to ART on stable virological response over an 11-year follow-up period, among HIV-infected individuals in the French ANRS C08 APROCO-COPILOTE cohort.

Methods: The APROCO-COPILOTE cohort enrolled 1,281 individuals upon initiation of a protease-inhibitor (PI)-containing regimen between 1997-1999. Clinical and laboratory data were collected every 4 months. Standardized self-administered questionnaires collected data on psycho-social and behavioral characteristics, including adherence to ART, at enrolment (M0), at M4 and every 6 months thereafter over an 11-year period. At each follow-up visit a validated algorithm was used to build a three-level adherence score as follows: high, moderate and low adherence, reflecting patients who reported taking, respectively, 100%, 80-99.9%, or less than 80% of their prescribed ART doses in the previous 4 days. A stable virological response (SVR) was defined at each follow-up visit as having an undetectable viral load at all three most recent visits (current visit and previous visits 4 and 8 months beforehand). Patients who completed the adherence questionnaire at M4, and had at least one measure of both adherence and SVR during the ART maintenance period (M12-M132) were selected for the analysis. The association between early (M4) adherence and SVR was evaluated using a mixed logistic model, after adjusting for time-varying maintenance (after M12) adherence to ART.

Results: Among the 751 eligible patients, at baseline (M0) median (IQR) CD4 was 291 (141-435) cells/mm3, median (IQR) viral load was 26,000 (6,032-128,000) copies/ml, 149 (20%) patients had AIDS; at M4, 412 (55%) were highly adherent. High early adherence (OR 22.2, 95% CI 9.39-51.7) was associated with undetectable viral load at M4, and high late adherence (OR 3.83, 95% CI 1.49-9.68) with undetectable viral load at M12. The factor associated with attainment of undetectable viral load was high early adherence (OR 22.2, 95% CI 9.39-51.7) and high late adherence (OR 3.83, 95% CI 1.49-9.68). The association between adherence and undetectable viral load was significantly stronger among patients who had a PI-based regimen (OR 15.3, 95% CI 6.17-38.0) compared to those who had a non-PI regimen (OR 2.1, 95% CI 0.87-5.16).

Conclusions: Adherence to antiretroviral treatment (ART) plays a crucial role in determining virological response. However, few studies have investigated the relationship between the patterns of adherence and virological response over the long-term. The objective of this study was to assess the effects of early and late adherence to ART on stable virological response, even after adjusting for time-varying maintenance adherence.

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TUPEB292
HIV patient preferences for simplified treatment regimens and impact on self-rated treatment adherence
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Background: The development of effective single-tablet regimens for anti-retroviral therapy has led to the prospect of simplified treatment for HIV patients. We conducted a discrete choice experiment to estimate the relative strength of patient preference for simplified treatment regimens in relation to treatment adherence.

Methods: Data were from a prospective web survey of UK HIV patients (July to October 2014). A steering committee of clinicians, nurses, pharmacists, patient group representatives and academics guided the initial survey design. HIV patient organisations provided feedback on the pilot survey. Respondents were presented with 12 hypothetical choice scenarios of two hypothetical regimens that varied by number of tablets (1 to 4), mealtime dosing, increased risk of heart attack or insomnia (yes/no), and monthly to the healthcare system (£500/£600/£750/£1000). For each scenario, patients used a sliding scale (0 to preference) to 100 to rate the treatment option that they thought would maximise their adherence to treatment. The ratings were analysed in STATA v13.1 using a two-stage model to obtain an attribute weighting that indicated the likely impact on adherence.

Results: Out of 278 respondents, 72.6% were men who have sex with men ( MSM) and 14.7% were female. Median age was 44 (range 21-66) years. The time since diagnosis and duration of treatment was 8 (0-30) and 5 (0-27) years respectively, 96% were on a single-tablet regimen. 57% of patients were in treatment with ART since MSM 90.4%, median 50%. An increased risk of insomnia had the largest negative impact on likely adherence weightings (-9.6 [95% CI -10.5, -8.8], p<0.001), a single-tablet regimen had the largest positive effect (+7.0 [95% CI 5.5, 8.5], p<0.001). Avoiding mealtime dosing also had a significant positive impact on likely adherence weightings (+6.0 [95% CI 5.1, 6.8], p<0.001). An increased risk of heart attack had a significant negative impact on likely adherence weightings (-3.5 [95% CI -4.4, -2.6], p<0.001).

Conclusions: The adherence weightings estimated from these hypothetical scenarios indicate that single-tablet regimens and not being tied to mealtimes may improve treatment adherence. Treatments associated with insomnia and heart attack risk may have a negative impact on adherence.

TUPEB293
Physical and sexual violence independently correlated with reduced adherence to ART among women sex workers living with HIV in Vancouver, Canada
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Background: Limited research has explored how violence affects the HIV care continuum, particularly for women and key populations such as sex workers (SWs), who experience high burden of violence globally. Less is known about how these relationships function on a neighbourhood level. Therefore, this study investigated the independent effect of spatial physical and/or sexual violence on adherence to antiretroviral therapy (ART) among SWs living with HIV in Metro Vancouver, Canada.

Methods: Baseline and bi-annual questionnaire data were drawn from a community prospective cohort (An Evaluation of Sex Workers’ Health Access, ‘AESHA’, 2010-2013) of SWs and administrative data on ART dispensation (BC Centre for Excellence in HIV/AIDS Drug Treatment Program). Using geographic information systems and generalized estimating equations (GEE) logistic regression, we examined the independent relationship of spatial, client-perpetrated physical/sexual violence and having < 95% adherence (based on proportion of days of ART dispensation within 6-month follow-up periods), stratified according to residing within vs. outside the inner city epicentre of poverty, drug use and sex work scenes. For each participant, density of spatial violence was measured as the number of events of violence reported by the entire sample at each follow-up within a 250-meter buffer of participants’ residential locations.

Results: Among 86 SWs living with HIV who previously used ART, over a 3.5-year period (208 observations), there were 74 events of < 95% adherence, with 29% experiencing any physical/sexual violence. In bivariate GEE analysis, spatial density of violence was independently correlated with reduced ART adherence within (p=0.01) but not outside (p=0.23) the inner city epicentre. In the multivariable GEE model adjusted for key confounders, independently correlated with reduced ART adherence within (p=0.01) but not outside (p=0.23) the inner city epicentre. In the multivariable GEE model adjusted for key confounders, increased density of physical/sexual violence by clients was statistically significantly correlated with <95% adherence (AOR=1.01, 95%CI:1.00-1.02) within, but not outside, the inner city epicentre.

Conclusions: This research supports global calls to address violence against SWs as part of HIV programs, tailored for neighbourhoods, and structural policy reforms including de-criminalization of sex work to improve access to safer working conditions. Findings suggest that efforts to criminalize sex work, including new Canadian laws, could have major negative public health and human rights implications on engagement in the HIV care continuum.

TUPEB294
Thalidomide lead to an increase in T cell activation and inflammation on antiretroviral naïve HIV-infected individuals
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Background: Micro-inflammation is a characteristic of HIV infection that relates to organ/tissues deterioration and cell apoptosis over time. Efforts to mitigate inflammation are necessary as coadjuvant to antiretroviral therapy (ART). We hypothesize that thalidomide, a potent anti TNF agent, would lead to a decrease in HIV related micro-inflammation.

Methods: Open label controlled randomized pilot proof of concept clinical trial. 30 HIV+ ART naïve male adults with TCD4 ≥ 350 cell/mm³ were randomized to receive 100 mg of thalidomide BID for 3 weeks (Group-1, 16 patients) or Group (2-14 patients) and were to be followed by 48 week. Blood samples were collected at weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24 weeks for viral loads, CD4/CD8 T-cell counts, ultra-sensitivity C-reactive protein (US- CRP), CD3/ and/or HLA-DR on CD4+ and CD8+ T-cells, IL-1ß, IL-8, IL-10, IFN-γ, TNF, LPS were determined.

Results: Baseline characteristics were similar and viral loads remained stable in both groups. During thalidomide no class 3 or 4 adverse events have been detected. At the end of treatment, a decline of CD4/CD8 ratio (p=0.08) and CD4+ T-cell counts (p=0.04) were observed. Group 1 also presented increased activation status inferred by ‘CD38+HLA-DR’ on CD8+ (p< 0.005) or US-CRP (p< 0.01). All altered lab values detected in group 1 returned to baseline levels after thalidomide withdrawal. No differences on cytokines levels were detected. All these parameters remaining stable in group 2.

Conclusions: Although safe, short-term use of thalidomide among antiretroviral naïve individuals lead to an intense transitory increase in T cell activation and inflammation, with decrease of CD4+ T-cells without detectable change in viral replication, although it might be difficult to detect viral load changes among naturally viremic individuals. These results warrant further in vitro studies exploiting a potential purging activity of thalidomide.

TUPEB295
Effects of short-term probiotic ingestion in children with HIV-1 infection
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Background: The destruction of CD4+ T cells, particularly the Th17 subset, in the gut-associated lymphoid tissue, intestinal microbial translocation, and chronic systemic immune activation are the main pathogenic characteristics of HIV-1 infection. Several probiotics have been reported to have functions modulating intestinal microbiota, enhancing the barrier function of gut mucosa, and inhibiting the gut innate immunity. The aim of this study was to investigate the efficacy of a probiotic, Lactobacillus casei strain Shirota (LcS), on the status of immune activation and the intestinal microbial translocation in children with HIV-1 infection.

Methods: This was a prospective study that was conducted at the National Hospital of Pediatrics in Hanoi, Vietnam from May to August 2012. We included 80 children with HIV infection [HIV(+); 31 without antiretroviral therapy (ART) [ART(-); and 29 with ART for 3.5 years (median: range: 0-8.5) [ART(+)], and 20 without HIV infection [HIV(-)]; All participants were given oral LcS (6.5 × 10^8 cfu) daily for 8 weeks. Blood and stool samples were collected and analyzed for HIV RNA, cytokines, immunologically, and bacteriologically before and after LcS ingestion.

Results: No serious adverse events were observed during LcS ingestion in both HIV(+) and HIV(-) groups. After 8-weeks of LcS ingestion, the peripheral CD4+ T-cell and “Th2” sub-

Complementary and traditional medicines

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**Reduction in total HIV-1 proviral DNA following re-booster immunizations using the peptide-based therapeutic vaccine candidate, Vacc-4x, during ART**


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**Background:** This study (2012/1 - NCT01712256) investigated the impact of booster immunizations on sustaining vaccine effect in a therapeutic HIV vaccine setting. The effect of two Vacc-4x booster immunizations on total proviral DNA during ART, and on viral load (VL) set-point following a new ART interruption were determined.

**Methods:** At weeks (w) 0 and 2, eligible study participants from the clinical study (2007/1 - NCT00569789) were given intradermal (i.d.) Vacc-4x booster immunizations (1.2mg) on ART with GM-CSF (60μg) i.d. as a local adjuvant. At w12, ART was interrupted for up to 18 weeks (w18). Study participants were thereafter followed on ART until w36. Total proviral DNA was measured at w0,4,16,28 and 36 using real-time PCR (Taqman) targeting the gag gene. VL set-point was defined as the mean of the last two VL values prior to ART resumption. All study participants provided signed informed consent. The per protocol population (PP) included participants with no major deviations that would challenge the validity of the data.

**Results:** This open, multicenter, clinical study conducted from 12.2012 to 01.2014 enrolled 33 participants from 9 clinical trial sites within the US and Europe. In the PP, a statistically significant reduction in total proviral DNA (45%) between w0 and w4 was observed (Wilcoxon signed rank p-value 0.030, n=26) which could suggest immune-based killing of infected cells while on ART.

The duration of ART prior to the first boosting immunization was mean 36 months (n=22) (min 26; max 47 months). The VL set-point in this study (2012/1) had a geometric mean (GM) value of 26278 copies/ml and was significantly lower than the pre-ART VL set-point (GM VL 74048 copies/ml) (p<0.021, n=13). The VL set-point in this 2012/1 study (GM VL 18162 copies/ml) was reduced compared to the 2007/1 study VL set-point (GM VL 42035 copies/ml), however the difference was not statistical significant, paired t-test p-value 0.453 (n=18).

**Conclusions:** Vacc-4x booster immunizations safely restored virus control to the VL set-point established following primary Vacc-4x therapeutic vaccination. The reduction in total proviral DNA supports the potential for Vacc-4x therapeutic vaccination to impact on HIV reservoirs during ART and to contribute to HIV cure strategies.

**TUPE297**

**A feasibility study of weight-based pegylated IFN-α2b immunotherapy to target persistent HIV-1 on ART**


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**Background:** We started to evaluate feasibility, safety and the effects of peg-IFN-α2b on levels of integrated HIV-1 DNA in 20 HIV-1 infected subjects receiving suppressive ART. 1 μg/kg/week peg-IFN-α2b was added to current ART for 20 weeks, interrupting ART between weeks 5 and 9 of treatment.

**Methods:** A pilot study was started to evaluate feasibility, safety and the effects of peg-IFN-α2b on levels of integrated HIV-1 DNA in 20 HIV-1 infected subjects receiving suppressive ART. 1 μg/kg/week peg-IFN-α2b was added to current ART for 20 weeks, interrupting ART between weeks 5 and 9 of treatment.

Curative interventions (including those aimed at reservoir depletion)
Results: Study disposition (7-Jan-2015): 22 screened; 20 enrolled (2 not qualified); 20 exposed to treatment (17 completed ART interruption); 9 concluded treatment; 8 undergoing treatment and 3 prematurely discontinued (2 toxicities during ART interruption, 1 voluntary withdrawal). Enrollment is closed. At baseline, participants had median 756 CD4+ T cells/µl (IQR 842-930), all had VL < 50 copies/ml. Baseline rectal biopsies showed detectable HIV-1 RNA positive cells by in situ hybridization in all individuals tested.

Safety data on 20 participants were evaluated (cumulative 202 visits, ~ 404 person-week on treatment, 54 person-week follow-up). 15/17 participants had complete labs for the 4-week ART interruption. Of these, 8/15 sustained VL < 400 copies/ml (with 6 VL < 50 copies/ml); 7/15 had rebounds between 421 and 10104 copies/ml. 12/15 sustained CD4+ T cell count > 350 cells/µl during the ART interruption. Of the participants with post-intubation follow-up, 10/13 achieved VL < 40 copies/ml 4 weeks after resuming ART. 3 participants experienced neutropenia: 4 grade-2 ANC at treatments weeks 2, 5, 9 and 16 (managed with Filgrastim and/or dose reduction) and 2 grade 4 ANC at weeks 5 and 12 (withdrawn from study). No grade ≥ 3 depression or reportable SUSAR were observed.

Conclusions: A 20-week course of weight-based peg-FN-α2b, inclusive of a 4-week ART interruption, in subjects with chronic HIV infection receiving suppressive ART is feasible and tolerable, but intense safety monitoring of ANC and CD4 counts should be implemented for enhanced safety.

TUPEB298
Optimized antiretroviral therapy during allogeneic hematopoietic stem cell transplantation in HIV-infected individuals
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Background: Absence of latency infected memory CD4+ T cells is a major barrier to HIV cure. With allogeneic hematopoietic stem cell transplantation (allogHSCT), host hematopoietic cells are replaced with donor hematopoietic cells after cytotoxic therapy and graft versus host (GVH) effects. If antiretroviral therapy (ART) is continued during allogHSCT, it should protect donor hematopoietic cells from infection and result in a reduction or elimination of HIV. However, ART is often interrupted during allogHSCT due to drug interactions, mucositis and vomiting, or organ dysfunction.

Methods: We performed a pilot study on the safety and feasibility of continuing optimized ART during allogHSCT in HIV-infected individuals being treated for hematologic malignancy. Optimized ART included: 1) avoidance of ritonavir-based ART to minimize drug interactions, 2) ART changes for organ dysfunction and 3) subcutaneous enfuvirtide (ENF) during post-transplant cyclophosphamide and if oral ART was not tolerated.

Primary endpoints were incidence of adverse events (AE) from ENF and maintenance of ART through day 60. Secondary outcomes included HIV persistence measures.

Results: Six HIV+ individuals enrolled, five received allogHSCT and one died from malignancy prior to allogHSCT. The remaining 5 patients tolerated ENF without AEs. Patients 1-4 reached day 60 without interruption of ART but required ART changes. Patient 1 achieved 100% donor chimerism by week 8, with undetectable plasma HIV and negative viral outgrowth assay (VOA). The patient died at week 49 with liver failure. Patient 2 has mixed chimerism (87% donor) at week 52 with undetectable plasma HIV, but positive VOA. Patient 3 achieved 100% donor chimerism by week 4 with undetectable plasma HIV but became non-adherent with ART, and at month 5 had viral rebound and meningencephalitis. Patient 4 has mixed chimerism at week 24 (73% donor) with undetectable plasma HIV but positive VOA.

Conclusions: During allogHSCT, with optimized ART, it is feasible to maintain ART but regimen changes are common due to drug interactions and organ dysfunction. ENF is a well-tolerated alternative to oral ART. Interruption of ART during allogHSCT can cause a severe acute retroviral syndrome. At early time-points, with mixed chimerism, HIV persists but further studies are needed over time.

Clinical approaches to drug and alcohol dependence treatment: harm reduction

TUPEB299
Impact of opioid substitution therapy on antiretroviral therapy: a systematic review and meta-analysis
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Background: Injecting drug is an important driver of HIV transmission in Eastern Europe, Central and South Asia, and some mixed-epidemics in Africa. Although current injecting can reduce the effectiveness of antiretroviral treatment (ART), emerging evidence suggests that opiate substitution therapy (OST) could alleviate this effect. We conducted the first systematic review to evaluate the impact of OST on ART related outcomes among people who inject drugs (PWID).

Methods: We searched Medline, PsyInfo, Embase, Cochrane and Web of Science data bases and conference abstracts for primary cross-sectional, longitudinal and surveillance studies published between 1996 and November 2014 that measured the impact of OST (compared to no OST) among PWID. Outcomes of interest included: coverage of ART (the proportion of PWID with current ART use), adherence to ART above a predefined threshold (usually >95%), viral suppression after ART initiation, discontinuation of ART and mortality. Meta-analysis was conducted using random effects modelling, and heterogeneity assessed using Cochran’s Q statistic.

Results: We identified 4691 titles and abstracts, from which 33 studies, conducted among 16 populations of PWID in North America (n=9), Europe (n=9), Indonesia (n=1) and China (n=1) were included. The most frequently reported outcomes were viral suppression and ART coverage. OST was associated with a two-fold increase in both ART coverage (OR 2.03; 95% CI: 1.68-2.37, I²=77%, 9 studies) and adherence (OR 2.01, 95% CI: 1.41-2.60, I²=97%, 9 studies) and a 17% decrease in the odds of ART discontinuation (OR 0.83, 95% CI:0.71-0.95, I²=26%, 7 studies). OST was also associated with an 78% increase in odds of viral suppression (OR=1.78, 95%CI:1.40-2.16, I²=91%, 13 studies), but had no impact on mortality (HR=1.01, 95% CI:0.60-1.62, I²=70%, 5 studies). There was considerable heterogeneity for all studies except for ART discontinuation.

Conclusions: This systematic review suggests OST could have a multi-faceted role in improving ART outcomes among PWID, adding to the considerable evidence for the beneficial effects of OST for the treatment of HIV among PWID. We note the concomitant need to synthesize qualitative and programme evidence to delineate models of ART-OST integration and delivery to maximise such potential.
**TUPEB300**

Adolescent representation among clients accessing HIV testing at a large tertiary facility in north-central Nigeria

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**Background:** Globally, HIV-related mortality has dropped by 30%, in adolescents living with HIV (ALHIV), it has increased by 50%. The WHO has cited lack of access to HIV Testing & Counseling (HTC) and subsequent care-as a factor. Adolescents comprise ~22% of the general Nigerian population, and nearly 6% of Nigerian PLHIV are adolescents. In national HIV seroprevalence surveys, adolescents comprised 16.6% of all tested, and 9.7% of pregnant women tested. This study was conducted to determine adolescent representation among clients accessing HTC at a large referral facility in North-Central Nigeria.

**Methods:** This retrospective study was conducted at Federal Medical Center Keffi, Nasarawa State, where ~7,000 HIV+ clients are enrolled. HTC data from Jan. to Dec. 2013 were reviewed for Adult, Pediatric and PMTCT Units. Data for adolescents aged 10 to 19 years were extracted and analyzed. Chi-square was used to compare proportions.

**Results:** A total of 6,336 clients including 325 adolescents accessed HTC in the review period; 81% of tested adolescents were female, of whom 49% were pregnant. Median age for all adolescents tested was 18yrs (IQR 16-18.5); for pregnant adolescents, 18yrs (IQR 17-19, range 15-19). HIV prevalence was higher in non-pregnant (14.1%) vs pregnant adolescents (2.5%), p<0.0002. Further results are presented in Table 1.

**Conclusions:** Adolescents’ HTC access did not reflect their large representation in the Nigerian population. In this study, adolescents were underrepresented among all tested and all pregnant women tested, compared to national survey figures. Our results portray a gap in HTC accessibility for adolescents in the real-world, non-survey setting. There is an urgent need to control transmission in this population, specifically in the non-pregnant. We propose that adolescent HTC be made more accessible beyond antenatal testing, and supported to be available in greater independent access. These strategies will facilitate timely testing, improved impact of HIV prevention, early treatment of ALHIV, and reduced mortality in this population.
TUPEB302
Low birth HIV infection rate in infants from high-risk-for-transmission pregnancies in South Africa

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Background: Successful interventions to prevent mother-to-child transmission of HIV have reduced the infection rate in 6 week old infants in the Western Cape province, South Africa to 0.99% (2014 data).

It is well established that early diagnosis and treatment of HIV-infected infants improve health outcomes. Universal PCR testing at birth is desirable but unaffordable for resource-limited settings. As pregnancies at high risk for transmission may contribute disproportionately, targeted testing early after birth may expedite identifying infected infants.

Here we report preliminary findings of an ongoing study of targeted early HIV diagnosis for infants at high risk of intra-uterine transmission in Cape Town, South Africa.

Methods: High-risk-for-transmission pregnancies are identified by reviewing labour ward records at a primary care midpoint obstetric unit and at an academic referral hospital. Screening is performed by research nurses using predefined criteria, namely insufficient or interrupted exposure to antiretroviral therapy or prophylaxis, a maternal viral load of greater than 10,000 copies/ml (where available) or premature or low birth weight infants. Samples for molecular HIV testing are taken as early as possible after birth, with subsequent early therapy initiation in infected infants.

Results: Of 286 birth PCRs from high risk pregnancies, 5 were positive (1.75%). Within this at-risk population, none of the predefined potential risk factors increased the relative risk of transmission.

Follow-up PCR tests on 233 (81%) infants found an additional 4 positive patients at weeks 7, 9, 19 and 27 of age respectively (total positivity rate 3.9%). No differences in risk factors were identified between positivity at birth and at follow-up. In only 131 (56%) of cases was follow-up testing done between 5 and 8 weeks of age.

Conclusions: A relatively low rate of HIV transmission was identified from presumed high-risk-for-transmission pregnancies. Despite guidelines recommending PCR testing at 6 weeks, repeat testing was delayed in about half of patients. Late diagnosis motivates strongly for improved diagnostic algorithms with more frequent testing. Further research is required to identify factors which would influence when the mothers return for repeat testing as this might inform programmatic recommendations.

ARV management strategies: children and adolescents cohort studies

TUPEB303
High sensitivity CRP (hsCRP) levels in long-term survivors of perinatal HIV infection

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Background: Perinatally HIV infected children are now young adults because of long term HAART. Long term HAART is known to be associated with side effects including insulin resistance and lipodystrophy. While hsCRP is used as a general predictor of future coronary events little information is available on hsCRP in long-term survivors of perinatal HIV as they progress towards adulthood.

Methods: Data was collected by retrospective chart review over a 10 year period (2004-2014) for HIV positive, Viral Load, CD4% and HAART in a closely followed cohort of perinatally HIV infected youth in our clinic. Student-t test was used as a test of significance.

Results: 48 patients (25 M and 23 F, Ages 8-26 years - median age 18) had 151 hsCRP values available. 96% of patients were Black/Hispanic and 4% Caucasian. 8 patients had one hsCRP value, while others had at least two or more levels tested over 10 years. According to median age 16, hsCRP levels were significantly higher in those >= 18 years old (m=24.2, n=0.1-19.8) than those <18 (m=14.8, n=0-2.126); p-value=0.06. hsCRP levels were significantly lower with CD4% <25 (m=0.32, n=0.1-8.5) as compared to hsCRP levels with CD4% >25 (m=2.36, n=0.1-19.88); p-value=0.049. hsCRP levels were significantly higher in patients on double Protease Inhibitor (PI) therapy (m=2.51, n=0.15-14.55) compared to those on 1 PI or none (m=1.61, n=0.1-8.5); p-value=0.079. hsCRP levels in the overweight and obese female group were (m=3.38, n=0.6-11) as compared to females with normal BMI (m=1.89, n=0.15-12.6); p-value=0.1. We also looked at hsCRP levels in relation to viral load <1000 and >1000, undetectable versus detectable viral load, BMI in males, and CD4% <10, which showed no significance.

Conclusions: While hsCRP levels show a rising trend with age, our findings suggest that hsCRP levels may be a useful screening test for cardiovascular risk in long term survivors of perinatal HIV infection. Overweight and obese females, patients on double PI therapy, and patients with CD4 counts >25% have higher hsCRP levels; these patients may need further studies to assess cardiovascular risk as the patients age into adulthood.

TUPEB304
Durability of first-line antiretroviral therapy (ART) in children in the European Pregnancy and Paediatric HIV Cohort Collaboration (EPPICC)

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Background: Global data on durability of first-line ART in children is scarce. We assessed time to switch to second-line therapy for any reason in EPPICC (Thailand and 13 European countries including Russia and Ukraine).

Methods: ART-naive children <18 years at initiation of combination ART (NNRTI or boosted PI or plus 2 NRTI) were included. Switch to second-line was defined as (i) change across drug class (PI to NNRTI or vice versa) and change of 1 NRTI; (ii) change within PI-class plus ≥1 NRTI; (iii) change from single to dual PI; or (iv) addition of a new drug class.

Documented switches for simplification, TB or pregnancy were ignored. A cause specific hazard model assessed time to switch and potential predictors, with death as a competing risk. Children were at risk from ART initiation until the earliest of: switch, death, last visit in paediatric care or 21st birthday.

Results: Of 3030 children, 47% were male and 84% perinatally infected. At ART initiation, median [IQR] age was 3.3 years [1.0-6.0], CD4% 20% [13-28] in < 5-years, CD4 count 200 cells/mm3 [55-362] in 25-years and 19% were CDC C. Initial regimens were 30% PI-based, 34% NVP-based, 31% EFV-based, and 4% NNRTI+3NRTI. Median duration of follow-up on ART was 5.1 years [2.4-8.0]. Overall, 86% (363) died, 111% (4 lost to follow-up and 684 (22%) met the definition of switch: median time to switch was 28 months [19-57]. 5-year cumulative proportion switching was 22% [95%CI 20-34]. Reasons for switch (available in 236 [34%]) were: 69% treatment failure, 14% toxicity, 17% other. 70% of patients with missing reasons for switch had viral load (VL)≥10000/ml or CDC B/C event within 6-months of switch, varying by regimen (lowest for PIs [40%]). In multivariable analysis, older age and higher VL at ART start, UK/Treland & Rest of European region, and initiation on NVP-based or NNRTI+3NRTI regimens were associated with more rapid time to switch (Table 1).

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Table 1
TUPEB306

12-month response to early LPV-based antiretroviral therapy in West-African children treated before the age of 2 years, the MONOD ANRS 12206 cohort

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Background: Outcomes of early antiretroviral treatment (EART) initiation remains unknown. We described the 12-month virologic response to LPV-based ART in West-Africa.

Methods: All HIV-infected children <2 years of age confirmed by DNA-PCR were enrolled in a 12-month cohort based on LPV in Ouagadougou, Burkina Faso, and Abidjan, Côte d’Ivoire. Viral load was measured at 0 and 12 months. CD4 count and virologic success (VS) at 12-month (<500 copies/ml) and correlates of VS using a logistic regression were assessed. HIV-1 genotyping was performed when VL>1000 copies/ml.

Results: In the context of low early infant diagnosis coverage (16% in Abidjan; 29% in Ouagadougou), 228 HIV-infected children <2 years of age were screened between 05/2013 and 06/2014. 210 (66%) children were initiated on EART. The median ages at diagnosis and at ART initiation were 8.6 months and 13.5 months, respectively. 63% were from Abidjan, 53% were girls, 48% were not exposed to a PMTCT-intervention. The median CD4% at 0-month was 24% and 17% among children from Abidjan and Ouagadougou, respectively. At 12-month on ART, 17% of children died (7% were lost-to-follow-up (3%)). 170 (75%) were initiated on LPV and 45 (21%) were initiated on EFV. The median CD4% at 12-month was 24% and 17% among children from Abidjan and Ouagadougou, respectively.

Conclusions: We observed an excellent virologic response with a 12-month VL <500 copies/ml in 140 (90%) children. The low frequency of VL <500 copies/ml could be explained by the high rate of treatment adherence (97% at 12-month). The major risk factors for treatment failure were low CD4% at baseline (OR 2.35 [1.67, 3.32]; p <0.001).

TUPEB307

Determinants of durability of first-line ART regimen and time from first-line failure to second-line ART initiation. The IEDeA paediatric West African Database (pWADA)

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Background: In resource-limited settings, antiretroviral therapy (ART) options are limited in HIV-infected children. It is important to understand reasons for switching to second-line treatment and document time to switch in those failing first-line ART.

Methods: We included children aged ≥15 years enrolled in seven clinical sites participating in the IEDeA paediatric West-African collaboration. We estimated the incidence of switch (21 drug class change) within 24 months of first-line ART and associated factors were identified in a multinomial logistic regression. Clinical failure was defined as the (re)appearance of WHO stage 3 or 4 events after ≥24 weeks on ART in a treatment-adherent child. Immunological failure was defined as delaying or refusing to age-related immunological thresholds after ≥24 weeks on ART. Among children in treatment failure, the 24-month probability of switching to second-line ART and the associated factors were estimated using a competing risk approach.
the competing event was death. We excluded children who switched to second-line ART follow-
ing the withdrawal of nevirapin in 2007.

Results: Overall, 2820 children were included at a median age of 5 years at ART initiation. Most initiated a non-nucleoside reverse transcriptase inhibitor-based regimen (70.9%), however 144 (5%) were on nevirapin. At 24-month post-ART, among the remaining 2876 children not on nevirapin, 165 (5.9%) had died, 702 (24.9%) were lost to follow-up and 188 (7%) had switched to second-line ART. The most frequent reasons for switch were drug stock-outs (20%), toxicity (18%), treatment failure (10%) and poor adherence (6%). By 24 months post-ART, 322 (12%) were in failure after a median delay of 7 months. 205 (94%) experienced clinical failure alone, 96 (30%) immunological failure alone and 21 (6%) had both. Of these children, 21 (6.5%) switched to second-line ART after a median time of 21 weeks in failure. This was associated with older age (sHR: 1.21, 95% Confidence Interval (CI): 1.10-1.33) and longer time on ART (sHR: 1.16, 95% CI: 1.07-1.25).

Conclusions: Switches after clinical immunological failure were insufficiently covered. These gaps reveal that it is crucial to advocate for both sustainable access to first-line potent ART and alternative regimens to provide adequate roll-out of paediatric ART programmes.

Clinical issues in men who have sex with men

TUPEB308

Hospitalisation and predictors of morbidity in community-based cohorts of HIV-positive and -negative gay and bisexual men

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Background: There is evidence that among HIV positive people a significant burden of morbidity is due to non-AIDS-related complications. To date it has been difficult to determine what part of this excess risk is due to the health effects of HIV, its treatment, or to lifestyle factors common to the gay and bisexual (GBM) population. We aimed to calculate overall and cause-specific hospitalization rates and risk factors for hospitalizations in HIV negative (HIV-ve) and HIV positive (HIV+ve) GBM and compare these with rates in the general population.

Methods: We conducted a record linkage study of two cohorts of HIV-ve (n=3325) and HIV+ve (n=557) GBM recruited in Sydney, New South Wales (NSW). Participants were probabilistically linked with their respective administrative hospital data from 01 July 2000 to 30 June 2012. Age and year adjusted relative risk (RR) for hospitalization was calculated using an Andersen-Gill model for repeated events. Age and year specific hospitalization rates for each cohort were compared with those in the NSW male population and summarized as standard-ized hospitalization ratios (SHRs). Incidence rate ratios with 95% confidence intervals were estimated using Poisson regression models to assess risk factors for hospitalization.

Results: The median age/follow-up was 35.3/10.1 yrs and 40.9/11.9 yrs in the HIV-ve and HIV+ve cohorts, respectively. 2,207 hospitalizations were observed in the HIV-ve cohort during 13,025 person year (PYs) (crude rate: 16.9/100 PYs (95%CI:13.7-19.7)); and 2,278 hospitalizations in the HIV+ve cohort during 5,580 PYs (crude rate: 40.8/100 PYs (95%CI: 39.2-42.5)). HIV+ve individuals had an increased risk of hospitalization compared with the HIV-ve individuals [RR: 1.98 (95%CI:1.64-2.40)]. Adjusted hospital admission rates were lower in the HIV+ve cohort [SHR: 0.72 (95% CI:0.67-0.78)]; and higher in the HIV+ve cohort [SHR: 1.45 (95%CI:1.33-1.56)] compared with the general population. The primary causes of hospitalization dif-
fered between groups. Poorer socioeconomic indicators and drug use were associated with hospitalization in both cohorts.

Conclusions: HIV+ve GBM continue to experience excess morbidity compared with HIV-ve GBM men and the general population. GBM identity did not confer any excess risk. The primary risk factors for hospitalisation in the HIV+ve cohort related to HIV infection.

Clinical issues in people who use drugs

TUPEB309

Factors associated with ART adherence and plasma HIV-1 RNA suppression among crack cocaine users in Vancouver, Canada

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Background: Crack cocaine use has been shown to increase the risk of HIV infection and contribute to poor adherence to antiretroviral therapy (ART). However, little is known about facilitators of or barriers to ART adherence and viral suppression among individuals using crack cocaine. Therefore, we sought to identify correlates of ART adherence and viral suppression among crack cocaine users receiving highly active antiretroviral therapy (HAART) in Vancouver, Canada.

Methods: Data were derived from a prospective cohort of HIV-positive people who use illicit drugs in Vancouver between December 2005 and November 2013. We used multivariable mixed-effects modelling to longitudinally identify factors associated with ≥95% adherence to ART (estimated based on prescription refill compliance) and plasma HIV-1 RNA suppression (< 50 copies/mL) among HAART-exposed crack cocaine users. In a sub-analysis, we evaluated the impact of opioid substitution therapies on ART adherence and viral suppression among dual crack cocaine and opioid users.

Results: Among 438 HAART-exposed crack cocaine users, 240 (56%) had ≥95% adherence to ART at the previous 6 months at baseline. In multivariable analyses, older age (adjusted odds ratio [AOR]: 1.65; 95% confidence interval [CI]: 1.33-2.04) was independently and posi-
tively associated with ART adherence, while homelessness (AOR: 0.58; 95% CI: 0.44-0.77), at least daily crack cocaine smoking (AOR: 0.64; 95% CI: 0.50-0.81), and at least daily heroin use (AOR: 0.43; 95% CI: 0.29-0.65) were independently and negatively associated with ART adherence. None of the addiction treatment modalities assessed (e.g., inpatient treatment, outpatient detoxification, and drug counseling or peer-support meetings) were significantly associated with ART adherence. The results were consistent with viral suppression, except that among 293 dual crack cocaine and opioid users, participation in opioid substitution therapies was positively associated with viral suppression (AOR: 1.87; 95% CI: 1.25-2.79).

Conclusions: Among our sample of HAART-exposed crack cocaine users, homelessness, and high-intensity crack cocaine and heroin use were independently associated with sub-optimal ART adherence and viral non-suppression. Except for opioid substitution therapies, the addiction treatment modalities do not appear to facilitate ART adherence or viral suppression. These findings suggest an urgent need to identify evidence-based addiction treatment options for crack cocaine use that also confer benefits to ART-related outcomes.

TUPEB310

Advanced liver fibrosis and mortality of HIV/HCV co-infected patients with alcohol use disorders

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Background: Liver fibrosis is the main predictor of progression to end stage liver disease. HIV/HCV co-infection and alcohol use disorders (AUD) negatively impact liver fibrosis and sur-

vival. We aimed to analyze the role of HIV/HCV co-infection and alcohol use in mortality of patients with AUD.

Methods: Observational study in patients referred to treatment of AUD between 1999 and 2011 in Barcelona, Spain. Characteristics of patients and blood samples for HIV infection (EIA and HIV-1 RNA) and HCV infection (EIA and HCV RNA) were obtained at admission. CD4 cell count and use of HAART at admission were obtained from clinical charts. Advanced liver fibrosis (ALF) was defined by FIB-4 > 3.25 [FIB4 = (Age*AST)/(Platelet*ALT1/2)]. Patients were followed up until December 2013 and causes of death were ascertained through ICD-10 codes and the death registry.

Results: 1,021 patients were consecutively admitted (80% M); age at admission was 44 years (IQR: 38-51 years), duration of AUD was 18 years (IQR: 11-24 years), daily alcohol con-
sumption was 190 grams (IQR: 120-250 grams). Almost 17% had history of injection drug use. Overall, 22% of patients had ALF according to FIB-4.

Prevalence of HIV and HCV infection was 7% and 20%, respectively and, 7% were HIV/HCV co-infected. Median CD4 cells among the HIV+ patients was 313 cells/mL (IQR: 140-550) and prevalence of HAART use at admission was 51%.
TUPEB312
Prescription opioid injection is strongly linked with illicit drug-related vulnerability and plasma HIV-1 RNA viral load detectability among HIV-positive illicit drug users in a Canadian setting
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Background: Prescription opioid analgesic (POA) use is rising across North America and is associated with unpreceded morbidity and mortality from accidental opioid overdose. Further, the diversion of FOAs has led to high rates of illicit POA use among people who inject drugs (IDUs). However, we are unaware of any research characterizing POA injection among HIV-positive IDUs, including the impact of POA injection on plasma HIV-1 RNA viral load suppression. Thus, using longitudinal data, we sought to identify the prevalence and correlates of POA injection among ART-exposed IDUs in a setting of universal no-cost HIV/AIDS treatment and care.

Methods: We used data from the ACCESS study, an ongoing prospective cohort of community-recruited HIV-positive illicit drug users linked to comprehensive HIV clinical data. Generalized linear mixed-effects regression was used to model the relationships between injection-related harms for POA injection.

Results: Between December 2005 and November 2013, the study enrolled 715 participants with median age 43.6 years. The prevalence of recent POA injection peaked at 22.6% in November 2006. At the most recent follow-up, 13.8% of participants reported injecting POAs in the previous six months. In a multivariable analysis, younger age (adjusted odds ratio [OR]: 1.06) and later year of observation (AOR: 1.01) as well as drug-related behavioral characteristics, including drug dealing (AOR: 4.46), daily crack smoking (AOR: 1.69), and daily cocaine injection (AOR: 1.95) were significantly and positively associated with POA injection. Participants who recently injected POAs were also significantly less likely to exhibit non-detectable plasma HIV-1 RNA viral load (AOR: 0.70). After p < 0.05.

Conclusions: Among this group of HIV-positive IDU on ART, periods of illicit POA injection were significantly associated with a constellation of high-risk illicit drug using exposures as well as a lower likelihood of optimal virologic outcomes. These findings contribute to a list of significant social and structural barriers IDUs face in achieving optimal HIV outcomes, despite the setting of universal HIV treatment. Efforts to both minimize drug-related risk behaviors and support ART adherence should be inclusive of people who inject POAs.

PEP
TUPEC499
Delayed HIV seroconversions in patients receiving post-exposure prophylaxis (PEP)
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Background: Some patients who attend clinics to prevent HIV acquisition after a sexual exposure have a delayed seroconversion despite counseling. Our objective is to assess the rate and factors associated with a delayed HIV seroconversion, select those patients with higher risk and propose them additional preventive strategies as closer and longer follow-up or preexposure prophylaxis.

Methods: Demographics, sexual behaviour, PEP use, HIV testing and sexually transmitted infections (STI) history were compared between patients with a delayed seroconversion and non-seroconverters, matched by gender, age and date attending the clinic from a cohort of 3089 HIV uninfected patients followed-up due to a sexual exposure to HIV from 2003 to 2013.

Results: 69 out of 3089 patients (2.2%) seroconverted after a median (IQR) of 18 (9-34) months since the last visit for sexual exposure. CD4 T-cell count at HIV diagnosis was significantly higher in those patients in whom HIV was detected earlier (566 vs 441 cells/mm3 for patients with HIV diagnose before and after 18 months after last visit in clinic, p < 0.01). HIV seroconverters were predominantly male (90%), with 36 years old, MSM (96%) and Caucasian (67%). No differences were observed between seroconverters and non-seroconverters regarding birth place (Spain 67% vs 71%, p = 0.1), risk of exposure (high 18% vs 20%, p = 0.8), current PEP prescription (77% vs 70%, p = 0.4), hours from exposition to PEP prescription (18 vs 19 hours, p = 0.9), good adherence to PEP (81% vs 86%, p = 0.4) and presence of coinfections at baseline (hepatitis A, B and C or syphilis). Conversely, the proportion of MSM (96% vs 73%, p = 0.001), sexual partner with known HIV infection (52% vs 33%, p = 0.1), previous PEP (19% vs 31% p = 0.001) was strongly associated with delayed seroconversion.

Conclusions: Leaving the hospital AMA may lead to sub-optimal patient outcomes. IDU was strongly co-related with discharge AMA, strengthening of addictions medicine inpatient clinical services and support programs may help to reduce AMA discharges.
Background: Challenges associated with the care for survivors of sexual assault at risk for HIV remains largely unstudied. Evidence from the Thohoyandou Victim Empowerment Programme’s sexual and gender based violence cohort (n=19,975) in Limpopo, South Africa offers compelling arguments for the integration of longer-term, more rigorous and holistic post-exposure prophylaxis (PEP) monitoring as standard practice.

Methods: Data captured (2002 - 2014) was disaggregated according to type of assault, resulting in a cohort of 6,828 survivors of sexual abuse. This includes 5,934 (86.9%) survivors of rape and 894 (13.1%) of non-penetrative sexual abuse (Table 1). Client demographics (including sex), case information, PEP-related variables, perpetrator details, and support received were reported. Analyses included descriptive characteristics, univariate and multivariate logistic regressions using SPSS 19.

Results: Nearly half of all cases were adolescents (49.5%) and the majority were females (90.4%). Factors linked to rape compared with non-penetrative sexual abuse were: adolescence or adult age (p<0.001); female sex (p<0.001); history of assault (p=0.007); and pregnancy (p=0.001), 66% of the cohort (76% of rape survivors) was PEP eligible based on serostatus, time-to-report, and assault type. Among those who initiated, PEP completion data was recorded for 41.7%. Completion rates were 91.6%. Child and female survivors were less likely to initiate PEP (95% CI: 0.28-0.81), high school education or less (AOR=0.60, 95% CI: 0.38-0.94), higher Sexual Orientation (AOR=3.29, 95%CI:1.79,6.06) and reporting use of other preventive strategies such as abstaining from anal intercourse (AOR=2.06, 95% CI:3.63-11) or sero-sorting for condomless anal intercourse (AOR=1.92, 95% CI:1.27-2.89). HIV-positive participants who ask their partner’s serostatus were more likely to be aware of PEP than those who do not ask (AOR=3.86, 95% CI:1.61-9.25), PEP awareness was negatively associated with self-identified Aboriginal ethnicity versus White (AOR=0.15, 95% CI:0.07-0.34), non-gay sexual orientation (AOR=0.47, 95% CI:0.28-0.81), high school education or less (AOR=0.60, 95% CI:0.38-0.94), higher Sexual Orientation-Personual sub-scale scores (AOR=0.56, 95% CI:0.39-0.79), and lesser agreement with the statement “I always have condoms when having sex” (agree versus strongly agree: AOR=0.47, 95% CI:0.29-0.76).

Conclusions: PEP awareness is high, has been rarely used (2.6%), and is positively associated with certain behaviours with greater potential for HIV transmission. Further research is needed to investigate how best to incorporate this strategy within combination HIV prevention.

PrEP

TUPEC502 Willingness to receive PrEP among HIV-uninfected Chinese MSM who are users of a popular geosocial networking application

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Background: Pre-exposure prophylaxis (PrEP) against HIV has recently been recommended as a prevention option for MSM who practice unprotected sex. Previous studies have revealed that MSM users of geosocial networking applications (Apps) are more inclined to engage in risky sexual behaviours. This study aimed, therefore, to investigate their willingness to receive PrEP in a Chinese population where PrEP has not been introduced.

Methods: Between November and December 2014, five waves of invitations to a web-based survey were sent to all MSM located in Hong Kong using the geosocial networking App Grindr. Study domains included demographics, sexual behaviours, self-perceived HIV risk and views on PrEP. Basic information about PrEP (such as its usage and effectiveness) was provided. Telephone numbers of community-based organizations were shown to participants at the end of the survey for those wanting to know more about PrEP. The study was non-remunerated.

Conclusions: Willingness to receive PrEP is high, has been rarely used (2.6%), and is positively associated with certain behaviours with greater potential for HIV transmission. Further research is needed to investigate how best to incorporate this strategy within combination HIV prevention.

PrEP
Results: Among the 401 HIV-negative Chinese MSM (82.0% Hong Kong permanent residents) recruited, 47.1% had engaged in unprotected anal sex and 1.7% had sex with an HIV-infected partner in the previous year. Only three (0.7%) had received post-exposure prophylaxis. Majority (79.6%) had never come across any information about PrEP, and none had ever received PrEP. On a scale of 1 (lowest) to 10 (highest), 68.6% gave a score 7 or above for their willingness to use PrEP. Half (55.4%) considered that PrEP should be made accessible to all MSM to prevent HIV in the community. Their major concerns of PrEP included its side effects (74.3%), affordability (63.1%) and effectiveness in reducing HIV transmission (68.1%). Some 30.2% agreed that PrEP would decrease their motivation of using condom during sex. Linear regression showed that willingness to receive PrEP was positively associated with participants’ self-perceived HIV risk.

Conclusions: Although many MSM who practice risky sexual behaviours are interested in using PrEP, only a few had come across information about the intervention. To maximize public health benefit, more information on PrEP should be provided to address MSM’s concerns before making it accessible to the community.

TUPEC503
PrEP in real-life settings: good adherence and no increase in high-risk behavior

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Background: Little is known about pre-exposure prophylaxis (PrEP) use and adherence in real-life settings and its impact on high-risk behaviors is unclear. We aimed to evaluate adherence to follow-up and treatment, and behavioral changes in a high-risk clinical population.

Methods: We prospectively assessed patients receiving PrEP (TDF-FTC) at our clinic from 2011-2014. After their initial visit, patients were seen at 3-month follow-up intervals (FU). Treatment adherence and behavioral data were measured by self-report at every FU visit. Adherence and behavioral changes were analyzed by chi-square and time to treatment discontinuation was estimated by Kaplan-Meier analysis.

Results: 112 patients were prescribed PrEP. The main indication for PrEP was regular unprotected anal intercourse (64%). Patients requesting PrEP were male (99%) and MSM (98%) with a mean age of 33 (Range=20-61y). The majority of patients had a history of STDs (40%) and 67% reported having more than 10 sexual partners. On average, condom use was 59% for receptive anal intercourse and 63% for insertion. Among the 87 patients with available FU data, median FU was 12 weeks. In the first 3 months after starting PrEP, 92% of patients attended a FU visit. Furthermore, 86% of patients reported taking PrEP daily, whereas 2% had adherence problems and 4% took PrEP intermittently. Overall, 18 patients (21%) stopped PrEP; 44% of which occurred in the first 3 months of FU. Five patients (5/18, 28%) discontinued due to adverse events: four patients had elevated creatinine and 1 patient suffered from nausea and vomiting. Increases in high-risk behavior following PrEP use were not observed. There was no difference among the reported number of sexual partners (p=0.557) and condom use (p=0.293).

Conclusions: Patients receiving PrEP seem adherent to treatment and to follow-up. However, one-fifth discontinued prophylaxis. PrEP does not promote an increase in high-risk behaviors.

TUPEC504
Concerns and benefits of PrEP: lessons from the national PrEP demonstration project formative study in Nigeria

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Background: The use of antiretrovirals (ARVs) as pre-exposure prophylaxis (PrEP) reduces the risk of HIV transmission in serodiscordant couples in Africa. The design of effective strategies for delivery and optimal uptake of this new prevention tool begins with an understanding of likely public concerns. To inform design of the national PrEP Demonstration Project in Nigeria, we conducted a formative study to identify: (a) a Demonstration target group, (b) effective approaches to public health messaging about PrEP, (c) possible community concerns and logistic challenges, and (d) options for addressing these challenges when implementing a PrEP Demonstration project in Nigeria.

Methods: The sample represented a broad spectrum of relevant stakeholder groups, including: (1) health care professionals and policy makers concerned with HIV treatment and prevention, (2) local communities, (3) high-risk HIV populations, and (4) civil rights organizations. Qualitative data were generated in three phases. First, individual in-depth interviews (N=101), focus groups (N=12 groups; 6-12 participants per group), and telephone interviews (N=113) were conducted. Then, informative meetings with mixed stakeholder groups (N=2 meetings) were carried out to seek feedback on initial findings, and to use findings to identify specific barriers and facilitators to implementing PrEP for serodiscordant couples (the identified Demonstration target group). Lastly, an online survey to generate wider perspectives was completed by 70 voluntary participants from around the world. Qualitative data were inductively analyzed to construct categories addressing study-related objectives.

Results: Findings suggest PrEP will be widely accepted in Nigeria as an additional option for HIV prevention for heterosexual HIV serodiscordant couples. Perceived benefits included preserving serodiscordant marriages, increasing options for conception for serodiscordant couples, and reducing HIV transmission risk. Concerns include likely increase in risky sexual behavior, stigmatization of PrEP users, possible drug side effects, and non-adherence to drug regimen.

Conclusions: Despite general enthusiasm for PrEP concerns suggest there might be barriers to PrEP uptake by beneficiaries. A robust campaign and delivery strategy to address barriers is critical. Involving communities through advocacy, providing accurate information to the public and combating stigma in communities are steps towards eliminating barriers and gaining PrEP acceptance as a HIV prevention tool in Nigeria.

TUPEC505
HIV pre-exposure prophylaxis (PrEP) product preference among women in the VOICE-D (MTN-003D) study

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Background: HIV PrEP is only effective if used consistently and correctly, thus a deeper understanding of women’s product preferences, and the correlates of those preferences, is valuable in guiding future research. VOICE-D (MTN-003D), a qualitative ancillary study conducted after release of the VOICE results, retrospectively explored participants’ tablet and gel use, as well as their preferences for other potential PrEP products.

Methods: We conducted a mixed methods analysis of data from VOICE-D participants. During in-depth-interviews (IDIs), women were presented with pictures and descriptions of potential PrEP products including the oral tablet and vaginal gel tested in VOICE, and asked to discuss which products they would prefer to use and why. Seven of the original products displayed were combined into preferred product categories based on exploratory factor and latent class analyses. We examined demographic and behavioral correlates of these preferred product categories. IDIs with participants were conducted, coded, and analyzed for themes related to product preference.

Results: Of the 68 female participants who completed IDIs (22 South Africa, 24 Zimbabwe, 22 Uganda), median age was 28 (range 21-41), 81% were HIV-negative, and 90% were married or had a primary sex partner. Four preferred product categories were created: 1) oral tablets; 2) vaginal gel; 3) injectable, implant, or vaginal ring; and 4) film or suppository. A majority of women (55%) expressed a preference for products included in category 3. Characteristics significantly associated with each preferred product category differed (Table 1). VOICE study product assignment was only significantly associated with category 2: vaginal gel. Participants’ explanations for their preferred product selections included duration of activity, ease of use, route of administration, provider- vs. self-administration, and degree of familiarity with product.

<table>
<thead>
<tr>
<th>Preferred Product Category</th>
<th>Factors Significantly Associated with Preference for Product Category (p&lt;0.05 Fisher’s exact test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1: Tablet</td>
<td>HIV-positive Age 25</td>
</tr>
<tr>
<td>Category 2: Gel</td>
<td>Vaginal gel VOICE study product assignment Age 26+</td>
</tr>
<tr>
<td>Category 3: Implant, Injectable, or Ring</td>
<td>Not from Uganda Completed secondary school From South Africa Does not live with primary sex partner Partly 1 Completed secondary school Hied highest socioeconomic status</td>
</tr>
</tbody>
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Table 1. Correlates of preferred products

Conclusions: While there was interest in a variety of potential PrEP products, a majority of VOICE-D participants preferred long-acting methods. Preference for a particular product category was associated with varying participant characteristics. Analyses of the correlates of product preference can inform messaging and market segmentation for different products as well as research funding and resources to invest in products that target populations are most interested in using.
TUPEC506  
Patient-provider communication about sexual behaviors and pre-exposure prophylaxis: results from a national online survey of men who have sex with men in the United States

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Background: Successful implementation of HIV pre-exposure prophylaxis (PrEP) will depend on whether men who have sex with men (MSM) are willing to disclose HIV risk behaviors to healthcare practitioners. A recent online survey studied MSM to assess their comfort and experiences discussing sexual risk behaviors with primary care providers (PCPs).

Methods: In August 2013, U.S. members of a website for MSM seeking sex partners completed surveys assessing sexual behaviors, experience and interest in chemoprophylaxis, comfort disclosing same-sex behaviors, and experiences discussing sex with PCPs. Analyses were restricted to respondents identifying a PCP and indicating interest in using PrEP. Logistic regression models with robust variance estimations accounting for clustering by state identified factors associated with effective communication.

Results: Surveys were analyzed from 1,394 respondents. Their mean age was 44; 87% were white, 4% Black, 7% Latino, 69% had completed college, and 47% earned ≥$60,000 in the prior year. In the prior 3 months, 48% had condomless anal intercourse (CAI) with ≥3 partners, and 29% reported serodiscordant CAI. Forty-three percent were uncomfortable discussing male-male sex with PCPs, and 61% had not discussed CAI. Lack of discussion with PCPs about PrEP (84%) and beliefs that PCPs would not be willing to prescribe PrEP (76%) were perceived as barriers to accessing chemoprophylaxis. Accordingly, 53% of respondents would prefer to obtain PrEP from sources other than their PCPs. Comfort disclosing same-sex behaviors to PCPs was associated with income ≥$60,000/year (adjusted odds ratio [aOR] 1.89; 95% confidence interval [CI] 1.23-2.92), prior STI (aOR 1.60; CI 1.24-2.07), and depression (aOR 1.54; CI 1.11-2.13), and inversely associated with heterosexual identity (aOR 0.30; CI 0.21-0.67) and preference to obtain PrEP from non-PCP clinicians (aOR 0.08; CI 0.05-0.08). MSM who discussed CAI with PCPs more often identified as Latino (aOR 2.21; CI 1.25-3.92) and indicated awareness of post-exposure prophylaxis (aOR 1.79; CI 1.40-2.29), and less often preferred non-PCP clinicians as a source of PrEP (aOR 0.14; CI 0.10-0.18).

Conclusions: Suboptimal communication about sexual risk behaviors could prevent many MSM who are already engaged in healthcare from accessing PrEP from their PCPs. Interventions to optimize MSM-provider communication about HIV risk behaviors are needed.

TUPEC507  
Absence of sexual behavioral disinhibition in a PrEP adherence trial: considerations for medical providers who prescribe PrEP for men who have sex with men (MSM)

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Background: Antiretroviral pre-exposure prophylaxis (PrEP) has been shown to decrease HIV incidence in MSM. Although earlier trials did not find evidence of increased condomless sex in trial participants, recent evidence suggests that some medical providers remain concerned about behavioral disinhibition after starting PrEP, which could limit access for those who need it most. We compared sexual behavior data pre- and post-initiation of PrEP among MSM enrolled in a study designed to enhance PrEP adherence.

Methods: Between November 2012 and December 2013, 50 Boston-area MSM were randomized into either a PrEP-specific adherence intervention, which included four weekly sessions to address barriers and facilitators of PrEP use, or a time-matched control: sessions that emphasized general health information, but also provided information about PrEP. Participants self-reported sexual behavior at baseline and six month follow-up visits via computer survey. Using SPSS, differences in sexual behavior were examined using ANOVA.

Results: Participants were primarily White (94%) and college educated (64%). Rates of condomless sex did not differ significantly between the three months prior to initiation of PrEP (baseline) and the final three months of the six month trial (post-initiation of PrEP) (F[1, 38] = 1.90, p = 0.17, η2 = 0.047). Over that same time period, change in total number of sex acts (F[1, 38] = 1.10, p = 0.30, η2 = 0.028) and the proportion of total sex acts which were condomless (F[1, 37] = 0.14, p = 0.71, η2 = 0.004) was not significant.

At the 6 month follow-up, Tenofovir and FTC were detected in the blood of 90% of participants, with 74% of participants having levels consistent with daily use. None of these findings differed significantly between the two randomized conditions.

Conclusions: In this open-label PrEP study of Boston MSM, behavioral disinhibition was not seen in conjunction with PrEP use. Before study entry, participants were already engaging in condomless sex, and during the study, generally adherent. Medical providers who prescribe PrEP to MSM who engage in condomless sex may want to focus on optimizing adherence in this population, rather than behavioral disinhibition.

TUPEC508  
Significant increases in HIV pre-exposure prophylaxis (PrEP) uptake in Boston, a Boston Community Health Center in 2014: who are the recent users?

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Background: Although the US FDA and CDC approved the use of tenofovir-emtricitabine for PrEP in 2010, uptake was initially slow. However, in 2014, PrEP use markedly increased among Boston MSM.

Methods: Fenway Health (FH) is community-based facility in downtown Boston that has longstanding expertise in HIV primary care and prevention research. FH has used the CentrictTM electronic medical record for patient care since 1997, which was reviewed to perform the current analyses to characterize recent socio-demographic, behavioral and clinical trends in PrEP utilization.

Results: In 2011, 5 FH patients (pts) initiated PrEP; whereas 20 initiated in 2012, 102 in 2013, and 536 in 2014 (with 88.5% still using PrEP as of 12/31/14; longest duration: 3.8 years). PrEP users at FH were predominantly white (79.7%), though 8.0% were Black and 12.3% were Latino. Most (97.1%) PrEP users were male; 95.1% of 447 pts whose sexual orientation was recorded identified as gay or bisexual. Only 15 transgender people and 2 women accessed PrEP. PEP users were geographically dispersed, living in 158 different postal codes, with the largest cluster in a nearby neighborhood with 7.8% of PrEP users. The most common reasons for PrEp initiation were: engaging in condomless anal intercourse (64.5%), being in an HIV serodiscordant relationship (14.5%), wanting an additional level of protection during sex (8.6%).

The major payors for PrEP were private insurers (80.7%), Medicare (9.0%), Medicaid (8.7%). Seventy-seven pts (11.7%) subsequently terminated PrEP use. The most common reasons for discontinuation were: changes in risk behavior/relationships (38.9%), drug-related side effects or toxicities (18.2%). Only 1.2% cited cost/insurance issues. Of those who terminated PrEP, 25.5% restarted. Four pts who initiated PrEP subsequently became HIV-infected, but had either discontinued PrEP or were non-adherent at the time of infection. In 2014, 25.2% of pts with a new bacterial STD, and 33.3% of pts using PrEP, subsequently initiated PrEP.

Conclusions: PrEP use has recently markedly increased among MSM accessing services at a Boston community health center. Although many high risk pts initiated PrEP, further research is needed to understand reasons why some who might benefit did not access PrEP, particularly MSM from racial and ethnic minority communities.

TUPEC509  
Pre-exposure prophylaxis (PrEP) knowledge and use in a population-based sample of younger Black men who have sex with men (YBMSM) in Chicago

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Background: In the United States early evidence exists of racial disparities in PrEP knowledge, seeking behavior and uptake. YBMSM in particular have lower PrEP engagement when compared to other racial/ethnic groups, even in the context of increased health care access due to the Affordable Care Act. We examine factors associated with PrEP knowledge and uptake from the first population-based sample of YBMSM 16-29 years of age.

Methods: A representative sample of YBMSM was generated using Respondent Driven Sampling (RDS) in Chicago (n=623) from June 2013 to July 2014. HIV antibody/AgRNA testing was performed using dry blood spots. Outcomes included PrEP knowledge and previous PrEP use. Several sociodemographic, behavioral, clinical and social factors were collected to examine associations with outcomes. Bayesian Model Averaging was used to select variables into final multivariable logistic regression models.
**TUPEC510**

**PrEP in the real world: implementation of PrEP in a medium-sized city community health clinic**

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**Background:** Truvada (TVD) used for HIV Pre-Exposure Prophylaxis (PrEP) was approved by the FDA in July 2012 to reduce the risk of sexually acquired HIV-1 in high risk adults. PrEP was shown to be safe and efficacious in clinical trials, however, longitudinal real world data are lacking. We describe a team approach to implementation of PrEP over a two year period, and report on patient health outcomes.

**Methods:** From August 2012 to Jan 2015, we evaluated 102 patients for PrEP. Our team approach started with high risk evaluation, HIV education, and rapid HIV Ab test. Sexual history and physical exam was completed by a medical provider. A clinical pharmacist addressed potential efficacy, adverse events, and possible financial obstacles with the patient. Patients were seen every three months by a medical provider, and comprehensive harm reduction and prevention education given at each visit.

**Results:** All 102 patients evaluated were high risk, defined as having unprotected sex and at least one of the following: are casual partners of people known HIV status, have multiple sexual partners, are in a sero-discordant relationship, had a recent sexually transmitted infection (STI), are engaged in transactional sex. 94 of 102 (92%) patients started PrEP; 10 of 94 (11%) patients discontinue PrEP during the reported time period. All 94 individuals who started PrEP remained HIV negative while on treatment. There was no increase in the STI rates observed when compared with the historical timed data, and the overall reported adherence rate was greater than 90%.

Ten patient interviews suggest that the decision to take PrEP is motivated by disease prevention, that sexual behaviors do not change, and peace of mind as well as staying HIV negative are positive outcomes for patients.

**Conclusions:** To date, in our medium-sized city community clinic, utilizing a team approach, all 94 patients remained HIV negative while on treatment, had an adherence rate >90%, had no increase in STI rate, and had no change in their sexual routines.

**TUPEC511**

**Fertility intentions, pregnancy and PrEP use in African HIV serodiscordant couples**

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**Background:** Understanding fertility intentions among HIV serodiscordant couples and their use of peri-conception HIV risk reduction strategies is important for the development of safer conception programs.

**Methods:** We are following 1013 Kenyan and Ugandan HIV serodiscordant couples in the Partners Demonstration Project, a multi-site, pre-exposure prophylaxis (PrEP) and antiretroviral therapy (ART) delivery program. We described fertility intentions and pregnancy rates of HIV infected and uninfected women. Using multivariable generalized estimating equations, we determined the association of immediate fertility intentions with sexual behavior and PrEP use by HIV uninfected women.

**Results:** Two-thirds (67%) of women in the cohort are the HIV infected partner. 65% of HIV infected women and 38% of HIV uninfected women have no children with their study partner. At enrollment, 7% of women reported having an immediate fertility intention (within 1 year), and 54% reported intentions to have a child in more than 1 year. To date, overall pregnancy incidence is 18.5 and 25.8 per 100 person years among HIV infected and uninfected women and substantially greater among women with immediate fertility intention (76.1 per 100 person years).

Women with an immediate fertility intention were more likely to report condomless sex for at least 80% of sex acts (adjusted odds ratio [OR] 4.46, 95% confidence interval [CI] 3.33-5.69) and consistent use of PrEP (at least 80% of doses dispensed based on MEMS, adjusted OR 1.83, 95% CI 1.38-2.76).

**Conclusions:** In an HIV serodiscordant couple cohort, many women express intentions to become pregnant and pregnancy rates are high. PrEP use was high among women reporting immediate fertility intentions and is an important component for safer conception programs.

**TUPEC512**

**Differences in HIV pre-exposure prophylaxis use and intention to use between stimulant and alcohol-using men who have sex with men in Boston, United States**

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**Background:** Heavy alcohol and stimulant use are associated with elevated HIV risk among MSM and there is some concern that these behaviors may also be a potential barrier to uptake of HIV pre-exposure prophylaxis (PrEP). The objective of this study was to assess acceptability and feasibility of PrEP among alcohol and non-injection drug users in Boston.

**Methods:** From September 2012-2013, a quantitative assessment was conducted with MSM who reported condomless sex with another man in the context of stimulant (crack/cocaine and crystal methamphetamine) and alcohol use. Participants were asked about awareness, acceptability, and use of PrEP, perceived barriers to use, and potential for changes in sexual behavior after PrEP uptake. Multivariable modified Poisson models were used to estimate risk ratios for associations between stimulant versus alcohol use and sexual behaviors and PrEP-related factors, adjusted for demographic and social factors.

**Results:** Of 254 participants enrolled, 132 (52.0%) were stimulant users and 48.0% were exclusively alcohol users. Median age was 31 years (stimulant users: 36; alcohol users: 27), 63.0% of the sample was white/Caucasian (stimulant users: 56%; alcohol users: 70.5%), 18.5% Black/African-American (stimulant users: 25.0%; alcohol users: 5.7%), and 14.4% Latino (stimulant users: 12.9%; alcohol users: 16.4%). Of the stimulant users, 13 (9.9%) had previously used PrEP. No alcohol users had used PrEP. Both alcohol (73.0%) and stimulant (83.3%) users demonstrated substantial interest in using PrEP. In multivariable models, stimulant use was associated with increased risk of condomless condomless anal sex with ≥3 partners (aRR=2.13, 95% CI 1.44-3.10), more frequently having heard of PrEP (aRR=1.31, 95% CI 1.04-1.65), more concern that substance use would affect PrEP use (aRR=2.28, 95% CI 1.38-3.75), and more frequently reporting that they would not need to worry about condomless sex with HIV infected partners following initiation of PrEP (aRR=0.07, 95% CI 1.39-6.82).

**Conclusions:** Despite potential barriers to PrEP use, interest in PrEP was high, with greater awareness and experience with PrEP among stimulant users. PrEP implementation programs with alcohol and non-injection drug users should consider differences in barriers to PrEP use and potential for differential behavioral compensation between users of different types of substances.
Text messaging responses correlate with tenofovir-diphosphate dried blood spot concentrations among men who have sex with men on pre-exposure prophylaxis

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Background: The effectiveness of pre-exposure prophylaxis (PrEP) is strongly linked to adherence. Methods to reliably measure adherence are needed. We sought to validate a daily text messaging adherence metric (individualized Texting for Adherence Building, iTAB) using a biologic marker (tenofovir diphosphate, TFV-DP, levels in dried blood spots, DBS).

Methods: CCTG 595 is an ongoing 48-week RCT testing the efficacy of iTAB to promote PrEP adherence in HIV-uninfected men who have sex with men (MSM). Analysis was performed on subjects randomized to receive iTAB with week 12 DBS TFV-DP levels and iTAB data available. TFV-DP levels were compared to proportion of messages responded to positively (Yes, I took my medication) and adherence patterns over the 34 days (two red blood cell TFV-DP half-lives) prior to week 12. Baseline risk factors and demographics were explored as covariates of adherence. Methods for statistical analysis included scatter-plot, correlation test, and Ward Hierarchical Clustering for adherence patterns.

Results: Among 152 subjects included, the mean TFV-DP concentration was 1353±558 fmol/punch. Participants reported taking a mean of 87% of doses as measured by positive iTAB responses. There was a significant correlation between TFV-DP concentrations and proportions of positive iTAB responses (r=0.26, p=0.001). Subjects with TFV-DP≥819 (consistent with >5 doses/week) had a higher proportion of positive iTAB responses (89 versus 76%; p=0.003). Subjects clustered into 3 adherence groups by text responses over the 34 days (Figure): perfect (r=137), high (r=73), and low adherence (r=0.57). Perfect/high adherers combined had significantly higher TFV-DP concentrations than moderate adherers (p=0.037). Baseline variables associated with better adherence cluster included older age (p=0.002), non-Hispanic ethnicity (p=0.027) and less drug use (p=0.005).

Conclusions: Early adherence to PrEP was high among those assigned to text messages. Subjects with a higher proportion of positive iTAB responses had significantly higher TFV-DP levels and were more likely to have TFV-DP levels consistent with taking at least 5 doses/week. Since iTAB response data correlates with a biologically confirmed adherence marker (TFV-DP levels), iTAB might be useful to monitor MSM on PrEP.

PrEP utilization estimates in Australia

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Background: Daily pill Truvada is recommended for preexposure prophylaxis of HIV (PrEP) in people at high risk for infection. The uptake levels remain low internationally. The population-level benefit of PrEP will require much higher levels of use than is observed. In Australia, gay and other men who have sex with men (GMSM) contribute most to HIV transmission. We estimated how many GMSM are likely to request PrEP as it becomes available for prescription.

Methods: We used data from the Australian Bureau of Statistics (2013) and the second Australian Study of Health and Relationships (ASHR2, 2013) to estimate the size of the population of GMSM. PrEP eligibility for GMSM was defined by the national PrEP guidelines. Input indicators from a series of studies, including the national behavioural surveillance (Gay Community Periodic Surveys, GCPS) and other studies conducted in Australia in recent years, were applied to estimate the numbers of men eligible for PrEP based on each individual and any behavioural eligibility criteria as per the national PrEP guidelines. We also estimated how many eligible GMSM are likely to request Truvada for primary HIV prophylaxis.

Results: The estimated 143,000 Australian men would identify as gay/homosexual plus 95,000 as bisexual or other GMSM. In GCPS, 15.7% of the HIV non-positive GMSM reported sustained risk behaviour (6 or more sex partners in the last 6 months). Having at least one episode of receptive condomless anal intercourse (CLAI) with any casual HIV-infected or status-unknown male partner in the last 6 months appeared the most common behavioural eligibility criterion for PrEP (5% of HIV non-positive GMSM). 5.7% would satisfy any of the behavioural eligibility criteria. In the recent Australian study of current and likely PrEP use, 44.9% of gay/ homosexual GMSM reported interest and being likely to uptake PrEP.

Conclusions: We estimated the size of the group of GMSM eligible for and most likely to request PrEP in the near future. This estimation helps predict services and medication needs for PrEP provision. We discuss the methods, assumptions and finding of this estimation in light of the integration of PrEP into the HIV prevention strategy.

HPTN 067 ADAPT: ‘PrEP Ubuntu’ and experiences with open-label PrEP among South African women

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Background: Uptake and adherence to oral FTC/TDF PrEP among African women has been highly variable between studies. There has been no published experience with open-label access to PrEP in women after the concept was proven effective. Qualitative research performed at the Cape Town site of the HPTN 057 ADAPT trial focused on women’s experiences with PrEP and randomly assigned dosing regimens (daily, twice weekly with a post-dose, and pre/post-sex dosing).

Methods: Convenience sampling from trial participants (N=179) identified focus group (FG) participants, while combined convenience and targeted sampling to include participants who indicated poor adherence/discontinued product use was used for in-depth interview (IDI) participants. Six FGs (n=42) and 18 IDIs were conducted using a semi-structured interview guide. Data was transcribed and double-coded using framework analysis.

Results: Adherence facilitators included keeping tablets on-hand, support from others, and PrEP efficacy beliefs, with daily PrEP users also noting use of cell-phone reminders or linking doses to recurring events. Barriers included forgetting, fear of disclosure of study participation and side-effects. The post-sex dose in the non-daily arms was noted as a poor fit to the typical post-sex situation (away from home, resting with partner). The main advantage of daily PrEP over non-daily was routine. Across arms, a theme of participant struggle with community and pre/post-sex dosing.

Conclusions: Daily dosing was deemed to have multiple advantages, with post-sex dosing poorly ‘matched’ to the common post-sex experience. In a struggle between community and research, women’s responses ranged from disengagement from PrEP to ‘PrEP Ubuntu’—where Ubuntu highlights the social intricacies of PrEP use and the potential influence of PrEP users who seek to tip community perceptions in an effort to improve community-wide HIV-prevention. Successful PrEP roll-out will undoubtedly rely heavily on these PrEP champions.
HIV evolution in breakthrough infections in a human trial of oral PrEP with FTC/TDF

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Background: Daily PrEP with FTC/TDF is a novel HIV prevention strategy. Since current PrEP regimens are not 100% protective, it is essential to understand the characteristics of acute infections that occur during PrEP. We investigated viral evolution dynamics in participants infected with HIV who were assigned to daily FTC/TDF or placebo during the CDC-sponsored TDF-2 PrEP trial.

Methods: HIV dynamics were investigated in the 4 participants who seroconverted in the FTC/TDF arm and in 3 viral load-matched seroconverters assigned to placebo. Two of the 4 infections in the FTC/TDF arm had no detectable FTC or TFV in plasma. HIV env (V1-V5) was amplified from plasma HIV RNA by single genome amplification at the seroconversion visit and 8-12 months later. Time since infection and number of transmitted/founder (T/F) viruses was estimated by exploring env diversity at seroconversion. Viral diversity was inferred by analysis of ‘geno-diversity’ from the PolyPhen-Fitter by the Phylogenetics. For env protein diversity was inferred by analysis of ‘geno-diversity’ from the PolyPhen-Fitter by the Phylogenetics.

Results: At seroconversion, the average virus diversity in the seroconverters assigned to placebo or who were non-adherent was 0.69% (0.11%-2.0%) compared with 0.05% and 0.07% in the two adherent PrEP participants. HIV infections in adherent participants followed a star phylogeny and were initiated by a single T/F virus. In contrast, infections in the 2 non-adherent PrEP participants and 2 of the 3 placebo controls were heterogeneous (mean 3 T/F viruses) and did not follow a star phylogeny. Virus diversity 8-12 months after infection remained higher in seroconverters assigned to placebo or who were non-adherent to PrEP (1.6% [range 1.1%-2.3%]) compared with the 2 adherent participants (0.3% and 0.9%). At 1 year, mean nucleotide divergence from the most common T/F viruses was also lower in the adherent seroconverters compared with the placebo and non-adherent seroconverters (0.5x10^-1 vs 1.9x10^-1) at substisite/year, p<0.0001.

Conclusions: HIV sequences from PrEP-adherent seroconverters were more homogeneous and evolved more slowly than those from placebo or non-adherent seroconverters. If confirmed in other PrEP trials, these findings suggest that transient PrEP exposure during acute infection may have a long-lasting effect on virus evolution. Our observations underscore the need to better understand the potential impact of PrEP on HIV control.

RISK COMPENSATION AMONG MEN WHO HAVE SEX WITH MEN (MSM) IN SOUTHERN CALIFORNIA FOLLOWING THE INITIATION OF PRE-EXPOSURE PROPHYLAXIS (PrEP)

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Background: A concern of using pre-exposure prophylaxis (PrEP) for HIV prevention is risk compensation, where PrEP users may take more sexual risks. Methods: We examined sexual risk behaviors following TDF/FTC PrEP initiation among men who have sex with men (MSM) enrolled in CCTG 595, a PrEP adherence study. Self-reported number of sexual partners by HIV status and unprotected receptive and insertive anal sex acts (over the previous month) were compared at study weeks 0 and 24 using the Wilcoxon signed-rank test. Analyses were limited to participants who completed the week-24 survey.

Results: The 268 MSM were: 36 years old; 30% Hispanic; 85% White and 5% Black. The number of HIV-positive partners in the prior month increased from week 0 to 24 (p<0.05). The number of HIV unknown status partners in the prior month declined from week 0 to 24 (p<0.05). The number of unprotected receptive anal sex acts in the prior month marginally increased from week 0 to 24 (p=0.06). The number of unprotected insertive sex acts in the prior month did not significantly change (p=0.58).

Conclusions: These preliminary analyses in MSM suggest an increase in the number of HIV positive partners in the first 24 weeks following PrEP initiation. However, because there was only a marginal increase in unprotected sex and a reduction in partners of HIV unknown status, the evidence for risk compensation among this population of PrEP initiating MSM is limited. Future analyses will include data up to one year to determine if these trends change over time.

HIV-negative male couples’ attitudes about pre-exposure prophylaxis (PrEP), and PrEP use within the context of their relationships and sexual agreements

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Background: Between one- and two-thirds of US MSM acquire HIV from their primary relationship partner (male couple). One promising biomedical approach to preventing new HIV infections is PrEP - a daily regimen of HIV treatment (i.e., Truvada™) taken by those who are HIV-negative and at risk for HIV infection. Studies on HIV pre-exposure prophylaxis (PrEP) show clear efficacy as a biomedical approach to preventing HIV transmission, although studies note that HIV-negative MSM support PrEP use, their knowledge about PrEP varies. Moreover, little is known about male couples’ attitudes about PrEP and whether PrEP could be integrated into their sexual agreements.

Methods: The present study is part of a larger intervention project aimed to help male couples form and adhere to a sexual agreement via an online interactive HIV prevention toolkit. Active and passive recruitment strategies were used to enroll 29 consented HIV-negative male couples [60% African American], of which 21 completed the first cohort. For each couple, interviews were conducted in which the MUDEAVAG sexual agreement was discussed. Using interview transcripts, we identified and analyzed themes for integrating PrEP into an agreement.

Results: Themes for integrating PrEP into an agreement included condom use and adherence. Our findings are data rich. Some couples were supportive of PrEP, but conditionally and/or believed PrEP should be used with condoms. PrEP support for relationships included enhancing sexual needs and/or to protecting them from potential “slip-ups.” Less PrEP support centered on riskier behaviors and medication side effects. Couples had mixed attitudes about using PrEP in agreement: some thought PrEP should only occur with condom use while others said it could help reduce risk while enhancing pleasure by forgoing condoms and/or increase comfort and communication about sex and reduce worry about HIV.

Conclusions: Our findings highlight the need to use examples and scenarios of how PrEP use may benefit male couples’ relationships and risk for HIV when developing content and activities for our online prevention toolkit.

Reasons for accepting or declining HIV pre-exposure prophylaxis in a diverse black US population

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Background: Studies on HIV pre-exposure prophylaxis (PrEP) show clear efficacy associated with adherence, and previously unpredicted patterns of non-adherence for which fully adequate explanations remain elusive. In an attempt to better understand perceptions of PrEP as potential reasons for adherence or lack thereof, we examine reasons for the acceptance or refusal of PrEP in a large diverse black population in Philadelphia.

Methods: Between July 2012 and December 2014, African Americans of lower socioeconomic status in a large HIV testing program in Philadelphia’s city health centers, and African and Caribbean immigrants in a large community-based HIV testing program were administered an anonymous survey. Included among survey questions were questions about acceptance or refusal of PrEP, and reasons for acceptance or refusal. Responses for each were categorized and analyzed using the Epitools package.
Results: During the study period 8889 individuals met criteria for this analysis. Of these 6114 were African American and 2755 African or Caribbean. Overall, 49.7% were female. PEP acceptance rates were similar for American men (62.3%) and women (59.2%), but lower and different for immigrant blacks (49.3% for men, 34.2% for women, \( p < 0.0001\)). Main reasons for acceptance of PEP were fear of HIV, a familiarity with the concept of prevention, and recognition of one’s HIV risk. Reasons for refusal of PEP were a lack of recognition of risk, a dislike of medicines/trips, a desire to use alternative prevention methods, and a distrust of the medical establishment. Among immigrants only, trust of clinicians’ recommendations was cited as an additional reason for acceptance.

Conclusions: Understanding the reasons for accepting or declining PEP among at-risk communities are key to partnering effectively with such communities to make PEP available. Addressing risk perception and barriers to medication use are two important ways of improving acceptance of PEP.

TUPEC520

Individual and sexual network characteristics are associated with HIV serodisclosure in the global iPrEx study

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Background: Accurate HIV serodisclosure is an important sexual risk-reduction strategy because it enables seroconvertive behaviors. Pre-exposure prophylaxis (PrEP) is a viable HIV prevention strategy but there are concerns that PEP may cause individuals to forego other risk-reduction efforts, like serodisclosure. We are unaware of any study that has examined serodisclosure before and after PEP use. This study analyzes serodisclosure patterns among MSM and TGW. Logistic regression using generalized estimating equations modeled serodisclosure before and after PrEP use. This study analyzes serodisclosure patterns among MSM and TGW. Logistic regression using generalized estimating equations modeled predictors of serodisclosure to sexual partners in the past three months.

Results: A total of 1593 HIV seronegative participants and 2643 partnerships were analyzed. Among those with available data from CASI, the median age of participants was 28 years (range 18-70); 89% (n=1418) were MSM and 11% (n=174) TGW; 66% (n=1059) were Hispanic/Latino; 42% (n=662) were married or partnered; and 70% (n=1191) received PEP at enrollment. Overall, 60% reported disclosing HIV status to their last sexual partners. In bivariate analysis, participants in the USA; greater age; persons whose most recent sexual partner involved both a sexual and emotional connection; and higher education were associated with higher odds of serodisclosure. Participants in Thailand and those who identified as Hispanic/Latino had higher odds of serodisclosure. Controlling for all other variables, participants in the USA, relationships involving a sexual and emotional connection, and education were independently associated with HIV serodisclosure. No differences were observed between participants who received PEP and those who did not.

Conclusions: This study suggests that serodisclosure in MSM and TGW may be associated with individual and sexual network characteristics, and may have no relationship with PEP use. Serodisclosure between persons on or off PEP did not significantly differ at baseline despite prior participation in PEP trials. These findings provide an early assessment to address concerns that PrEP might lead individuals to forego risk reduction strategies like serodisclosure and can help inform future interventions to promote communication of HIV status.

TUPEC521

Validation of a Truvada for PrEP algorithm using an electronic medical record

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Background: TenofurEfavirenz/Emtricitabine (TVD) combination was approved for a Pre-exposure Prophylaxis (PrEP) indication in the US in July 2012. There are no IC9D or procedure codes that reliably predict subjects who take TVD monotherapy for PrEP from those subjects who receive TVD for HIV or Chronic Hepatitis B (CHB) treatment, or Pre-Exposure Prophylaxis (PEP). An algorithm was developed to identify presumptive TVD for PrEP subjects from large-scale administrative databases based on excluding subjects with diagnosed cases and prescriptions documenting HIV, CHB, or PEP.

Methods: The present study validated the algorithm with a focused chart review using an Electronic Medical Record (EMR). Two blinded investigators independently reviewed each electronic chart for subjects who were prescribed TVD and assigned them as a) PrEP, b) HIV+, c) CHB, or d) PEP. Non-parametric models were used in the computation of AUC statistics.

Results: 10,645 subjects from the EMR started TVD therapy after January 1st 2012, and the algorithm classified 6.3% (671) as PrEP, 0.24% (26) as CHB, 0.12% (13) as PEP and 93.3% (9,935) as HIV+. 70.3% of the subjects were male and 29.1% female. A random 1% of HIV+ subjects and all charts from other groups were reviewed (810 charts). The chart review results were categorized based on the gold standard and the algorithm were classified. AUC for TVD subjects was 0.90, with a sensitivity of 90% (95% CI 0.92 - 0.99) and a specificity of 98.8% (95% CI 0.97 - 0.99). Among those categorized by the algorithm as PrEP, 9.9% (95% CI 7.9-12.5) were identified by the chart review as TVD monotherapy for high risk sexual PrEP, while 4.0% (95% CI 2.6 - 5.8) were CHB subjects. The positive predictive value of the algorithm, or those assigned by the chart review and the algorithm as PrEP was 72.4% (95% CI 68.9 - 75.8).

Conclusions: A PrEP algorithm of exclusion demonstrated high sensitivity and specificity, and accurately categorized other TVD indications. The chart review suggests that 1 out of 10 subjects on TVD monotherapy are taking it for short periods after episodes of high risk sexual exposure.

Microbicides (including vaginal and rectal microbicides)

TUPEC522

Safety of cervical and vaginal biopsies in microbicide and contraceptive research

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Background: Cervical and vaginal (CV) biopsies are commonly performed in clinical studies of microbicides for HIV prevention and contraceptive research to assess biologic responses, investigate product safety and determine local drug tissue levels. Similar genital biopsies are commonly performed clinically, however, safety data from genital biopsies performed for research purposes have yet to be collectively analyzed and published. Summary data on biopsy safety in special populations, including postmenopausal, HIV+ and women with reproductive tract infections, are also lacking.

Methods: We searched PubMed and ClinicalTrials.gov and contacted principal investigators from trials of microbicides, multipurpose prevention technologies and contraceptives to collect data on biopsy protocols and procedures. Data on adverse events (AEs) that were deemed related to biopsy procedures were abstracted.

Results: We identified 34 studies (21 microbicide, 8 contraceptive and 5 others) in which CV biopsies were taken. A total of 1,409 women donated 8,330 CV biopsies (2,911 cervical, 5,419 vaginal). On average, 3 CV biopsies (range 1 - 5) were obtained at each visit. Three days was the shortest interval between consecutive biopsies (range 3 - 50 days). All clinicians reported using no pre-procedure antiseptic preparations. Investigators reported using either no pre-procedure pain control methods or combinations of topical anesthesia (xylocaine spray, benzocaine gel) and distraction (cough). Biopsy sites were treated with hemostasis with pressure, silver nitrate, Monroe’s solution and, rarely, sutures. Biopsy-related AEs were reported in 45 (3.2%) of participants. Studies included special populations such as postmenopausal women (n = 17), women with symptomatic bacterial vaginosis (n = 33), HIV- Kenyan women (n = 38), HIV+ female sex workers (FSWs) (n = 20) and highly HIV exposed seronegative FSWs (n = 18). Among these special populations, no biopsy healing abnormalities were observed.

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Conclusions: CV biopsies are associated with a low rate of AEs that are usually mild with complete resolution. Post-procedure bleeding is the most common AE. Although most studies with biopsies were performed in developed countries on healthy premenopausal women, there are emerging data that CV biopsies among special populations of women, including HIV-infected women and women living in high HIV prevalence areas are also safe and well tolerated.

TUPEC523
Pharmacokinetics of tenofovir and emtricitabine delivered by vaginal tablets
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Background: Vaginal tablets offer advantages over gels. Elimination of plastic applicators reduces cost and environmental impact and allows for discreet storage and insertion. Tablets are smaller and lighter than gels in applicators, lowering shipping/storage costs and increasing convenience.

Methods: This prospective parallel, double-blinded, randomized study examined the pharmacokinetics (PK) of: 1) 40 mg tenofovir (TFV); 2) 40 mg emtricitabine (FTC); 3) 40 mg TFV combined with 40 mg FTC; and 4) placebo. 48 healthy, non-pregnant, HIV-uninfected women (12 per group), aged 18-40 participated in the study. Participants completed the single-use phase followed by the multiple use phase (14 days of daily dosing). Vaginal tablets in a single use phase followed by a multiple use phase (14 days of dosing)

Women were randomized to treatment, number of tablets in the single use phase (1 tablet), and number of tablets in the multiple use phase (1 tablet followed by a second tablet 12 hours later and then1 tablet at each day 24 hours after the last dose of the multiple use phase.

Vaginal biopsies were collected at baseline and 5 hours after the single use and 2, 4, 6, or 24 hours after the last dose of the multiple use phase.

Results: Median TFV tissue levels were at the target of 105 ng/mg after administration of TFV and TFV-FTC tablets. Concentrations after 14 days were similar to those after a single dose. Importantly, median TFV-OP concentration were above the target of 105 ng/mg after TFV and TFV-FTC tablets, with concentrations 1 log higher after 14 days after a single use. FTC levels in tissue were at least an order of magnitude higher than the FTC EC50. In some cases, the tablet disintegration rate was slower than the target of 30 minutes.

Conclusions: This first human study of vaginal microbicide tablets demonstrates efficient drug release and intracellular metabolism. TFV and TFV-OP tissue concentrations were comparable to the clinical TFV 1% gel. Combination with FTC added consistently high FTC and FTC-TP tissue concentrations. Further work to improve disintegration speed is ongoing.

TUPEC524
Factors linked to transitions in adherence to antiretroviral therapy among HIV-infected illicit drug users in a Canadian setting
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Background: HIV-positive people who use illicit drugs typically achieve lower levels of adherence to antiretroviral therapy and experience higher rates of sub-optimal HIV/AIDS treatment outcomes. Given the dearth of longitudinal research into ART adherence dynamics, we sought to identify factors associated with transitioning into and out of optimal adherence to ART in a longitudinal study of HIV-infected people who use illicit drugs (PWUD) in a setting of universal no-cost HIV/AIDS treatment.

Methods: Using data from a prospective cohort of community-recruited HIV-positive illicit drug users confidentially linked to comprehensive HIV/AIDS treatment records, we estimated longitudinal factors associated with losing or gaining ≥95% adherence in the previous six months using two generalized linear mixed-effects models.

Results: Among 703 HIV-infected ART-exposed PWUD, becoming non-adherent was associated with periods of homelessness (Adjusted Odds Ratio [AOR] = 2.52, 95% Confidence Interval [95% CI]: 1.56 - 4.07), active injection drug use (AOR = 1.25, 95% CI: 1.01 - 1.56) and incarceration (AOR = 1.54, 95% CI: 1.10 - 2.17). Periods of sex work (AOR = 0.51, 95% CI: 0.34 - 0.75) and injection drug use (AOR = 0.62, 95% CI: 0.50 - 0.77) were barriers to becoming optimally adherent. Methadone maintenance therapy (MMT) was associated with becoming optimally adherent (AOR = 1.87, 95% CI: 1.50 - 2.33) and was protective against becoming non-adherent (AOR = 0.52, 95% CI: 0.41 - 0.65).

Conclusions: In conclusion, we identified several behavioural, social and structural factors that shape adherence patterns among PWUD. Our findings highlight the need to consider these contextual factors in interventions that support the effective delivery of ART to this population.

TUPEC525
The impact of health literacy and physician-patient dynamics on health outcomes in adult HIV patients
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Background: Health literacy has been shown to impact health in HIV-infected patients. However, little research has examined the characteristics of the relationship between the patient and the provider in an adult HIV outpatient setting. Physician-patient dynamics, notably communication styles and modalities, are integral to maximizing health outcomes, particularly in HIV-infected patients.

Methods: HIV-related health literacy (HIV-HL Scale) and patient’s perceptions of their providers (Patient Satisfaction Questionnaire) were determined via questionnaire in 201 HIV-infected outpatients (mean age = 50.4 ± 10.1 years; 45.2% female; 80% Black, 19% Hispanic/Latino) from the University of Miami Jackson Memorial Medical Center Adult Outpatient HIV Clinic. Health outcomes were defined by patients’ most recent CD4 counts and if patients had achieved virologic suppression (< 20 copies/mL).

Results: After controlling for age, gender, and education level, patients with higher HIV-related health knowledge had higher CD4 counts (β = .238, p = .011; model R2 = .391, p = .025). Greater ratings of physicians’ interpersonal ratings were significantly associated with greater CD4 counts (β = .21, p = .003) and lower viral loads (r = -.18, p = .014); those who were virally suppressed had significantly higher interpersonal ratings of their physician than those who did not (t(193) = 2.12, p = .036); controlling for age, gender and HIV knowledge, each 1-point increase in physicians’ interpersonal ratings were associated with a 1.46 times greater odds that the patient was undetectable (OR = 1.46, 95% CI: 1.05-1.91). Furthermore, after adjusting for age, gender, and HIV knowledge, patients with higher interpersonal ratings of their physicians had higher CD4 counts (β = .221, p = .015; model R2 = .11, p = .009).

Conclusions: Although peripheral to the standard course of treatment, health knowledge, communication styles, and interpersonal interaction are an integral part of HIV patient care that impacts health outcomes. The additional importance of education and physician-patient communication should be incorporated in provider training; system-level policy changes should include the value of both education and interpersonal style in treatment protocols and address the potential to improve communication.

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Approaches to improving adherence to prevention interventions
TUPEC526
Prevalence and correlates of non-disclosure of maternal HIV status in Kenya
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Background: Prevention of mother-to-child HIV transmission programs (PMTCT) usually test pregnant women alone for HIV. Non-disclosure of maternal HIV results to their male partner may deter utilization of PMTCT interventions to reduce HIV transmission.

Methods: We enrolled mother-infant pairs attending week 6 and month 9 immunizations at 140 maternal and child health clinics across Kenya, with a second survey of HIV-positive moth-
ers in 30 clinics in Western Kenya to increase statistical power to assess HIV-related outcomes. Consenting women completed a questionnaire that assessed disclosure of HIV status (positive or negative) and among HIV-positive women, utilization of PMTCT interventions. Multivariate logistic regression, adjusting for facility-level clustering, was used to determine correlates of HIV test results non-disclosure among women reporting current partnership and association with uptake of PMTCT interventions.

Results: Between June and December 2013, 2819 women were enrolled of whom 2491 (88.4%) reported having a current partner. Of these, 129 (5.2%) reported non-disclosure of HIV status to their partners. Being unmarried [aOR=3.11 (1.34-6.24)], unemployed [aOR=3.52 (1.21-10.6)], partner antenatal clinic non-attendance [aOR=3.11 (1.34-6.24)], maternal HIV-positive status [aOR=4.12 (2.76-6.27)] and frequent threats of harm [aOR 5.16 (1.76-15.16)] were independently associated with non-disclosure of HIV test results. Among 420 HIV-positive women who reported having a current partner, male partner status was HIV-positive in 54.3%, HIV-negative in 21% and unknown status in 24.8%. Fifty three (12.8%) HIV-positive women, with a current partner reported non-disclosure. Of these, 8 (15.1%) had HIV-positive partners, 10 (18.9%) HIV-negative partners and 35 (66.0%) had partners of unknown HIV status. HIV-positive women who did not disclose results were less likely to use antiretrovirals during pregnancy [aOR 0.26 (0.14-0.49)], during labour [aOR 0.40 (0.21-0.74)], during breastfeeding [aOR 0.43 (0.24-0.79)] or give their infants antiretrovirals [aOR=0.08 (0.02-0.25)].

Conclusions: We found low rates of non-disclosure of maternal HIV status among all women, but higher among those who were HIV-positive. Non-disclosure among HIV-positive women was associated with reduced use of antiretrovirals during all time periods. Promoting partner disclosure among HIV-positive women may be a useful strategy to facilitate adherence for enrollee."}

### TUPEC528

**Difficulty accessing addiction treatment predicts injection initiation among street-involved youth in a Canadian setting**


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**Background:** Preventing transitions to injection drug use is central for reducing HIV transmission among vulnerable street-involved youth. Although addiction treatment is a key intervention to reduce problematic high-risk drug use, engagement with addiction treatment and injection initiation among youth has not been well explored. To help identify potential areas for intervention, this study examines the relationship between having difficulty accessing addiction treatment and injection initiation among street-involved youth.

**Methods:** Data were derived from the At-Risk Youth Study (ARYS), a prospective cohort of street-involved youth aged 14-26 who use illicit drugs, from September 2005 to May 2013. Cox proportional hazards regression was used to identify factors independently associated with time to injection initiation.

**Results:** Among 462 participants who were injection naive at baseline, 97 (21%) initiated injection drug use over study follow-up and 129 (27.3%) reported having difficulty accessing addiction treatment at some point during the study period. The median and IQR for the number of study visits was 4 (2-6). In a multivariate Cox analysis, which was adjusted for gender, ethnicity, number of years since initiated non-injection hard drug use (e.g., cocaine, heroin, crystal methamphetamine), recent non-injection cocaine use, recent crack cocaine smoking, recent crystal methamphetamine use, and recent non-injection heroin use, having difficulty accessing addiction treatment remained independently associated with injection initiation (Adjusted Odds Ratio= 1.94; 95% Confidence Interval: 1.11 - 3.38; p-value =0.02).

**Conclusions:** Study findings suggest that having difficulty accessing addiction treatment is a common experience among street-involved youth and is associated with injection initiation. Numerous barriers to accessing addiction treatment among youth have been previously described and include age restrictions, wait times, and stigma. Addressing these barriers may support efforts to prevent injection initiation and subsequent risk of HIV transmission among at-risk youth and should be made a public health priority.

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**TUPEC527**

**African women’s perceptions of honesty and dishonesty about product use adherence in the context of HIV prevention research during the VOICE (MTN-003) trial**


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**Background:** Following null effectiveness results and evidence of low product use from pharmacokinetic drug testing in VOICE, the VOICE-D (MTN 003D) ancillary study used a variety of strategies in an attempt to elicit candid accounts from participants about why actual product use was lower than reported. There is need for innovative strategies to facilitate PMTCT interventions uptake by HIV-positive women reluctant to disclose their status.

**Methods:** 175 former VOICE participants were enrolled between December 2012 and March 2014 in South Africa (n=49), Uganda (n=61) and Zimbabwe (n=65). Participants were randomly selected from a list of those permitting further research contact and who met pre-specified eligibility characteristics. Data from 156 in-depth interviews and 12 Focus Groups collected in 2 study stages were coded and analyzed thematically in NVivo10, following audio-recording, transcription and translation from local languages. Interviews were conducted by non-VOICE social scientists in offsite locations.

**Results:** Women at all sites apparently understood the importance of daily product use and honest reporting, but widely acknowledged that research participants lie. While some indicated there were “habitual liars,” many emphasized that telling the truth about product nonuse was “very difficult” and described how participants felt ashamed of admitting nonuse because they had not followed study instructions and then “wasted” (discarded) products. Some participants spoke of selling unused products. Women were afraid of being reprimanded, “talked about” or scolded by trial staff, particularly nurses, but yet most acknowledged that staff were friendly and non-punitive. Many narrators were analogous to pupil/teacher relationship dynamics, whereby participants wanted their behavior to appear “good” and believed that the truth about product nonuse would lead to being “expelled” from the study. Early study termination was primarily undesirable because of reimbursement money, and not wanting to “fail.” Many suggested realistic blood-monitoring during trials would improve use and honest reporting. Narratives of dishonesty suggested a wider social context of hiding products from partners and distrust about relationships engage in more extrarelational sex. The remaining three studies evaluating number of partners) in HIV-negative adults in SSA.

**Background:** Evidence from three studies suggests that HIV-negative partners in serodiscordant relationships engage in more extrarelational sex. The remaining three studies evaluating number of partners (n=13) and social desirability bias (n=12). Pooling of data was prohibited by marked heterogeneity in study outcome measures. However, many studies showed improvements in both condom use (n=11) and number of partners (n=15), while only one study demonstrated slightly increases in risk behaviour with condom use. Members from the general population appear to undergo modest improvements in risk behaviour and to sustain these over follow-up periods of 12-24 months. In contrast, evidence from three studies suggests that HIV-negative partners in serodiscordant relationships engage in more extrarelational sex. The remaining three studies evaluating number of partners found negligible changes post-testing.

**Conclusions:** With the exception of serodiscordant couples, we have found little evidence suggesting that awareness of one’s serostatus causes behavioural disinformation among HIV-negative individuals. Promisingly, there is reasonable evidence that testing can result in improvements in risk behaviour. Further studies have implications for UTT in SSA as well as future modelling studies. Future work should include qualitative studies exploring the determinants of behavioural modification and the precise role of counselling in driving these changes.

**Prevention for the general population**

**TUPEC529**

**How do HIV-negative individuals in sub-Saharan Africa change their sexual risk behaviour upon learning their serostatus? A systematic review**

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**Background:** HIV/AIDS poses a significant public health burden on sub-Saharan Africa (SSA). While mathematical modelling studies have highlighted the potential of universal testing and treatment (UTT) as an HIV elimination strategy, behavioural patterns of the majority HIV-negative population are often overlooked. We aimed to determine how sexual risk behaviour of HIV-negative individuals in SSA changes upon learning their serostatus.

**Methods:** We systematically reviewed the published literature according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Two electronic databases - EMBASE and Medline - were searched for studies published between 2004 and 2014. We included studies that measured quantitative behavioural changes (condom use or number of partners) in HIV-negative adults in SSA.

**Results:** From 2185 unique citations, 14 studies representing 29,668 participants met our inclusion criteria. Most studies were at high risk of sampling bias (n=13) and social desirability bias (n=12). Pooling of data was prohibited by marked heterogeneity in study outcome measures. However, many studies showed improvements in both condom use (n=8 of 13) and number of partners (n=5 of 11), while only one study demonstrated slight increases in risk behaviour with condom use. Members from the general population appear to undergo modest improvements in risk behaviour and to sustain these over follow-up periods of 12-24 months. In contrast, evidence from three studies suggests that HIV-negative partners in serodiscordant relationships engage in more extrarelational sex. The remaining three studies evaluating number of partners found negligible changes post-testing.

**Conclusions:** With the exception of serodiscordant couples, we have found little evidence suggesting that awareness of one’s serostatus causes behavioural disinformation among HIV-negative individuals. Promisingly, there is reasonable evidence that testing can result in improvements in risk behaviour. Further studies have implications for UTT in SSA as well as future modelling studies. Future work should include qualitative studies exploring the determinants of behavioural modification and the precise role of counselling in driving these changes.
TUPEC530
Development and initial validation of an instrument to measure beliefs among women in Puerto Rico about biomedical interventions and the biological factors that facilitate inbounds and outbound HIV transmission
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Background: High rates of sexual mixing with MSM contribute significantly to the HIV burden among women in San Juan, Puerto Rico, where female HIV incidence is attributed primarily to heterosexual contact (67%). Some women do not possess accurate beliefs about the biomedical interventions inhibiting transmission or biological variables enhancing transmission. Knowledge in these areas could potentially increase HIV prevention behaviors. This study developed and initially validated a Spanish-language instrument measuring beliefs about HIV transmission in the presence of the following: factors facilitating inbound transmission (STIs/oral infections, adolescent cervical ectopy, postmenopausal elevated CCR5 expression, and hormonal contraception), factors facilitative of outbound male to female transmission (viral load and STIs), and PEP and HAART efficacy.

Methods: Women recruited via social media (N = 100) in October, 2014, responded to a 67-item Likert scale, illustrating scenarios of unprotected vaginal intercourse in the presence of varying biological risk factors or biomedical interventions. Responses were based on their opinion about HIV transmission likelihood. Principle Component Analysis (PCA) was used to perform dimension reduction, and to confirm internal validity.

Results: The majority of respondents were Hispanic (94%), ages 21-30 yrs (72%), with no children (67%), and a baccalaureate degree or beyond (72%). Reliability analysis indicated that the instrument is internally consistent (Cronbach’s Alpha > .5). PCA revealed four respective sub-dimensions, accounting for 71% of total variance, related to beliefs about HIV transmission in the presence of the following: biomedical interventions (BMI), STIs and infections (STII), hormonal contraception (HC), and outbound infectivity (O). Most respondents did not possess accurate beliefs about the augmented inbound risk of HIV infection during adolescence (70%), or post-menopause (79%); nor did they perceive heightened risk in the presence of hormonal contraception (74%), or STIs/oral infections (60%). The majority had incorrect beliefs about PEP (89%) and PEP (82%); and most participants did not relate HAART non-adherence to transmitted drug resistance (62%).

Conclusions: Results suggest that this brief, Spanish-language, clinically-administered measure of women’s beliefs about factors facilitating or inhibiting HIV transmission may contribute to knowledge-based interventions helping women adopt prevention behaviors. Further scale validation is recommended on a larger, less homogenous Hispanic population.

TUPEC531
Factors associated with uptake of HIV counseling and testing in Cross River State, Nigeria
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Background: HIV counselling and testing (HCT) is a key intervention strategy for effective HIV control in most developing countries as it increases access and knowledge of HIV status, encourages safer sex and is an entry point for HIV care treatment and support services. We determined factors associated with uptake of HCT among the general population in Cross River state.

Methods: The survey sampled females aged 15-48 years and males aged 15-64 years in Cross River State using probability sampling. Interviewer administered questionnaire was used to obtain data on HCT uptake and assessed using a cross-sectional analysis. Logistic regression was used to identify factors associated with uptake of HCT while controlling for potential confounding factors.

Results: A total of 950 respondents were surveyed with equal representation of both male and female (50%). Majority of respondents had at least secondary level education (73%) and were older than 24 years (65%). Overall, uptake of HCT was 62%, with more females than males ever tested for HIV (66% vs. 59%, p<0.04). Compared to those with no formal education, those with primary (AOR=2.11, 95%CI:1.30-3.44), secondary (AOR=4.14, 95%CI:2.55-6.73) and tertiary education (AOR=5.73, 95%CI:3.02-10.88) were more likely to have ever tested for HIV. Females (AOR=1.40, 95%CI:1.06-1.86) compared to males and those with comprehensive HIV knowledge (AOR=2.66, 95%CI:1.99-3.57) were more likely to have ever tested for HIV. Compared to those who were currently married/cohabiting, singles were less likely (AOR=0.67, 95%CI:0.45-0.98) to have ever tested for HIV. Compared to those aged <25 years, those aged >=25 years were more likely to have ever tested for HIV (95%CI:0.45-0.98) to have ever been tested for HIV. Compared to those who were currently married/cohabiting, singles were less likely (AOR=0.67; 95%CI:0.45-0.98). Compared to those who were currently married/cohabiting, singles were less likely (AOR=0.67; 95%CI:0.45-0.98). Compared to those who were currently married/cohabiting, singles were less likely (AOR=0.67; 95%CI:0.45-0.98). Compared to those who were currently married/cohabiting, singles were less likely (AOR=0.67; 95%CI:0.45-0.98).

Conclusions: Results suggest that brief, Spanish-language, clinically-administered measure of women’s beliefs about factors facilitating or inhibiting HIV transmission may contribute to knowledge-based interventions helping women adopt prevention behaviors. Further scale validation is recommended on a larger, less homogenous Hispanic population.

TUPEC532
HIV decline associated with changes in risk behaviors among vulnerable young people in Nepal: analysis of population-based HIV prevalence surveys between 2001-2012
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Background: Objective of the study was to assess changes in HIV risk behaviors and HIV prevalence among young key populations in Nepal, through repeated anonymized unlabeled HIV prevalence surveys.

Methods: A total of 7505 young key populations aged 18-24 years [2767 injecting drug users (PWID); 852 men who have sex with men/transgender (MSMTG); 2801 female sex workers (FSW) and 1035 male labour migrants (MLM)] were recruited randomly over a 12-year period, 2001-2012. Local epidemic zones in Nepal were analyzed separately.

Results: We found a very strong and consistent decline in HIV prevalence over the past decade in all local epidemic zones in Nepal among most young vulnerable groups: PWID (from 32% to 1%, p<0.001), MSM (from 4% to 1%, p<0.001) and FSWs (from 3% to 1%, p<0.01). Change in mean age at starting first injection and frequency of injection among young PWID were dissimilar across the epidemic zones. Young MSM/TG with knowledge of HIV/AIDS was increased over time but no change was observed in mean age at starting anal sex. The age at starting labor work abroad was decreased overtime among young MML and the knowledge of HIV/AIDS was low among them (<12%). A variation in places to solicit clients was observed differently across local epidemic zones among young FSW.

Conclusions: In Nepal, the decline in HIV prevalence was consistent and most likely associated with an increase in use of condoms and safe needles/syringes. The large reduction in HIV related risk behaviors may have resulted from available interventions (peer education, HIV testing and counselling, harm reduction programme), and continuation and expansion of such interventions is recommended in Nepal.

TUPEC533
Using peer to peer approach to promote uptake of HIV/SRH services among young people (10-24 years): experience with young key populations (YKPs) in 3 central districts of Uganda
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Background: Young people from key populations including People living with HIV, men having sex with men, sex workers, fisher folks and bodaboda/ truck drivers between 14-24 years were selected and equipped with knowledge and skills, through basic training in SRH/HIV integra-
Among the different YKPs.

out to fellow peers. However there is need for further studies to ascertain its effectiveness.

conclusions:

before to 5996 after the intervention.

7,519 after the intervention and those between 20 and 24 years increased from 4,896 before to 14,885 after the intervention. Highest impact was registered among the fisher folks from 37 before to 5996 after the intervention.

Conclusions: Peer to peer approach seems to yield high return and could be effectively used to increase uptake of HIV/SPR services among YKPs if they are well facilitated to reach out to fellow peers. However there is need for further studies to ascertain its effectiveness among the different YKPs.

TUPEC534

Street culture, survival and HIV risk among street-connected girls in a resource-limited setting


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Background: The objective was to describe how the culture and survival strategies of street connected girls and adolescent women (SCGAW) in Eldoret, Kenya, put them at high risk for HIV.

Methods: This qualitative study was conducted from August 2013 to February 2014. A total of 65 street connected boys and girls aged 11-24 years were purposively sampled from the three referral points: 1) A dedicated study clinic for vulnerable children and youth at MoI Teaching and Referral Hospital; 2) Primary locations in which street children reside “bases/barracks”; 3) Street youth community-based organizations.

In-depth interviews and focus group discussions were used to collect data. All data were audio recorded, transcribed, translated to English, and a content analysis performed.

Results: A total of 31,522 YKPs including 16,486 males and 15,036 females were reached in the 8 months with 7,495 and 24,027 accessing services before and after the intervention respectively. YKPs between 10 and 14 years accessing services increased from 476 before to 1,620 after the intervention, those between 15 and 19 years increased from 2,123 before to 5,519 after the intervention and those between 20 and 24 years increased from 4,896 before to 14,885 after the intervention. Highest impact was registered among the fisher folks from 37 before to 5996 after the intervention.

Conclusions: Peer to peer approach seems to yield high return and could be effectively used to increase uptake of HIV/SPR services among YKPs if they are well facilitated to reach out to fellow peers. However there is need for further studies to ascertain its effectiveness among the different YKPs.

Themes $Sub-Theme$ $Quotes$

Initiation rituals $Girls viewed as sexual object$ Female (20 years): The boys at the base must also welcome the girl by raping her although she agrees with one of them, he can take her as the wife and then he will be the one to protect her.

Initiation rituals $Low self-esteem$ Female FGID (14-17 years): Yes, because the same was done to me. It harders her. I will accept it because I want her to feel what I felt—okay, aha. (Interviewer: So you will allow your man to do a combination (gang rape) on another girl because the same was done to you?!) I will accept.

Rape $Normalization of rape$ Female (21 years): Yes rape is acceptable. If you are being forced to have sex or being...raped by a fellow street boy and another person passes there and sees the action, he...will just tell you to cooperate and finish but will not interfere. Even the leaders of the ...base cannot help. He will just tell the boy to give him something small so that he doesn't...call a group of boys to beat him.

Rape $Managing unry girls$ “...you can even threaten her with a knife or jumppanga...” (Interviewer: what is jumppanga?)...catching her on the throat with your elbow...oh (Interviewer): jumppangata?... (Respondent): you can be like two boys. He holds her while you rape her and after that you exchange positions...(Interviewer: okay, who most rape girls?... The big boys...big in age or size?... people around my age...” (Male, 20 years).

Rape $Lack of law-enforcing structures at society level$ Make FGID (18-24 years): You know “Gasa” is just a name for a police, if you are “mshela”(street youth) and you go to the police, they just say that you know each other... You know each other... You know streets is just considered as one thing...One thing, so if you go to the police they say you know each other, aha another one?... If you rape a girl even if she is not from the base, when she goes to report, the first thing they will ask is “where have you been raped?” And if it “managal” (SCCY boys) and they ask you if you know the person who has raped you, they also tell you that, that place is dangerous, “Why did you choose to pass through there?” so it depends on where you have been raped. So if you have been raped at the base... There is no problem; there is nothing they can do. You can’t be caught.

Promotion of Pregnancy $Satisfying male ego$ Female barricads leader 20 years: For example if you are married and your husband sees other girls on the streets with children... because most of the street girls give birth to boys, you will find your husband beating you up for no reason. He will later tell you that you don’t give birth. He will say “You don’t want to give me a child and other people’s (SCCY) mates are giving birth.” So you just have to conceive and give birth so that you make him happy and he will not beat you.

Transactional sexual encounters $Multiple sexual partners$ Female 15 years: “Yes, For example if I have a boyfriend who doesn’t give me money, I will prefer to go to the one with money. So I will have sex with the one with money to give me money then in the evening I go back to my boyfriend. My boyfriend doesn’t need to ask me where I get the money because if he doesn’t give me money and only provides is food and clothing, then what does he expect me to do.”

Misconceptions about contraceptives $Injectable contraceptives$ Female 15 years: Some girls also say that they cannot use family planning methods because they say that the injection makes people lose their fertility. And some also say that if they use a condom, it makes sex not sweet... The girls prefer condoms but boys don’t want. They (referring to the SCCY boys) have now ended up impregnating all of my friends. There are only two who are not pregnant.

Misconceptions about contraceptives $Condom-use$ Barrack’s leader 24 years: Because they tell us (referring to health educators) that condoms should not be in contact with oil but it already has oil in it. As for me, I wouldn’t advise others to do as I do, but what I know is that the hole (referring to vagina) that I enter because it’s not like I just got a woman and I enter (sex). When you find a woman and she tells you to buy a condom, you buy them then you go to the base (SCCY meeting place), and because we are known there, we take two polythene bags, we put them on before we put on the condom. They say you leave some space at the front of the condom, and then you imagine you did some sweat at your front, so the oil gets into your desk (penis)... So you find that, with the condom only even if you wanted to go 5 rounds you will only go once because of the oil... You know when you pump, your blood also gets hot and thus the desk (penis) becomes hot too and that’s when you get the oil...
TUPEC535

Understanding opportunities for HIV prevention and care for street connected children and youth in western Kenya


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Background: To effectively inform HIV prevention and care programs based on the needs of street connected children and youth (SCCY), we sought to elucidate the contextual and cultural forces that structured sexual activity and the implications for health. Methods: This qualitative study was conducted from August 2013 to February 2014 in Eldoret, Kenya. We recruited SCCY aged 11-24 years who had lived on the street for ≥3 months to participate in 25 in-depth interviews and 5 focus group discussions stratified by age and sex, that were audio recorded, transcribed, translated to English, and thematically analyzed. Results: In total we interviewed 65 SCCY: 69% were male with a median age of 18 years (IQR: 14-20.5 years), and 81.5% participants reported being currently sexually active. Sex played a central role in the context and culture for youth on the street. Commencement of sexual activity is largely driven by sexual activity making early sexual debut, multiple partners, and the ability to remain celibate realises the ends of street life. Rules based on cultural norms dictated acceptable and unacceptable sexual acts. Gender inequities were prominent in SCCY’s sexual practices and were at the core of misconceptions related to STI transmission and prevention. Boys sought sex for pleasure, power, and dominance in the street social hierarchy. Whereas for girls, engaging in sex was perceived as the primary tool for survival and protection, with little choice in the matter, resulting in profound sexual and gender-based violence. Male SCCY discussed that females were responsible for spreading STIs due to women’s hygiene, urination, and prostitution. We found that circumcision increased the risk of HIV transmission. Boys had a general distrust of condoms and perpetuated fallacies associated with their use. Conclusions: Our findings revealed many misconceptions and practices that are a result of the sociocultural context on the streets, which are essential to consider when implementing an effective HIV prevention and care program for SCCY. There is an urgent need for distinct HIV prevention programs for boys and girls focusing on sexual education.

TUPEC536

Effects of the PREPARE multi-component, school-based HIV prevention programme on adolescent sexual risk behavior and access to condoms, contraception and HIV testing: cluster randomized controlled trial (RCT)


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Background: Unwanted pregnancies and sexually transmitted infections, including HIV, are among the social and health consequences of early adolescent sexual debut and unprotected sex. We evaluated the effects of a multi-component, school-based HIV prevention intervention to delay sexual debut and increase condom use (primary outcomes), decrease HIV, and increase access to condoms, contraception and HIV tests (secondary outcomes) among young adolescents in the Western Cape, South Africa. Methods: During 2013-2014 we conducted a cluster RCT among Grade 8 students in 42 randomly selected public high schools. After agreeing to participate, schools were randomly allocated to intervention or comparison arms. In intervention schools we implemented a 21-session after-school sexual health educational programme, school health service and school sexual violence prevention programme. Comparison schools had usual care. Participants completed questionnaires at baseline, 6 and 12 months. Regression was undertaken to provide outcomes at 6 and 12 months with ORs for dichotomous variables and coefficients for continuous variables, adjusted for baseline demographics, the baseline measure in question and clustering. Results: One school dropped out before data collection. Of 6244 sampled adolescents in 41 schools, 3451 (55.3%) had signed parental consent and assented to participate. Retention at 12 months was 87.6%. In the intervention arm 614 participants (33.6%) attended at least 50% of educational sessions and 16.0% used the health service. At 12 months, there were no differences between arms in one year incidence of sexual debut (10.6% versus 9.3%; OR: 1.09; 95% CI: 0.81-1.44), condom use at last sex (74.1% versus 80.3%; OR: 0.70; CI: 0.30-1.63), procurement of condoms or HIV tests. Participants in the intervention arm (versus comparison arm) had better knowledge (mean: 0.49; SD: 0.24 versus mean: 0.43; SD: 0.22; Beta: 0.06; CI: 0.03-0.09), were less likely to report IPV (34.6% versus 39.7%; OR: 0.77; CI: 0.61-0.99) and were more likely to have accessed contraception (24.8% versus 18.7%; OR: 1.47; CI: 1.12-1.92). Stronger effects were obtained among participants who attended more sessions. Conclusions: The intervention may not have changed some sexual behaviours, but may have led to less violent sexual relationships and lower risk of unwanted pregnancy. We need effective ways to improve intervention uptake.

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Correlates of intimate partner violence perpetration among young urban Tanzanian men

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Background: Evidence suggests that interventions with youth that prevent intimate partner violence (IPV) perpetration may also reduce HIV risk. However, to date, few studies have examined determinants of young men’s perpetration of IPV in sub-Saharan Africa. As a result, we have a limited understanding of the etiology of IPV perpetration that could inform prevention efforts. The objective of this study was to examine associations between exposure to childhood violence, alcohol use, and normative beliefs (gender role attitudes and acceptance of IPV) and physical IPV perpetration among young urban Tanzanian men. Methods: To address this objective, we used baseline data from an ongoing cluster-randomized HIV prevention trial with 1,298 men (mean age = 26), who were recruited through social clubs called “camps” in Dar es Salaam, Tanzania. Camps are stable social networks with elected leadership and mostly male members. Past-year physical IPV perpetration was assessed using an adapted version of the World Health Organization violence against women instrument. Multilevel modeling was used to examine associations between the hypothesized set of determinants of IPV and the frequency of physical IPV perpetration while adjusting for clustering within camps. Results: Decreasing age (p = 0.005, p < 0.02) and increasing number of past-year sexual partners (p = 0.027, p < .0001) were associated with increasing IPV perpetration. Men who were married (p = 0.098, p < 0.05), reported having experienced sexual violence before the age of 12 (p = 0.237, p < .0001), or had ever consumed alcohol (p = 0.109, p < 0.001) reported higher levels of IPV perpetration than men who were unmarried, had not experienced childhood sexual violence, and had never used alcohol, respectively. More equitable attitudes towards gender roles were negatively associated with IPV perpetration, but this association was attenuated to non-significance when attitudes towards IPV were added to the model. Less accepting attitudes towards IPV were protective of past-year IPV perpetration (p = 0.046, p < 0.05). Conclusions: Interventions seeking to reduce HIV among Tanzanian men should target youth and aim to eradicate childhood exposure to sexual violence, prevent alcohol use, and change attitudes towards partner violence. While more research is needed, changing attitudes specifically related to violence may be more effective than more broadly shifting gender norms.

TUPEC538

Optimising adolescent HIV care in a large Kenyan care and treatment centre

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Background: The global increase in adolescent HIV-related deaths between 2005 and 2011 has been attributed to lack of prioritization of adolescents in national HIV programmes. In 2013, the Kenya Ministry of Health (MOH) developed and piloted a standardized adolescent package of care (APoC) for adolescents living with HIV/AIDS (ALHIV). Although the MOH has not rolled out the APoC, Kenyatta National Hospital (KNH) fully rolled out APoC in February 2014. We evaluated quality of care of ALHIV following the implementation of the package at KNH.
Toward adolescent friendly voluntary medical male circumcision services: older adolescents report relatively less satisfaction with counseling

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Background: Voluntary Male Male Circumcision (VMMC) is a WHO recommended HIV prevention strategy, with HIV counseling and testing (HTC) and VMMC counseling forming part of this comprehensive prevention package. Majority of the VMMC clients in Tanzania (75%), as in most countries, are adolescents aged 10-19 years; however there are younger and older boys at different sexual maturity stages, with potentially different needs for information. This presents counselors with a challenge and has the potential to result in variations in client satisfaction with counseling.

Methods: 320 VMMC clients aged 15 years and above and from 11 purposefully sampled health facilities (out of a total of 25 facilities) were observed during service and interviewed afterwards, as part of a cross sectional study conducted in Iringa and Njombe regions, Tanzania in 2013 to examine integration of HTC within VMMC services. STA12.1 was used for analysis to calculate percentages; construct client satisfaction scale; X2 test was applied to look for significance.

Results: Mean age of participants was 22 years (15-64 years). Overall client satisfaction with counseling was high; a minimum of 87% of clients agreeing or strongly agreeing that the counselor had met individual assessed criteria. However, 18-19 year olds reported being relatively less satisfied in comparison to other age groups (see table below). Assessment of individual items in the satisfaction scale reveals a consistent lower rating by 18-19 year olds (p<0.05). There was improved documentation of key client care indicators including family and social assessment (84.6% to 91.5%, p<0.001), Tanner staging (2.0% to 16%, p<0.001), mental status (27.7% to 55.7%, p<0.001) and health information provision (0.4% to 52.2%, p<0.001). Condom provision improved from 5.7% to 9.1%, p=0.047 for all adolescents. Incremental disclosure assessment increased from 22.3% to 84.4%(p<0.001). The proportion of adolescents with completed disclosure increased from 10.9% to 55.3% (p<0.001) after controlling for baseline characteristics.

Conclusions: Implementation of a comprehensive package of care with optimization of adolescent focussed components can contribute to improved quality of care and outcomes. Long term impact on treatment outcomes and quality of life of HIV infected adolescents require further evaluation.

TUPEC540
The impact of food insecurity on sexual HIV risk negotiation with clients by youth sex workers living with and affected by HIV

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Background: Previous research has determined that food insecurity is associated with heightened vulnerability to HIV and reduced access and retention in HIV care. Much of this research has been conducted in resource-poor countries, with limited data from resource-rich settings, despite evidence that food insecurity is concentrated among key affected populations, such as youth and sex workers (SWs). The objective of this research was to longitudinally examine the independent effect of food insecurity on sexual HIV risk negotiation with clients among youth SWs (aged 14-29 years) in Vancouver, Canada.

Methods: Longitudinal data (baseline and six biannual follow-up questionnaires) was drawn from An Evaluation of Sex Workers’ Health Access (‘AESHA’), a prospective community cohort of 723 street and off-street SWs between 01/2010-08/2013. Youth and adult SWs are recruited through street, indoor and online outreach to sex work venues. Bivariable and multivariable generalized estimating equations (GEE) logistic regression was used to examine the independent effect of measures of food insecurity (e.g. modified Radimer/Cornell Food Insecurity Scale; such as food-related financial concerns/cost of food; concerns of food running out; exchanging sex for food) and client condom refusal.

Results: Of the 708 SWs included in this study, 220 (31.1%) were youth, contributing 639 observations over the 3.5-year study. Of the 220 youth SWs, 34.6% (n=76) reported client condom refusal during the study period. In multivariable GEE analysis, after adjusting for other HIV risk pathways (e.g. injection and non-injection drug use; client sexual/physical violence), financial food insecurity retained an independent effect on client condom refusal (adjusted odds ratio: 2.19, 95% confidence interval: 1.28-3.74).

Conclusions: Despite food banks and charitable food sources in a high-income setting, one third of youth were considered food insecure. This study underscores the necessity of access to nutritious food for marginalized youth, HIV/STI education and services among youth involved in sex work, and food security for youth as a prerequisite to positive health outcomes for those both living with and affected by HIV. This research highlights the need for youth-centered programs to address the social determinants of health, including food security, that are directly linked to HIV risk negotiation and access to treatment.
take root; (2) established: drug use has existed for some time; or (3) pervasive: drug use is spreading into new sub-groups/areas.

Results: We conducted 436 in-depth interviews from September 2013 to August 2014, corroborating that drug use increasing across all regions, with rapid increases in female PWID. Most PWID were 15-35 years and worked as bus touts, laborers, fisher men, miners or sex workers to stoke or survive or support their habit; most were concentrated around bus stops along the coastal transit corridor, in abandoned buildings, and in low-income residential areas. A minority of “invisible” PWID were reported among military officers, police, or working-class people. In Dar es Salaam, the most commonly used drug was smoked alone or combined with tobacco and heroin (“cocktail”). Heroin was available in all regions and reported to originate from Dar es Salaam. Cocaine was less common, likely due to high price and variable availability. Substances such as petrol, shoe polish, and glue were used as inhalants; diazepam misuse was common. Regional findings are reported in Table 1.

TUPEC543

Urgent need for harm-reduction interventions in Mozambique: results from the Integrated Biological and Behavioral Surveillance Survey among people who inject drugs

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Background: While studies highlight the importance of a comprehensive package of harm-reduction interventions to reduce HIV transmission among people who inject drugs (PWID), little is known about behaviors among PWID in Mozambique that increase their risk of HIV infection. Mozambique conducted its first Integrated Biological and Behavioral Surveillance (IBBS) Survey in 2014 using respondent-driven sampling to estimate HIV prevalence and associated risk behaviors among PWID.

Methods: Survey implementation occurred in two major urban areas: Maputo (n=353) and Nampula/Nacala (n=139). Specimens were collected for STI testing and a behavioral questionnaire was administered to PWID, defined as anyone ever having injected drugs. We present RDSS-derived point estimates.

Results: Participants were mostly male (94.1% and 97.1% from Maputo and Nampula/Nacala, respectively) with mean age of 22 (range 19-56) and 28 (range 18-60). HIV prevalence was 50.3% and 36.8%, while 7.5% and 7.6% screened positive for hepatitis B, and 44.6% and 7.5% screened positive for hepatitis C. STI symptoms or diagnosis in the last 12 months was reported by 9.6% and 38.4%, of which 61.7% and 77.3% sought treatment. Contact with an HIV peer educator was reported by 9.5% and 40.8%, while 26.8% and 60.0% received condoms in the past 12 months. Access to new injection equipment was reported by 98.6% and 78.9%, however, 53.9% and 65.9% reported needle sharing; of those who injected in the past 30 days, 10.8% and 8.0% injected with a used needle at last injection. Among those who had sex in the last 12 months, non-condom use at last sex was reported by 47.6% (n=121) and 68.9% (n=93), while 11.4% (n=47) and 10.3% (n=20) received condoms in exchange for sex.

Conclusions: PWID are at high risk of HIV infection in Mozambique. A comprehensive package of harm-reduction interventions, with consideration of regional differences, is urgently needed to reduce the risk of infection among this population. Mozambique can gradually introduce harm-reduction policies beginning with enhanced peer education programming targeting PWID, distribution of safe injection kits and integrated HIV and STI health services within addiction treatment services. Additional studies are required to assess the feasibility of needle and syringe programs or opioid substitution therapies in Mozambique.

TUPEC544

Seek, test, treat and retain (STTR) for people who inject drugs (PWID) in Kenya: findings from the third intervention period of a stepped wedge study

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Background: HIV infections in sub-Saharan Africa increasingly occur among people who inject drugs (PWID). Needle and syringe programs (NSPs) and PWID-specific ART support have been nearly non-existent, though Kenya is among the first to implement NSP at a country-wide level starting in 2013. The World Health Organization (WHO) recommends earlier antiretroviral therapy (ART) to enhance viral suppression among persons at high risk of transmission including people who inject drugs (PWID). We present data from an implementation science study to improve testing, linkage and retention in HIV care of PWID in Kenya.

Methods: Evaluation is being done using a stepped wedge cluster-randomized design. We are using respondent-driven sampling (RDS) to reach PWIDs for HIV-1 prevalence and...
viral load determination [SEEK]. We continue collecting study data in additional time periods as PWID service sites roll out, including behavioral data collected using tablets, rapid HIV testing [TEST], POC CD4 determination for HIV-positives, and assignment of peer case managers [PCMs] to those with CD4 < 500µl to link to ART with adherence [TREAT]. Both PCMs and PWD will receive small conditional cash transfers for PWD adherence to HIV care visits [RE- TAIN]. Recently, we added phyllogenetics and Hepatitis C Virus testing to our methods.

Results: 1346 individuals were screened during the third intervention period with 1293 found to be eligible and enrolled (91.1%). Most enrolled participants were male (88.2%). Median age was 22 years, age ranged from 15 to 82 years. Median age at first injection was 27 years. 213 of 1293 (16.5%) were HIV-positive. About 14.1% (n = 30) of those with HIV infection (n = 213) were newly diagnosed by our study. 54 participants were eligible to be assigned to a PCM and initiate ART. Of those, 50 initiated ART, 49 successfully continued on ART, 0 stopped taking ART, and 1 died. Thus 98% were retained in care (48/49 retained).

Conclusions: Current Kenyan guidelines restrict access to ART among PWD. The combination of RDS and rapid testing is an effective strategy for finding PWD with HIV infection, including those not previously diagnosed. Linkage to care by PCMs has been very effective for ART initiation and retention.

**TUPEC545**

More vulnerability, more risk: findings from a cross-sectional qualitative study on the multiple vulnerabilities experienced by people who inject drugs (PWD) in Bihar and Manipur, India

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**Background:** While sexual transmission remains the primary mode of HIV transmission in India, drug users are also disproportionately affected. People who Inject Drugs (PWD) are at high risk of acquiring HIV and other blood-borne viruses, such as Hepatitis B and C. Studies report that unsafe injection practices along with low condom use put PWD at dual risk for HIV. As part of the Hridaya programme, the Indian component of the five-country, Dutch government-funded Community Action on Harm Reduction initiative (CAHR), operational research was conducted to gain in-depth knowledge on multiple vulnerabilities for HIV acquisition among PWD in the states of Bihar and Manipur.

**Methods:** A cross-sectional qualitative study was conducted with PWD in two Hridaya programme states, Bihar and Manipur. A total of 40 in-depth interviews were undertaken with PWD diagnosed with HIV recently (2010-2013). Four focus group discussions with PWD and with female injecting drug users (FIDUs), spouses and partners of PWD were conducted. Lastly, ten key informant interviews were conducted. Atlas 8 software (version 7) was used to code and categorise data into themes. In thematic analysis, the various topics that emerged from the interviews were analysed.

**Results:** Findings showed that there is overlap between injecting networks and sexual networks. Within injecting networks, each and every aspect — from the type of substances used, the sourcing of substances, and the accessing of harm reduction services to the interaction of social, structural, political-legislative barriers — has the potential to contribute to vulnerability of PWD. Similarly, sexual networks of PWD constitute a complex web in which HIV awareness is in conflict with actual behaviour to access prevention services and disclose HIV status. Partners or spouses of PWD are also at higher risk which further increases the vulnerability of both PWD and their spouses/partners.

**Conclusions:** The interventions required to achieve harm reduction with PWD are complex. Injection drug use needs to be understood holistically, considering (a) the reasons for drug use in a particular community; (b) the options and opportunities for intervention; and (c) the necessity for support provided in a non-judgemental and sensitive way through peers, service providers, families and the community.

**TUPEC546**

Reach them early: identifying risk behaviours after onset of injecting to reduce sharing of injecting equipment: findings from the Hridaya drug use pattern assessment in India

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**Background:** Injecting drug use has emerged as an important route for HIV transmission in India. There are an estimated 200,000 People Who Inject Drugs (PWD) in India with an HIV prevalence of 7.14% (NACO, 2011). Injecting drug users are vulnerable to HIV infection due to risky injecting practices. The pattern of drug use through injecting and its association with vulnerability to blood-borne infections have not been well studied in Indian settings. As part of the Hridaya programme, the Indian component of the five-country, Dutch Government-funded Community Action on Harm Reduction initiative, India HIV/AIDS Alliance conducted a Drug Use Pattern Assessment to understand the profile of PWD, their patterns of drug use and risk behaviours, and the accessibility and availability of harm reduction services among PWD.

**Methods:** A multi-site, cross-sectional study was conducted with a mixed-methodology (quantitative and qualitative) approach. A total of 1,091 semi-structured interviews and 65 FGDs with PWD, and 34 key informant interviews were conducted in four states (Bihar, Haryana, Jammu and Uttarakhand). Respondents for semi-structured interviews were selected through simple random sampling using client information available from partner NGOs. Appropriate analytical techniques were employed using SPSS 20.0.

**Results:** 20% of PWD respondents initiated illegal injection at the age of 18 years or less. PWD respondents started injecting illicit drugs at the mean age of 23, after a progression from initial illicit substance use at the mean age of 16 and non-injecting illicit drug use at the mean age of 19. Of the 35% of respondents who shared injecting equipment, 88% had shared injecting equipment within one month of onset of injecting practice. Ever shared injecting equipment is significantly higher among those initiated illegal injection at earlier age (18 years or less) when compared with those who started illegal injection above 18 years old (p<0.05).

**Conclusions:** Though it takes a mean of seven years from the first illicit drug use to onset of injecting illicit drugs, sharing injecting equipment happens within one month of onset of injecting. In addition to early identification of PWD, appropriate strategies need to respond to client’s specific stage of substance use to reduce vulnerability towards HIV.

**TUPEC547**

Effective services for HIV prevention among people who inject drugs (PWDs) in Ukraine

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**Background:** HIV epidemic in Ukraine was estimated to be one of most rapidly growing in Europe and was driven primarily by PWD. Since 2003 Ukraine has been implementing nationwide prevention programs for PWD. In 2013 196,460 PWDs received HIV prevention services (63% of estimated population size). The study explores the level of HIV seroconversion and the most effective HIV services for its prevention.

**Methods:** Data on HIV test results were collected during 2013 using program monitoring database (SYREX) of ICF “International HIV/AIDS Alliance in Ukraine” which accumulates national data on prevention service provision. PWDs who were tested for HIV 2 or more times with the first negative result were included into analysis (n=33,000). 19,677 PWDs were tested twice during 2013. 7,792 PWDs had 3 tests and 5,531 PWDs had 4 and more HIV tests during the year. Regression analysis was performed to define the association between number and typology of services received and HIV seroconversion.

**Results:** Among all HIV negative IDUs in the cohort seroconversion occurred in 3% cases. The majority of new HIV positive cases occurred between first and second test (65%), 23% of additional infections occurred between second and third test, 5.5% between third and fourth, and 7.5% between fourth more rounds of testing. Consultation of outreach worker turned out to be the most effective method to prevent HIV, even once consultation in a year decreased the odds to be HIV-infected by almost 2 times (OR=2.3 [1.3; 4.0]). The syringe and condom distribution programs also have shown their effectiveness: increasing the number of distributed syringes (OR=3.65 [1.35; 9.8]) and condoms (OR=3.14 [1.5; 7.7]) decreased the odds to have HIV seroconversion. Needles separated distribution as well as distribution of informative materials did not have significant influence on seroconversion (p>0.05).

**Conclusions:** The analysis presents the complex array of the level of service effectiveness for PWD. The motivation to safer behaviour formed through outreach worker’s consultations together with syringe and condom distribution are significantly associated with negative HIV test results.

**TUPEC548**

Exploring HIV risks and treatment outcomes among people who use drugs enrolled in unregulated recovery house programs in British Columbia, Canada's Lower Mainland region: a qualitative study

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**Background:** The treatment of drug dependence has been increasingly identified as critical to reducing drug-related HIV risks and promoting optimal HIV treatment outcomes. Across North America, largely unregulated group housing programs operating under abstinence-based (e.g., 12-step) models, known as Recovery Houses, are among the most commonly available drug treatment programs. In British Columbia (BC), Canada, Recovery Houses are not
regulated and operate with little oversight from health authorities. Despite the proliferation of Recovery Houses, little research has been undertaken examining their impacts on drug-related outcomes, including HIV-related outcomes. We undertook this study to explore how the regulatory contexts and treatment approaches of Recovery Houses in BC’s Lower Mainland region influence HIV-related outcomes.

**Methods**: We conducted qualitative interviews with 27 people who use drugs (PWUD) who reported enrolment in Recovery House programs within the previous five years. These individuals were recruited from among participants in two ongoing prospective cohort studies comprised of HIV-negative and HIV-positive PWUD. We analyzed interview transcripts thematically and by drawing on the ‘Risk Environment’ framework.

**Results**: Participant accounts underscored how the social-structural contexts of Recovery Houses (e.g., lack of regulation, abstinence-based philosophies) fostered conditions that increased the potential for HIV risks and other adverse outcomes. Participants emphasized how many unregulated Recovery Houses promoted continued engagement in drug scene activities (e.g., injection drug use) due to their proximity to street-based drug scenes. Meanwhile, abstinence-based treatment philosophies adopted by Recovery Houses failed to accommodate participants’ drug use trajectories (e.g., lower frequency or episodic drug use) and undermined access to supports (e.g., harm reduction supplies) necessary for enacting risk reduction. In turn, our findings underscore how this interplay of social and structural factors fostered high-risk drug use practices within Recovery Houses (e.g., syringe-sharing), while evictions stemming from breaches of abstinence-based treatment contracts resulted in cascading harms (e.g., homelessness, public injecting) that increased vulnerability to HIV risks and treatment interruptions.

**Conclusions**: Our findings underscore the potential of unregulated drug treatment programs to perpetuate adverse HIV-related outcomes, highlighting the importance of ensuring that these programs operate under evidence-based treatment models and with sufficient oversight from health authorities.

### TUPEC549

**Controlling HIV among people who inject drugs in Eastern Europe and Central Asia: Insights from modelling**

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**Background**: Although there is evidence that needle and syringe programmes (NSP), opioid substitution therapy (OST) and antiretroviral therapy (ART) reduce HIV transmission, most Central and Eastern European sub-regions still have low coverage of these interventions.

**Methods**: We conducted a modelling analysis to estimate the impact on HIV transmission of OST, NSP and ART in St. Petersburg (Russia), Tallinn (Estonia) and Dushanbe (Tajikistan). For each site, we estimated the coverage needed of each intervention separately or in combination to:

1. achieve a 30%/50% relative reduction in HIV incidence or prevalence over 10 years; and
2. reduce HIV incidence to < 1% or prevalence < 10% after 20 years.

A sensitivity analysis for St. Petersburg considered the implications of including varying degrees of risk heterogeneity or sexual HIV transmission, as well as assuming the initial acute phase of HIV does not have such heightened HIV transmission risk.

**Results**: Among 1,038 participants, 826 (82%) reported engaging in risky income generation activities at some point during the study period. Drug dealing was the most prevalent form of income generation (52%). Factors positively and independently associated with risky income generation included: homelessness, high-intensity stimulant drug use, binge drug use, non-fatal overdose, interactions with police, and experiencing violence; regular employment was negatively associated with the outcome (all p < 0.05). Among those who reported risky income generation, 440 (55%) were willing to give up these income sources if they did not need money to purchase drugs, and those who reported drug dealing were most likely to give up this income source (n=283, 64%). These young people were significantly more likely to be older, homeless, engage in high-intensity drug use, have interactions with police, and have recently accessed addiction treatment (all p < 0.05).

**Background**: Although youth who are street-involved face increased risk of HIV infection through a range of social and structural factors, little is known about the HIV risks associated with deriving income from illegal and risky quasi-legal sources. This study investigates risky income generation activities among a sample of street-involved youth.

**Methods**: Data were collected between 2005 and 2012 from the At-Risk Youth Study (ARYS), which is a prospective cohort study of street-involved youth aged 14-26 in Vancouver, Canada. Generalized estimating equations were used to identify factors associated with risky income generation defined as reporting income from dealing drugs, sex work, recycling, squats, pan-handling, theft, robbing, stealing, or other criminal activities. We also examined which sources of income respondents would eliminate if they did not require money to purchase drugs.

**Results**: Among 1,038 participants, 826 (82%) reported engaging in risky income generation activities at some point during the study period. Drug dealing was the most prevalent form of income generation (52%). Factors positively and independently associated with risky income generation included: homelessness, high-intensity stimulant drug use, binge drug use, non-fatal overdose, interactions with police, and experiencing violence; regular employment was negatively associated with the outcome (all p < 0.05). Among those who reported risky income generation, 440 (55%) were willing to give up these income sources if they did not need money to purchase drugs, and those who reported drug dealing were most likely to give up this income source (n=283, 64%). These young people were significantly more likely to be older, homeless, engage in high-intensity drug use, have interactions with police, and have recently accessed addiction treatment (all p < 0.05).

**TUPEC550**

**HIV risk factors associated with risky and illegal income generation among street-involved youth in a Canadian setting**

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**Background**: Although youth who are street-involved face increased risk of HIV infection through a range of social and structural factors, little is known about the HIV risks associated with deriving income from illegal and risky quasi-legal sources. This study investigates risky income generation activities among a sample of street-involved youth.

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Prevention for male, female and transgender sex workers

TUPEC552
Interventions for commercial sexual workers: lessons and challenges from Rakai, Uganda

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Background: Commercial Sex Workers (CSWs) face a high burden of risk and other sexually transmitted infections (STIs). Despite this, coverage with prevention, treatment and support programs remains low among CSWs. We present data on the uptake of HIV prevention, treatment and support services among CSWs in Rakai District, Uganda following an intervention program scaling them.

Methods: Groups of up to 25 CSWs were identified in trading centres using local leaders and snowball sampling who were engaged in group discussions. Topics included self-assessment, of risk associated with HIV testing and counseling (HTC), and linkage into HIV/STI care and treatment. CSWs were offered free HTC services and HIV-positive tests were linked to HIV care using existing referral systems. HIV counselling visits health facilities after one month and to ascertain linkage to HIV care.

Results: Data collection included ACASI, qualitative face-to-face interviews, and blood tests for HIV, CD4. Topics explored in interviews were: sexual behavior, HIV risk and prevention, gender identity, stigma and violence among commercial sex workers in chennai, India

As personal and relational behavioral factors related to HIV risk behavior. Social, cultural and policy issues surrounding TGW revealed HIV prevention attitudes, risk and health-promoting behaviors that could inform interventions. Stigma and violence were reported by almost all respondents. One participant mentioned, “They called me "Devil" and wanted to kill me, they told mum that we don’t want to associate with your child . . . I was sent away from home and my mother felt very bad and didn’t know what to do . . . my mother’s house was burnt down; they tortured and beat me.”

Conclusions: There are no estimates of TGW population size in Uganda or the region, estimates might suggest TGW are <1% of general population. Our qualitative findings highlight the urgency to target this hidden key population with innovative, comprehensive and effective HIV prevention interventions that address high-risk behaviors such as inconsistent condom use, multiple partners, and structural issues of stigma, violence and alcohol use.

TUPEC554
Transcational sex and the challenges to safer sexual behaviors: a study among male sex workers in Chennai, India

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Background: Male sex workers (MSWs) are a significant but invisible population in India with elevated levels of HIV/STI risk. Baseline sex-work-related risk behavior data from a pilot randomized controlled trial that aimed to decrease HIV risk behaviors among MSWs in Chennai, India are examined.

Conclusions: Risky income generation was prevalent in our sample, and associated with known social and structural risk factors for HIV, such as high intensity drug use, housing marginalization, and interactions with the criminal justice system. The majority of participants were willing to give up their risky income sources if they did not need money for drugs, indicating that increasing youths’ access to addiction treatment and low-threshold employment opportunities may reduce risky income generation and related HIV vulnerabilities.

TUPEC551
Defining public disorder: conceptual implications for HIV prevention efforts

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Background: Public disorder is commonly used to describe a variety of activities such as public injecting, public drug dealing, and homelessness or street involvement among people who inject drugs (PWID). HIV prevention interventions among PWID have often focused on reducing public disorder in an effort to reduce HIV risk. However, observers have noted that open drug scenes, while appearing ‘disorderly’, are often highly ordered spaces within which behavior is circumscribed by structural factors within strict, and often complex, shared codes of social conduct. This complexity has implications for the development and implementation of HIV prevention efforts.

Methods: We employed Rhodes’ Risk Environment Framework, as well as notions of structural violence to elucidate how definitions of public disorder impact the effectiveness of structural HIV prevention efforts. We reviewed current HIV prevention approaches, identified their underlying approach to public disorder, and assessed how this impacted their effectiveness.

Results: Structural approaches to HIV prevention generally seek to re-order spaces to produce a lower incidence or intensity of HIV risk behaviors. For example, medically supervised injection facilities seek to reduce syringe sharing by altering injection spaces, as do abstinence-based or supported housing interventions. However, the failure of certain housing interventions suggests that the provision of ‘ordered space’ to replace ‘public disorder’ can, paradoxically, increase HIV risk. For example, abstinence-based housing may reduce the frequency of public drug use, but increase risky or rushed injection drug use in an effort to evade detection.

Conclusions: The effectiveness of structural HIV prevention approaches may be impacted by their potential for unintended consequences that paradoxically increase HIV risk among exceptionally vulnerable PWID subpopulations. Such unintended consequences may result from overly restrictive definitions of public disorder that fail to identify the underlying structural and social factors that order seemingly stochastic open drug scenes. We propose a re-thinking of public disorder, which takes into account the shared codes of conduct and socioeconomic hierarchies that are embedded within drug scenes, in order to improve HIV prevention outcomes.
Methods: Between December 2013 and May 2014, 100 MSWs completed a baseline assessment. Participants were ≥18 years, and reported current sex work. We report medians (with interquartile ranges [IQR]) for continuous variables and proportions for categorical variables. Wilcoxon-Mann-Whitney tests are used to examine differences between underlying distributions of sexual behavior measures by income source.

Results: Most (76.8%) participants identified as Kothi, and 50% completed secondary education or less. Participants were engaged in sex work for 5.0 years (IQR=2.0-3.5), and earned 3,000 (IQR=2000-8000) Rupees (< 50 USD) per month from sex work. Sixty-four percent reported ever testing for HIV and 20.2% for any STI. The most common reasons for starting and continuing sex work were money (83.0% and 93.0%, respectively) and pleasure (56.0% and 50.0%, respectively). Participants reported 8.0 (IQR=3.0-15.0) male clients and 2.0 (IQR=0.0-6.0) non-paying male partners in the past month. Participants reported 7.0 (IQR=0.0-15.0) condomless anal sex acts with male clients and 3.0 (IQR=1.0-6.0) with non-paying male partners in the past month. Compared to participants who indicated an additional source of income, participants whose only source of income was sex work reported significantly more male clients in the past week (7.5 vs. 4.0, p=0.001) and in the past month (10.0 vs. 6.0, respectively, p=0.017), as well as more condomless anal sex acts with male clients (8.5 vs. 5.0, respectively, p=0.007) and non-paying male partners (5.0 vs. 2.0, respectively, p=0.024) in the past month. Nearly 70% were offered more money to not use a condom during a sex work encounter, and two-thirds reported having difficulty using condoms with clients.

Conclusions: MSWs in India engage in high levels of sexual risk for HIV/STIs. Money appears to be a driving factor for engaging in sex work and higher risk sex with clients. HIV prevention interventions should focus on increasing safe sexual practices in the face of monetary disincentives to do so.

TUPEC556
Concealment and stigma in the context of adherence to ARV therapy amongst female sex workers in Bamenda, Cameroon, a qualitative study
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Background: Good ART adherence is needed to retain drug efficacy, minimize resistance and HIV transmission. Considering the adherence procedures given by the nurse adherence is not good in HIV positive female sex workers (FSW) in Bamenda. Then the aim of our study is to describe the potential barriers to ART adherence.

Methods: Study participants included were only HIV positive FSW receiving ART at Bamenda Day Care Treatment Centre. We conducted 5 Focus Group Discussions (FGDs), 7 in-depth interviews (IDI) with FSW experiencing virological failure and 3 FGDS with health care workers. Participants were divided into three adherence groups (poor, average and good), which were mixed together during FGDS.

Results: The participants included 53 female sex workers with a mean age of 28.5. Many participants valued their CD4 counts as the ultimate test of adherence: it was notable how many patients were able to remember their first CD4 counts. Participants talked about concealment of their HIV status as a strategy to protect their clients, avoid being talked about and avoid being perceived as a burden. Behaviour designed to conceal one’s HIV status from others fell in three broad categories: not disclosing status to others, avoiding being seen taking pills, and not being seen at a HIV clinic. “I just don’t think I can handle somebody finding out, even the idea of someone finding out scares me”. Many but not all participants had experienced stigma were recurred: de-valuing, fear of contagion, gossiping, discriminating against, insulting and revealing prejudiced views. Due to this stigma, patients often chose not to disclose to those around them, which in turn created barriers to taking pills and attending clinic visits. Patients were afraid of showing visible signs of disease, as this might result in a “forced” disclosure, which provided strong motivation for adhering.

Conclusions: Perception of stigma can have both a positive and negative effect. On the one hand, FSW adhere to avoid showing visible signs of disease. On the other hand, stigma deters patients from disclosing to others which can lead to problems taking medicine and visiting clinics. Therefore the need for behaviour change communication targeting FSW.

TUPEC557
Determinants of non-condom use among female sex workers in Iran: findings of the first national bio-behavioural study
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Conclusions: Perception of stigma can have both a positive and negative effect on the one hand, FSW adhere to avoid showing visible signs of disease. On the other hand, stigma deters patients from disclosing to others which can lead to problems taking medicine and visiting clinics. Therefore the need for behaviour change communication targeting FSW.

Methods: This survey was conducted in 2010, by recruiting 372 FSW through facility-based sampling from 21 sites in 14 cities in Iran. Data were collected through face-to-face interviews using a pilot-tested standardized risk assessment questionnaire. All analyses were weighted based on the response rate and adjusted for the clustering effect of the sampling sites. A multivariable logistic regression model was constructed to investigate the determinants of non-condom use among FSW in Iran.

Results: Mean age of participants was 32, 50% had primary school educations, 36% were married, and the majority reported sex work as their primary source of income. The frequency of non-condom in the last sexual contact with their paying and non-paying partners was 36.8% (95% CI: 33.6-40.1) and 63.0% (95% CI: 58.8-67.4), respectively. Regarding paying partners, older age (AOR=1.02, 95% CI: 1.00-1.04), being tested for HIV (AOR=0.47, 95% CI: 0.35-0.64), alcohol consumption before sex (AOR=0.69, 95% CI: 0.46-0.90), and number of paying partners in the last day of sex work (AOR = 0.91, 95% CI: 0.79-1.04) were significant predictors of non-condom use. For non-paying partners, older age (AOR= 1.06, 95% CI: 1.03-1.09), higher level of education (AOR=0.74, 95% CI: 0.54-1.00), number of sexual contact with monetary partner in previous month (AOR=1.10, 95% CI: 1.03-1.14), being tested for HIV (AOR=0.64, 95% CI: 0.40-0.98), alcohol consumption before sex (AOR=0.54, 95% CI: 0.31-0.92), condom rupture (AOR=0.33, 95% CI: 0.16-0.67), and having an alternative source
TUPEC558
Testing for HIV among female sex workers in Iran: findings of the first national bio-behavioural survey in 2010
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Background: HIV testing is crucial to detect infected people and link them to services. HIV testing rate among female sex workers as one of the key populations at risk for HIV, serves as one of the major indicators for access to prevention and care services. While the prevalence of HIV among FSW in Iran is 4.5%, frequency of testing for HIV is poorly understood among them. Here we are presenting the rate of HIV testing and determinants of testing for HIV among FSW in Iran.

Methods: This survey was conducted in 2010, by recruiting 872 FSW through facility-based sampling from 21 sites in 14 cities in Iran. Data was collected through face-to-face interviews using a pilot-tested standardized risk assessment questionnaire. Using dried blood spot (DBS) technique, the blood samples were drawn and were tested for HIV antibodies by ELISA. All analyses were weighted based on the response rate and adjusted for the clustering effect of the sampling sites. A multivariable logistic regression model was constructed to investigate the determinants of testing for HIV.

Results: Overall, 817 consented to provide blood samples and be tested for HIV. Mean age of participants was 32, around 50% had primary school educations, and 35% were married. Overall 47.8% (95% CI: 4.5-51.1) of study participants had ever tested for HIV; 84.4% of which knew their results. Around 55.3% (95% CI: 52:1-59:0) perceived themselves at risk of HIV infection. In the multivariable model for testing for HIV, condom use in the previous sexual contact with a non-paying partner (AOR: 2.35; 95% CI: 1.72-3.08), history of abortion (AOR: 3.66; 95% CI: 0.49-0.88) and group sex (AOR: 0.41; 95% CI: 0.26-0.64) were significant predictors of having tested for HIV.

Conclusions: The low prevalence of testing for HIV, among younger FSW in particular, calls for appropriate HIV testing and counseling programs to educate FSW on the importance of HIV testing and promote testing. As testing for HIV is a stigmatized behavior in the context of Iran, identifying barriers to testing for HIV in Iran is also critical.

TUPEC559
Induced abortion among female sex workers in Iran: findings of the first national bio-behavioural study in 2010
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Background: Due to the decriminalization of sex work and drug use in recent years, drug use and sex work have increased among young women. In Iran, the most affected group was women who inject drugs (FWS-IDU). Given the high vulnerability to HIV among FSW-IDU, we sought to investigate the impact of recent incarceration on access to HIV prevention supplies among FSW-IDU in Vancouver, Canada.

Methods: Longitudinal data (baseline and six bi-annual follow-up questionnaires) were drawn from an ongoing prospective cohort of 725 SWs recruited through street, indoor and online outreach across Metropolitan Vancouver (“An Evaluation of Sex Workers’ Health Access”) between 01/2010-06/2013. To account for repeated measures, bivariate and multivariable generalized estimating equations (GEE) logistic regression were performed to model the independent effect of exposure to recent incarceration (e.g., jailing or confinement in the last 6 months) on difficulty accessing sterile syringes and male condoms in the same period among FSW-IDU.

Results: Of 720 female sex workers included in this analysis, 338 (46.9%) currently injected drugs (FWS-IDU), contributing 1047 observations. Over the study period, one-third (32.3%) of FWS-IDU were incarcerated, with 29.3% and 20.1% reporting difficulty accessing sterile syringes and condoms, respectively. In multivariable analysis, after adjusting for key confounders, episodes of incarceration remained independently correlated with difficulty accessing sterile syringes (AOR=1.66, 95% CI 1.02-2.66). In bivariate analysis, there was little evidence that exposure to incarceration had an effect on access to condoms (OR=1.48, 95% CI 0.86-2.47).

Conclusions: This study found that FSW-IDU in Vancouver were incarcerated at alarming rates, and that recent incarceration had an independent effect on reduced access to sterile syringes. Despite efforts to reduce barriers, these findings suggest limited access to harm reduction supplies for women while in prison, as well as barriers to healthcare, HIV prevention and harm reduction resources that occur during entry or release from jail, detention or prison. Results suggest a critical need to scale up access to harm reduction supplies for highly marginalized women during these transition periods and supports national and international calls for the decriminalization of sex work and drug use.

Prevention for MSM
TUPEC561
The emergence of undetectable viral load as a HIV risk reduction strategy by Australian gay and bisexual men who have condomless sex with casual partners
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Background: Gay and bisexual men (GBM) use various risk reduction strategies (RRS) to reduce the risk of HIV transmission during anal intercourse. The international focus on HIV treatment as prevention suggests that some GBM may be more willing to rely on having an undetectable viral load to prevent HIV transmission during sex without condoms, although there has been little evidence of the use of this strategy between casual male partners.

Results: Of 720 female sex workers included in this analysis, 338 (46.9%) currently injected drugs (FWS-IDU), contributing 1047 observations. Over the study period, one-third (32.3%) of FWS-IDU were incarcerated, with 29.3% and 20.1% reporting difficulty accessing sterile syringes and condoms, respectively. In multivariable analysis, after adjusting for key confounders, episodes of incarceration remained independently correlated with difficulty accessing sterile syringes (AOR=1.66, 95% CI 1.02-2.66). In bivariate analysis, there was little evidence that exposure to incarceration had an effect on access to condoms (OR=1.48, 95% CI 0.86-2.47).

Conclusions: This study found that FSW-IDU in Vancouver were incarcerated at alarming rates, and that recent incarceration had an independent effect on reduced access to sterile syringes. Despite efforts to reduce barriers, these findings suggest limited access to harm reduction supplies for women while in prison, as well as barriers to healthcare, HIV prevention and harm reduction resources that occur during entry or release from jail, detention or prison. Results suggest a critical need to scale up access to harm reduction supplies for highly marginalized women during these transition periods and supports national and international calls for the decriminalization of sex work and drug use.

Prevention for MSM

TUPEC561
The emergence of undetectable viral load as a HIV risk reduction strategy by Australian gay and bisexual men who have condomless sex with casual partners
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Prevention for MSM
TUPEC563
When and how male couples form a sexual agreement in their relationship: qualitative findings toward development of a tailored online HIV prevention ‘toolkit’ for at-risk HIV-negative male couples

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Background: Although between one- and two-thirds of MSM in the US acquire HIV from their primary relationship partners, few evidence-based HIV prevention interventions exist for male couples. Researchers have assessed how dynamics of male couples’ relationships affect their risk for HIV, including sexual agreements. A sexual agreement is an explicit mutual understanding between two main partners about which sexual and other relational behaviors are allowed to occur within their relationship, and if applicable, outside the relationship. Many aspects of couples’ agreements have been well studied. However, how and when male couples form a sexual agreement in their relationship remains poorly understood, yet relevant for development of a tailored online HIV prevention ‘toolkit’ which aims to assist at-risk HIV-negative male couples, who lack an agreement, to form and adhere to one.

Methods: The present study is part of a larger intervention project aimed to help male couples form and adhere to a sexual agreement via an online interactive prevention toolkit. Active and passive recruitment strategies were used to enroll 29 consented HIV-negative male couples from Detroit, MI and Atlanta. GA to participate in semi-structured individual- and couple-level interviews. Interviews focused on couples’ sexual agreements and attitudes toward other preventive methods; all couples had an agreement. Interviews were digitally recorded, transcribed verbatim, and anonymized. Grounded theory was used to identify themes from the codes developed.

Results: Themes pertinent to when the agreement formed included early on (e.g., first date) to within the first year; themes related to how the agreement was formed ranged from ‘purposely’ to ‘circumstantial’ instances. Differences of when and how the agreement was formed existed by couples’ agreement type: couples with closed agreements were purposeful about having their conversations early compared to those with an open agreement, which tended to occur later in time and were oriented around circumstances or events.

Conclusions: Our findings highlight how and when male couples typically form a sexual agreement in their relationship, which can be used toward developing content and activities in an online HIV prevention ‘toolkit’ aimed at helping at-risk HIV-negative male couples form and adhere to a sexual agreement.

TUPEC564
Awareness and willingness to take pre-exposure prophylaxis (PrEP) among men who have sex with men and transgender women: preliminary findings from the PrEP Brasil study

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Background: Brazil is experiencing a severe HIV epidemic among men who have sex with men (MSM) and transgender women (TGW), particularly the youngest. The WHO issued recommendations for PrEP use in such populations; however, it is not yet implemented in most resource limited settings. Understanding awareness and willingness to use PrEP is essential to inform public policy formulation. In this study, PrEP awareness and willingness among MSM and TGW were assessed.

Methods: Using gay-friendly HIV testing venues in Rio de Janeiro (RJ) and São Paulo (SP), including 1 mobile unit and a LGBT NGO in RJ, a convenience sample of 780 MSM/TGW was evaluated from April 2014 to January 2015. Of these, 734 individuals ≥ 18 years, male at birth, who reported having sex with men within 12 months completed a self-administered ques-
Community mobilization intervention with men who have sex with men (MSM) increases uptake of regular HIV-testing in South Africa: 12-month impact evaluation results from project Boithato

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Background: Few South African MSM test regularly for HIV. Project Boithato was adapted from Movemment, a community mobilization intervention for MSM in the USA proven to increase HIV prevention behaviors through peer support. This evaluation of Boithato assessed effects on regular HIV testing uptake among MSM in two communities: Gert Sibande, the Boithato intervention community, and Ehlanzeni, the comparison community. Baseline HIV prevalence estimates were 28.3% and 13.7% respectively, with 22.1% and 39.6% of infections in each sample occurring within the prior year. Trained MSM-competent HIV services in non-stigmatizing, trained MSM-competent clinical settings in a high-incidence community. Mobilizing MSM peer support for HIV testing will increase timely diagnosis and linkage to care. Additional research on optimizing HIV-positive MSM for treatment is urgently needed.

TUPEC566

An event-level analysis of substance use, relational, and psychosocial factors affecting condom use during anal intercourse among self-identified HIV-negative and unknown status gay and other MSM in Vancouver, British Columbia

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Background: We sought to identify psychosocial and event-level factors associated with condom-use during anal intercourse among self-identified HIV-negative and HIV status unknown MSM in the Greater Vancouver Area.

Methods: We analyzed data from Momentum Health Study participants collected at enrollment on their most recent anal sexual encounter with each of up to five sexual partners in the past six months. Exploratory factors included event-level factors (substance use, partner’s serostatus, sexual history with partner, and sexual position), psychosocial scales (i.e., Van Den Ven et al., 2000; HAART Optimism, Nimmons & Folkman, 1999 Sexual Altruism; Kalichman & Rompa, 1995 Sensual Sensation Seeking; and Motkan et al., 2001 Cognitive Escape), and demographics. Of all sexual encounters where anal intercourse was reported, factors were associated with condom-use versus not were determined using manual backward stepwise multivariable generalised linear mixed models.

Results: The majority of participants reported at least one anal intercourse event in the past six months (65.0%, n=436/671). Two-thirds of all sexual encounters involved anal intercourse (64.1%, n=1866/2892) during which condoms were used for 56% of events. Condom-use was positively associated with higher sexual altruism community sub-scale scores (AOR=1.38, 95%CI:1.46-2.68) and negatively associated with greater HAART optimism (AOR=0.95, 95%CI:0.90-1.01), sexual sensation seeking (AOR=0.94, 95%CI:0.89-0.98), and cognitive escape (AOR=0.97, 95%CI:0.94-0.99). At the event-level with that partner, longer time since first sex and higher frequency of recent anal sex were both negatively associated with condom-use (AOR=0.99, 95%CI:0.99-0.99 and AOR=0.96, 95%CI:0.95-0.98, respectively). Compared with men who didn’t know their partner’s serostatus, participants who were certain their partner was HIV-negative or HIV-positive were less likely to report condom-use (AOR=0.24, 95%CI:0.08-0.72 and AOR=11, 95%CI:0.03-0.39, respectively). Event-level partner alcohol use was positively associated with condom-use (AOR=1.43, 95%CI:1.02-2.00) while partner crystal methamphetamine use was negatively associated (AOR=0.19, 95%CI:0.07-0.55). Event-level receptive-only versus both insertive and receptive sexual position was positively associated with condom-use (AOR=1.81, 95%CI:1.20-2.74). Lower odds of condom-use were associated with annual income >$30,000 (AOR=0.66, 95%CI:0.45-0.96) and being in a relationship >1 year (AOR=0.57, 95%CI:0.34-0.96).

Conclusions: Health promotion for gay and other MSM must consider how substance use, HAART optimism, partner familiarity, discussions of HIV serostatus, and psychosocial traits collectively affect condom-use decision-making.
Prevention for transgender persons

TUPEC567

Prevalence and correlates of injection of industrial silicone among transgender women in Argentina

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Background: Transgender women continue to contend with high rates of HIV infection in many settings. To enhance their feminine appearance many transgender women undergo medically unsupervised body modification procedures, such as self or peer-administered injection of industrial silicone. The use of non-sterile equipment and assisted injection has been associated with increased risk for HIV acquisition and skin and soft tissue infections, among other complications.

Methods: Data was drawn from a cross-sectional nation-wide study involving transgender women in Argentina conducted in 2013. We assessed the prevalence and correlates of industrial silicone injection among this population using multivariable logistic regression.

Results: In total, 450 transgender women were included. The median age was 30 (IQR 25-37) and 378 (83.6%) had a history of sex work. HIV or HCV infection was self-reported by 104 (23.1%) and 18 (4%) participants, respectively. Overall, 277 (61.6%) reported having ever injected industrial silicone. The injection was done by a transgender peer. In multivariable analysis, factors positively associated with injection of industrial silicone were: engagement in sex work (AOR =3.20, 95% CI 1.67-6.12), older age (AOR=1.05, 95% CI 1.02-1.08), having ever been arrested (AOR=2.0, 95% CI 1.06-3.80), having avoided healthcare due to transgender identity (AOR=1.61, 95% CI 1.01-2.56), and former-burn status (AOR=3.22, 95% CI 1.38-7.52). No association was found with self-reported HIV or HCV infection.

Conclusions: Our findings revealed that injection of industrial silicone is a common practice among transgender women in Argentina, especially among those engaged in high risk activities and those experiencing barriers to healthcare. Among those who used industrial silicone, this analysis was limited by self-report. Given the high prevalence of medically unsupervised and peer-assisted injecting in this sample, longitudinal studies are needed to investigate whether injection of industrial silicone is an important risk factor for HIV or HCV transmission among this population. Regardless, given the well-known morbidity as well as the potential for long-term sequelae, our findings call for targeted education and harm reduction programs to address this common practice.

Prevention for immigrants, mobile and displaced populations

TUPEC569

Assessment of HIV associated risk behaviour among internally displaced persons (IDPs) in Northern Nigeria

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Background: Nigeria has the second highest burden of people living with HIV globally. Since 2010, the Boko Haram insurgency has forced over 10 million persons mostly women and children to flee from their places of habitual residence in order to avoid the effects of armed conflicts. This has rendered millions of women and children disproportionately vulnerable to HIV. Internally displaced Persons (IDPs) are not included in Nigeria’s national HIV strategic plan. Moreover there is neither size estimate nor HIV data for IDPs in Nigeria.

Objectives: Our study provides further insight into HIV vulnerability of internally displaced persons (IDPs) in Northern Nigeria.

Methods: Through the cluster approach, quantitative research was conducted in December 2014 in the evacuation camps of the IDPs in Abuja and Nassarawa states of Nigeria. The study involved structured questionnaire administered to 200 IDPs. The respondents were recruited through the IDPs-Key Opinion Leaders identified by the Community Based Organizations providing succor in the two study location, while skilled interviewers administered the structured questionnaire. Respondents were assured of their confidentiality by using unique Identifier codes and pseudonyms. Ethical IRB approval was also obtained for the study.

Results: The mean age of the 200 respondents was 22 years (+/- SD. 72%) were women within the ages of 18-24years. 35% were married, while 50% have lost a key figure of their childhood or separated from their families and cannot tell if they are still alive. 15% reported encountering sexual violence by armed groups and had no access to prophylaxis pre-exposure (PrEP) or Health care Providers. Most of them lack employment opportunities, while 13% have resorted to survival sex in exchange for jobs, money, shelter and other basic amenities and in most cases, condom was not used (a significant size of 19% are unsure of their HIV status).

Conclusions: From this study, transactional sex, inconsistent condom use, sexual violence and lack of access to health facilities are factors that may increase the vulnerability of IDPs. Furthermore, a broader framework on comprehensive HIV comprehensive HIV and other sexual and reproductive health programming needs to be developed for the IDPs.
TUPEC571

**Couples testing and immediate antiretroviral therapy among serodiscordant couples in Vietnam: implementation study in resource-limited settings affected by drug use**


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**Background:** Injection drug use and heterosexual transmission from people who inject drugs (PWID) are the dominant modes of HIV transmission in Vietnam. HPTN 052 indicates that antiretroviral therapy (ART) reduces HIV transmission from HIV-positive to uninfected partners in serodiscordant couples (SDC); however, it excluded PWID. We assessed feasibility of providing couples HIV testing and counselling (HCTC) and immediate ART among SDC in drug use-affected provinces in Vietnam.

**Methods:** From March to December 2013, HCTC and immediate ART for SDC were offered in Dien Bien and Can Tho provinces; following consent, HIV-positive partners initiated ART immediately (irrespective of CD4 count). In addition to routine monitoring, viral load (VL) was assessed in HIV-positive partners at baseline and months 3 and 12. Couples received behavioural counselling and completed surveys, and uninfected partners received HCT, at baseline and months 3, 6, and 12.

**Results:** There were 532 newly diagnosed people with HIV (PLHIV); 259 couples completed HCTC and immediate ART for SDC. Of these, 56.6% reported current or past Illicit drug use, 85% were male, median age was 32 years, 51% had baseline CD4 count >350 cells/mm³, and median baseline VL was 5.0 log₁₀ copies/ml. 91.2% of HIV-positive partners were retained at month 12. Viral suppression (VL <1000 copies/ml) was achieved by 85 (71.4%) of 119 infected partners with median CD4 counts below and above 350 copies/ml was 88.8% and 95.1%, respectively. Consistent condom use in sexually active couples was 72.7% (801/110) at baseline and 99% (96/97) at month 12. Two uninfected partners seroconverted between enrolment and month 3.

**Conclusions:** The results suggest low uptake of HCTC and high uptake and adherence to ART in SDC, irrespective of CD4 count, in drug-use affected settings. No behavioural disinheritance was seen. Novel approaches to improve partner testing among newly diagnosed PLHIV are needed. Immediate ART among SDC likely presents a feasible and effective intervention to reduce HIV burden in Vietnam. Informed by this study, Vietnam is moving toward adopting immediate ART in SDC as national policy.

TUPEC572

**Healthcare providers’ understanding of HIV sero-discordance in South Africa and Uganda: implications for HIV prevention counselling**

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**Background:** HIV transmission within stable heterosexual couples accounts for nearly half of all new HIV infections in sub-Saharan Africa, consequently the uninfected partner within HIV-serodiscordant partnerships is a priority population for prevention counselling. It is important then to assess whether and how healthcare providers understand HIV serosdiscordance and how this understanding may impact HIV prevention counselling.

**Methods:** In-depth interviews and focus group discussions were conducted with 42 healthcare providers from 6 public sector clinics in eThekwini District, South Africa (2012) and with 38 healthcare providers from 5 public sector clinics in Mbarara District, Uganda (2013). Interview guides were designed to assess whether and how providers counsel people living with HIV about reproductive goals and safer conception strategies. Provider understanding of HIV-serosdiscordance was an emergent theme. Thematic analysis was used to explore provider understanding of sero-discordance and how this impacts safer conception counselling practices.

**Results:** In eThekwini, 93% of participants were women with a median age of 41 (range, 28-60) years. In Mbarara, 78% were female with a median age of 34 (range 24-57). Most providers in eThekwini assumed that HIV infected clients were in a seroconcordant relationship; in contrast, providers in Mbarara reported familiarity with careing for HIV-discordant couples. Providers displayed a range of understanding of how serosdiscordance may occur, cing immune intake, viral load suppression in the infected partner, chance and a very extended period. Incorrectly, occurrences of serosdiscordance were also attributed to God or “good blood”. Many providers stated that they did not know how one partner may be HIV-infected and the other is not. Providers who understood the mechanisms of serosdiscordance provided more accurate per-conception counselling to HIV-infected patients, while providers who articulated a misunderstanding of serosdiscordance did not provide accurate counselling.

**Conclusions:** The ability to provide effective and relevant counselling to HIV serosdiscordant couples is vital for HIV prevention efforts. Many providers express doubt and confusion regarding the epidemiology and mechanisms of serosdiscordance within stable sexual partnerships. Healthcare providers require ongoing training and support on serosdiscordance in order to provide accurate and effective per-conception counselling to infected men and women with uninfected partners.

TUPEC573

**Community cultural beliefs and disclosure to primary sexual partners among women living with HIV in Brazil, Thailand and Zambia: results from HPTN063**

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**Background:** Serostatus disclosure may be effective in decreasing HIV transmission between serodiscordant partners by raising risk awareness and heightening the need for prevention. For women living with HIV (WLWH), disclosure may be influenced by community cultural beliefs which shape relationship dynamics. Understanding the impact of cultural beliefs on disclosure among WLWH in different countries may inform intervention development.

**Methods:** HPTN063 was a longitudinal, observational cohort study of sexually active HIV-infected individuals, including heterosexual women, in care in Zambia, Thailand and Brazil. At baseline, a questionnaire measuring demographic, partner characteristics, intimate partner violence (IPV), fear of negative consequences following disclosure (loss of fines and IPV),
Prevention during acute and recent infection

TUPEC575

Influence of suspected source of infection on disclosure among people with acute HIV in Malawi

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Background: Disclosure of HIV serostatus to sexual partners is a valuable opportunity to reduce HIV transmission, particularly among individuals diagnosed with acute HIV (AHI), who may be better able to identify and notify the partner who may have infected them. Little research has been conducted, however, on how identifying one’s source of AHI can affect disclosure in Sub-Saharan Africa.

Methods: We conducted 40 in-depth interviews with 24 men and 16 women one month after their diagnosis of AHI in Lilongwe, Malawi. Participants were asked about their sexual behavior, disclosure to sexual partners, and reaction to AHI diagnosis. All interviews were conducted in the local language, simultaneously translated and transcribed, coded by a four-member team, and analyzed using a thematic analysis approach.

Results: Over half (23/40) of participants claimed to know who infected them, nine suspected but were not certain, and eight reported not knowing. Participants suspected individuals to be sources of their infection for a variety of reasons, including a sexual partner’s physical appearance and timing between sexual encounters and emergence of symptoms. Participants frequently assumed that the suspected source of their infection was aware of his or her own HIV-positive status, and thus knowingly exposed the participant to risk. This led to some participants being unwilling to disclose to the suspected source due to feelings of betrayal. Overall, 16 of the 23 participants who reported knowing the source of their infection disclosed to at least one partner, but only nine disclosed to all partners (both main and casual). Of those who had multiple partners, most disclosed to main partners but not casual ones. Reasons for not disclosing to casual partners included fear of casual partners spreading the news of their status and feeling casual partners were not worthy of being told. Disclosing frequently resulted in improved condom use and abstaining, but participants also reported relationships being terminated and strained.

Conclusions: Identifying a suspected source of infection can lead to feelings of betrayal and assumptions that partners already know they are infected, which can complicate disclosure. Further counseling on the importance of and strategies for disclosing to casual partners is needed.

Prevention for other vulnerable populations

TUPEC574

Perceptions of HIV burden and risk among Lake Victoria fishing communities: a qualitative study

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Background: In Kenya, fishermen and others engaged in the fishing sector in Lake Victoria are a key population for HIV interventions given their high HIV risk. Previous studies conducted in 2005 to 2010 among the ‘fisherfolk’ population in Kenya have estimated a HIV prevalence of 26% to 30%, which is much greater than the 8% prevalence of the general population (2012). We conducted a qualitative study among the Lake Victoria fishing communities to understand their perceptions about the HIV burden, their risk behaviors, and their utilization of health services.

Methods: This study was implemented in nine beaches located on the Kenyan border of Lake Victoria; study sites and participants were purposively selected through input from subject matter experts and community leaders. We conducted 25 focus group discussions and 29 key informant interviews among men and women engaged in the fishing sector. Interviews were conducted in Dholuo, the vernacular, or English and audio-recorded. After transcription and translation, interviews were coded using Nvivo and analyzed for emerging themes, using a thematic analysis approach.

Results: Participants were aware of the high HIV burden in their communities and its impact on their livelihoods. There was a high level of knowledge about HIV prevention, specifically the importance of using condoms and getting tested for HIV. Nevertheless, high-risk sexual behaviors, like concurrent multiple partners, low or no condom use, transactional sex, and alcohol and drug use with sex, were commonly practiced at multiple beaches along the lake. There was widespread knowledge about the benefits of antiretroviral therapy (ART) for treating HIV; however, difficulty in routinely visiting health facilities due to their migratory lifestyles and the stigma of taking medication were barriers to accessing health services and ART adherence.

Conclusions: Despite high levels of awareness about prevention measures, lifestyle characteristics and HIV-related stigma were challenges to practicing protective behaviors and accessing HIV health services among the ‘fisherfolk.’ Further understanding is required to better tailor HIV prevention interventions to address their high-risk behaviors, while prevention and treatment interventions must account for their migratory lifestyles. Developing community-level initiatives to reduce stigma is also critical for improving uptake of HIV prevention and treatment services.

Prevention among HIV-infected individuals

TUPEC576

Prevention strategies during anal intercourse and prevention-related attitudes of HIV-positive gay, bisexual and other MSM in Vancouver, British Columbia

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Background: Our objectives were to identify factors associated with condom-use during anal intercourse among HIV-positive gay, bisexual, or other men who have sex with men (MSM) in Vancouver and to determine what preventive attitudes and alternative strategies were employed by MSM who did not report using condoms.

Methods: We analyzed Momentum Health Study participants’ data collected at enrollment on their most recent sexual encounter with each of up to five sexual partners in the past six months. Exploratory factors included psychosocial scales (Van Der Ven et al., 2000’s HAART Optimism, Nimmons & Folkman, 1991’s Sexual Altruism; Kalichman & Rompa, 1995’s Sexual Sensation Seeking (SSS); McKim et al., 2001’s Cognitive Escape. Of all sexual encounters where anal intercourse was reported, factors associated with condom-use versus not were determined using manual backward stepwise multivariable generalised linear mixed models.
TUPEC577

**Relationship between social norms on condom use and inconsistent condom use among people living with HIV/AIDS in Guangzhou, China**

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**Background:** Previous studies have shown associations between social norms and risk behaviors among high risk populations for HIV infection. However, little is known about social norms and condom use among people living with HIV/AIDS (PLWHA). Since Chinese culture emphasizes collectivism and obedience of individual behaviors to social norms, the effects of social norms may be more pronounced. This study sought to examine the relationship between social norms on condom use and inconsistent condom use among PLWHA in Guangzhou, China.

**Methods:** We conducted a cross-sectional survey through convenience sampling among 412 PLWHA between March and June, 2013 in Guangzhou, China. Descriptive norm of condom use was measured as perception of number of friends thinking it necessary to use condoms when having sex. Inconsistent condom use was defined as not using condoms consistently in all sexual encounters.

**Results:** About three fourths (n=301, 73.1%) of 412 PLWHA were sexually active since HIV diagnosis. Among the sexually active patients, the average age was 36.5 years; about two thirds were male; the majority was Han ethnicity (92.7%); 55.5% discussed condom use with their friends and the rate of inconsistent condom use was 29.2%. In multivariate logistic regression, PLWHA were 74% less likely to report inconsistent condom use if they perceived most of their friends considering necessary to use condoms when having sex (aOR=0.26, 95%CI (0.11,0.61), p=0.002) compared to those who perceived less friends considering necessary to use condoms when having sex. HIV disclosure to family members was significantly related to reduced inconsistent condom use (aOR=0.16, 95%CI (0.08, 0.41), p<0.001), whereas living with family members compared to living with friends was associated with increased inconsistent condom use (aOR=0.06, 95%CI (1.39, 46.63), p=0.020).

**Conclusions:** This study provides important evidence for developing social norm-based HIV interventions among PLWHA, especially in countries like China. Future interventions focused on changing social norms on risk behaviors in the social network of PLWHA have the potential to reduce risk behaviors and improve condom use among PLWHA.

**TUPEC578**

Ongoing HIV-transmission risks and factors associated with HIV transmission risks among young people living with HIV (YPLHIV) in Uganda

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**Background:** of New HIV infections worldwide, an estimated 40% occur among young people, either perinatally or sexually. In Uganda young people living with HIV (YPLHIV) face significant challenges regarding their health, development, and economicopportunities. Additionally, they find difficulties communicating with their partners about their HIV status, safer sex practices, and childbearing desires. This abstract aims to investigate HIV transmission risks and HIV disclosure practices among Ugandan YPLHIV.

**Methods:** These data were part of a baseline survey conducted under the Link Up project, which provides sexual and reproductive health (SRH) services to young people in Uganda. Between September-October, 2014, 473 YPLHIV aged 15-24 years were recruited through peer-support groups in Luwero and Nakasongola districts. The survey elicited information on HIV-related behaviors, use of SRH and HIV services, HIV status disclosure, and stigma and discrimination. We assessed key descriptive indicators and examined their associations with condom use and HIV disclosure using multiple logistic regression.

**Results:** Participants had a median age of 20 years, 70% were female, 67% were single, and had lived with HIV for an average of 3.6 years. Thirty percent reported acquiring HIV perinatally, 68% were on ART, and 40% experienced physical, sexual or emotional abuse (past 12 months).

Inconsistent condom use was defined as not using condoms consistently in all sexual encounters. Both bivariate and multivariate logistic regression analyses were positively associated with condom-use (AOR=3.32, 95%CI:2.00-5.50). HAART Optimism and higher SSS and Cognitive Escape scores (AOR=0.86, 95%CI:0.78-0.94 and AOR=0.93, 95%CI:0.88-0.99, respectively). Higher Sexual Altitude community sub-scale scores were positively associated with condom-use (AOR=3.25, 95%CI:2.00-5.50). HAART Optimism was not significantly associated with condom-use. HIV-positive MSM who reported condomless anal intercourse were more likely to agree that “knowing a sex partner’s viral load is just as important as knowing their HIV status” (AOR=2.39, 95%CI:1.09-5.21).

**Conclusions:** Psychosocial traits, attitudes, and substance use are important predictors of condom-use and HIV-positive men who report condomless anal intercourse employ various prevention strategies that consider HIV status and viral load. These strategies do not appear to consider other STIs, like syphilis.
Conclusions: Women with HIV in this study had some clear attitudes and preferences regarding cervical cancer screening that should be taken into account in future interventions. HIV care providers should highlight the importance of having a Pap-test and should encourage women to disclose their HIV status when seeking health care, to ensure more timely diagnosis of cervical cancer. Our findings also highlight the potential importance of using email, SMS, and social media to motivate Pap-testing among women living with HIV.

TUPEC580
HIV-related stigma and depression among newly diagnosed HIV-infected men who have sex with men, in China

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Background: HIV-related stigma has a negative impact on the mental health of HIV long-term infected individuals. However, such an association among newly diagnosed HIV infected people has not been explored. Men who have sex with men (MSM) are vulnerable to depression due to social stress, lack of family acceptance, and risks of HIV infection. We explored HIV-related stigma and depression among newly diagnosed HIV infected MSM in China.

Methods: A randomized clinical trial of HIV prevention with positive among newly diagnosed HIV infected MSM was conducted in China, with 367 eligible participants recruited at baseline. One participant was omitted in the analysis due to missing data. HIV-related stigma was measured with a validated scale (Steward, et al, 2008) with four components - enacted, felt, vicarious, and internalized stigma (component score range: 0-30). Factor analysis confirmed the four-component structure in the Chinese MSM population. Chronbach’s alpha values were all ≥0.90. Depression was assessed from the Hospital Anxiety and Depression scale. Multivariable adjusted ordinal regression was conducted to analyze the associations between continuous stigma scores for each component and categorized depression groups (normal, mild, moderate, severe).

Results: The mean age of our study participants was 30 years-old. The majority were of Han ethnicity (93%), well educated (77%, over 12-year education), and single (84%). Twenty percent (73/366) had suspicious depression, and 16% (59/366) had borderline depression. Mean scores for felt, vicarious, and internalized stigma were 14.8, 4.9, and 8.1, respectively. Enacted stigma was excluded from the analysis, as one-third of participants did not respond to its items. A one-point increase in each of the stigma component scores was associated with a 5-11% increase in the odds of having depression (Table), with internalized stigma having the strongest association (OR=1.11, 95% confidence interval [CI]: 1.08, 1.14).

Conclusions: HIV-related stigma was positively associated with higher depression among newly diagnosed HIV infected MSM in China. Interventions to address coping with HIV stigma immediately following diagnoses, particularly for internalized stigma (shame, guilt, and contact avoidance) may reduce depression and improve long-term mental health.

Prevention in other institutional settings (including workplace / school / prison / army)

TUPEC581
HIV/AIDS in prison: a global systematic review of HIV incidence and AIDS related mortality

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Background: Prison populations have elevated levels of HIV infection and poor access to medical care including HIV prevention and treatment programs. Previous reviews have reported on HIV transmission and AIDS related mortality in the community setting but not in the prison setting. Therefore we reviewed the global situation of HIV incidence, cases of HIV transmission and AIDS related mortality among prison populations.

Methods: We systematically searched the peer reviewed and grey literature for relevant data published from January 2008 to April 2013. Additional data sources were identified through direct communication with researchers, key experts and from a survey of UN staff and prison authorities.

Results: In 2011, over 10.1 million people were held in prisons, with an estimated 30 million persons passing through a prison annually. Rates of imprisonment varied greatly across Regions from 67.5 per 100,000 in West and Central Africa to 332 per 100,000 in the Caribbean. HIV incidence data for prisoners were found for six countries and ranged from 0.6% to 11.2% per year. Case reports of HIV transmission in prison were found for six countries and ranged from zero to 543 cases per year. AIDS-related mortality rates for prisoners were located for one country and ranged from 10.5% to 22.9%. Case reports of AIDS-related deaths of prisoners were found for four countries and ranged from zero to 388 per year.

Conclusions: The world’s prisons hold vast numbers of individuals, many of whom are infected with HIV, yet information on HIV transmission and AIDS-related mortality was very scarce. HIV transmission in prison has substantial public health implications as tens of millions are imprisoned and released annually. HIV prevention and treatment strategies known to be effective in the prison setting, such as methadone maintenance treatment, needle and syringe programs, condoms and antiretroviral therapy should be provided to prisoners as a matter of urgency. Compassionate release should be available for inmates in the final stages of AIDS.

TUPEC582
Prevalence and correlates of occupational needle-stick injuries among active duty police officers in Tijuana, Mexico

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Background: For police officers, needle-stick injuries (NSI) are a serious occupational and healthcare risk for HIV and viral hepatitis. Despite legal syringe possession in Tijuana, Mexico, there is still a high incidence of needle-sharing and HIV infection. Alarmingly, there is currently no NSI response protocol and/or affordable access to post-exposure prophylaxis for Mexican police.

Methods: Tijuana’s Department of Municipal Public Safety is among Mexico’s largest municipal police force. With full departmental collaboration, our binaural, multi-sectoral team administered an anonymous work environment and occupational health survey (including handling and disposal of syringes, NSIs, access to healthcare) to active-duty police officers. Logistic regression was used to identify individual factors associated with NSIs.

Results: 503 officers surveyed in July 2014 were predominantly male (86.5%), 36-45 years old (46.3%) and had worked as a Tijuana police officer a mean of 10.8 years. Most (94.0%) reported encountering syringes when performing daily duties; 15.3% reported ever having at least one NSI, of whom 14.3% was within the last year. Among those ever reporting encountering needle/syringes while on duty (n=407), factors independently associated with an elevated odds of NSIs included frequently finding syringes that contain drugs (Adj OR: 2.98; 95% CI: 1.56-5.67) and reporting broken using needles (Adj OR: 2.25; 95% CI: 1.29-3.91), whereas
Collectivization, mobilization, stigma reduction programmes

TUPEC583
Endowment training intervention: changing attitudes toward opioid substitution therapy in 30 minutes

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Background: Opioid substitution therapy (OST) is internationally recognized as the most effective form of treatment for opioid dependence and is also among the most effective HIV prevention strategies available. In the US, however, treatment for opioid dependence has been more influenced by myths and prejudices than by the scientific evidence. To challenge pervasively negative attitudes we developed a brief intervention called Endowment Training Intervention (EnTr), building upon work in decision sciences and behavioral economics, EnTr targets attitude change via perceived ownership of a solution to a problem. The endowment effect documents that owning a particular good increases its value, even when ownership is experimentally induced and not necessarily sustained. Respectively, the ownership of ideas occurs by investing effort, and those ideas that are perceived to be of an internal origin are valued more. We expected that mental effort invested by prison medical administrators during a short task, is likely to bring about the desired effect: perceived ownership of an idea that OST is beneficial, and a preference for OST over other treatment methods.

Methods: ENTR employs a pre/post-test experimental design, where the experimental treatment is a brief (10 minutes) exercise that provides study participants with a list of 12 indicators of ownership an endowment of an idea that OST is beneficial, and a preference for OST over other treatment methods. The endowment effect documents that owning a particular good increases its value, even when ownership is experimentally induced and not necessarily sustained. Respectively, the ownership of ideas occurs by investing effort, and those ideas that are perceived to be of an internal origin are valued more. We expected that mental effort invested by prison medical administrators during a short task, is likely to bring about the desired effect: perceived ownership of an idea that OST is beneficial, and a preference for OST over other treatment methods.

Results: The results of the study confirmed our hypothesis, with the participants in the experimental group reporting more positive attitudes toward OST relative to those in the control group.

Conclusions: The inability of Ukrainian administrators to accept the scientific consensus regarding OST and a lingering bias toward the using process was successfully tackled by a brief intervention aimed at creating a perceived ownership of a solution to a problem.

TUPEC584
Stigmatized health care: a challenging issue for Iranian HIV+ patients

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Background: This study aimed to assess the stigmatized attitude among health providers toward people living with HIV/AIDS (PLWHA) and their willingness to provide service to these patients.

Methods: This is a descriptive-analytic study. The study population consisted of all medical personnel of public and private hospitals, in Shiraz, somehow dealing with PLWHA. The study was carried out on 575 health care providers of hospitals in Shiraz, as one of the metropolitan city of Iran. The data were collected from June to August 2014 and were analyzed during summer 2014.

Results: Almost half of the respondents are opposed to provide services to PLWHA. Most of the respondents stated that the reason for unwillingness to provide services was exposure to the disease (70.5%) and movement of these patients in unsuitable behavior (65.6%). The respondents who had an experience dealing with PLWHA were asked to express their behavior; only 45.5% stated that their attitude was normal with patients, while other respondents had a discriminatory feeling. 42.42% of the subjects had a state of fear, 16.45% refused reception, 15.42% disgusted, and 8.74% experience danger. The most dominant attitude of the health care providers toward HIV/AIDS patients was dealing with fear. A significant reverse relationship existed between stigmatized attitude of the personnel and their willingness to provide services to the prostitute, drug injector, and homosexual patients (p<0.05). Uni-variance regression also indicated the relationship of health care providers’ stigmatized attitude with their religious beliefs, stigmatized attitude of the society, and knowledge of the transmission routes.

Conclusions: Stigmatized attitude of the health professionals as one of the key people in dealing with PLWHA may result in undesirable consequences, such as dealing with fear, disgust, anger, and in some cases refuse to accept the patients. Therefore, decreasing irrational fear of personnel is important to reduce their stigmatized attitude. Obviously, this will improve the quality of services to PLWHA.

Hence, it seems that creating an effective knowledge about transmission and correcting the socio-cultural beliefs of health providers are two key strategies to deal with this problem.

TUPEC585
Opinions and experiences of HIV-status disclosure to sex partners: a qualitative study with gay men in Lima, Peru

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Background: Improved treatment creates the possibility of living in health for many years, creating new challenges including decisions regarding sero-disclosure to sex partners. This study explored HIV-status disclosure among gay men in Lima, Peru.

Methods: A study on the relationships and lives of gay couples included 60 in-depth interviews with gay men, including people living with HIV (PLHIV) and HIV-negative men.

Results: PLHIV expressed fear of possible outcomes of divulging their HIV-positive status to a sex partner. Fears included abandonment and consequences of further disclosures to others, and/or the inability to obtain new sex partners due to their HIV-positive status. PLHIV also expressed fear that a sex partner would acquire HIV from them. Especially when the sex partner did not know their HIV-positive status, PLHIV said that they always used condoms, often due to guilt. However, many PLHIV eventually disclosed their HIV-positive status to their sex partners, after establishing a stable relationship, reporting that their fears of HIV-status disclosure were unfounded and that their relationships continued. All participants expressed that any HIV-status disclosure (positive or negative) would only occur with a trusted sex partner with whom they could see a future. HIV-negative participants thought they would not disclose a potential HIV-positive status due to fear of stigma and discrimination. The reaction of HIV-negative participants to a potential HIV-positive disclosure depended on their level of commitment to their partner. Some HIV-negative members of very committed relationship said the relationship would continue unchanged. Many HIV-negative said that the romantic relationship would end following an HIV-positive disclosure, but that they would continue as friends and provide emotional support to the HIV-positive partner.

Conclusions: Fear of HIV continues and affects HIV-status disclosure, despite knowledge and experience of improved HIV treatment. HIV negatives are scared of HIV and this perpetuates the fear of stigma and discrimination among PLHIV. Even though PLHIV have access to treatment, their fears of other’s reactions prevent or delay HIV-status disclosure. Interventions with PLHIV and HIV negative gay men are urgently needed to promote timely HIV-status disclosure in supportive situations and to alleviate fear of HIV as a disease.

TUPEC586
Development and reliability of scales to measure stigma among men who have sex with men and female sex workers in West Africa: tools for stigma reduction programmes

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Background: Stigma is a multifaceted concept that affects key populations at higher risk for HIV, including men who have sex with men (MSM) and female sex workers (FSW).

Interventions to evaluate stigma reduction programmes for key populations are needed, but relatively few of these measures have been assessed in Sub-Saharan Africa. This study developed scales to measure stigma among MSM and FSW in two countries in West Africa.

ABSTRACTS
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Methods: Questionnaires were administered to 1,351 MSM and 1,380 FSW in two cities in Togo and two cities in Burkina Faso. Exploratory factor analysis was used. Factors were retained based on eigenvalues, the Kaiser’s criterion, scree plots, and interpretability. For ease of interpretation, promax oblique rotation was used because some correlation between factors was expected. Consistency assessment was conducted using Cronbach’s alpha and the Kuder-Richardson test.

Results: In total, 17 items were retained in the final MSM stigma scale. There were four factors, with 2-6 items loading on each factor. The factors were:
1) enacted stigma;
2) stigma from family and friends;
3) perceived healthcare stigma; and
4) enacted healthcare stigma.

The Cronbach’s alpha varied by city and ranged from 0.7322 to 0.8292. A total of 20 items were retained in the FSW stigma scale. The factors were similar to the MSM scale, with one additional factor: stigma from police. The Cronbach’s alpha of the scale varied by city and ranged from 0.7079 to 0.8292.

Enacted stigma included physical and sexual violence, torture, arrest, blackmail, verbal harassment, and police refusing protection. Stigma from family and friends included rejection and gossip. Perceived healthcare stigma included avoiding or fearing of seeking care. Enacted healthcare stigma included being denied services, not treated well, difficulties accessing care, and health workers gossiping. Stigma from police included witnessing, hearing about, or experiencing police confiscating condoms, or not carrying condoms to avoid trouble with police.

Conclusions: This preliminary study of metrics of stigma among MSM and FSW indicate that the scales have promising reliability. These scales will be used to examine stigma among MSM and FSW in Senegal and to assess the effectiveness of a stigma reduction programme in the health sector.

TUPEC587 Determinants of stigmatization of people living with HIV/AIDS in Burkina Faso

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Background: Stigmatization of people living with HIV/AIDS (PLWHA) negatively influences the response against the disease. Our goal was to identify the individual and contextual determinants of population’s stigma towards PLWH in Burkina Faso.

Methods: Secondary data set from the fourth Demographic and Health Surveys conducted in Burkina Faso in 2010 was analysed. The study included those who answered “yes” to the question “if they had ever heard about HIV/AIDS”. Thus, the final sample included 16,571 women and 7,162 men. We performed a multilevel logistic regression with MLwiN 2.29 software. The contextual level was represented by the thirteen regions of the country.

Results: A total of 23,673 individuals (15 to 59 years) was surveyed, of which more than one third (36.8%) was under 25 years old. The prevalence of stigma was 89% [95% CI: 88.59 - 89.45%] (women: 92.70% versus men: 87.10%, p < 0.001). At the individual level, sociocultural factors (lack of knowledge about HIV/AIDS OR=2.41***, religiosity mediating to media OR=1.62***, not doing the HIV test OR=1.34***), sociodemographic factors (young age OR=1.33***, female gender OR=2.08**, coming from rural area OR=1.29**) were seemed to be more associated with stigmatizing behaviors than economic factors (no education OR=2.50***, informal occupation OR=1.13**). At the contextual level, access to media (OR=1.70**) and knowledge about HIV contextual (0.70**) influenced stigmatizing behavior of individuals towards PLWHA. The entry of contextual factors in the final model lowered the contextual variance to 0.36% compared to the empty model (0.74**), but not significantly. In addition, there was no significant change of individual characteristics on stigmatization after taking into account contextual factors. The influence of contextual variance on stigmatization was not significant.

Conclusions: People with young age, female, less educated, with low knowledge about HIV/AIDS, living in the countryside with a low socioeconomic level in an environment with low awareness of the disease were more likely to stigmatize PLWHA. Therefore, there is a need to strengthen awareness programs through mass media for the benefit of this population, with the aim to move towards UNAIDS “zero discrimination” goal.
Conclusions: Lay providers are key in the scale-up of HTC services and reaching global targets. Supportive and clear policies which permit lay providers to administer both HIV RDTs and counseling are needed. The African region appears to have a very supportive policy environment for lay provider HTC. Countries in other regions should review these policies to enhance task-shifting in their context and better utilize lay providers.

TUPEC590
Criminalization of HIV transmission in France: knowledge of and concerns about HIV-related court-case verdicts in a representative sample of people living with HIV (ANRS VESP A2 survey)

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Background: In France, criminal prosecution for HIV transmission resulted in approximately 10 trials and sentences between the very first trial in 1998 and 2011. Prison terms were followed-up in French hospitals, those aware of and concerned about HIV criminalization. The objective of the present analysis was to characterize, among a representative sample of PLWH HIV-diagnosed >6 months. Socio-behavioural (face-to-face interviews) and medical (self-reported by PLWH) data were collected. Participants were asked if they were aware of HIV-related court case verdicts and if they were concerned about them. Multivariate analyses were performed on weighted and calibrated data.

Methods: ANRS VESP A2 was a cross-sectional survey conducted in 2011 on 3202 adult PLWH attending French hospitals HIV-diagnosed >6 months. Socio-behavioural (face-to-face patient interviews) and medical (provided by medical staff) data were collected. Participants were asked if they were aware of HIV-related court case verdicts and if they were concerned about them. Multivariate analyses were performed on weighted and calibrated data.

Results: Among the 3202 PLWH enrolled in the survey, 2411 (71.2%) were aware of the verdicts of whom 1207 (56.4%) reported they were concerned about them. Migrants from Sub-Saharan Africa (reference group) were the population with the greatest concerns compared with men who have sex with men (OR[95%CI] 0.77[0.60,0.97], p=0.047). Intravenous drug users (0.59[937.83], p<0.005), and other PLWH (0.70[940.98], p<0.04) living in precarious conditions (0.76[959.97], p<0.03) and having unprotected anal/vaginal sex with one’s main partner (1.39[91.01;1.91], p<0.044) were statistically associated with being concerned about the verdicts, while age, sex, educational level, disclosure to one’s main partner, time since HIV diagnosis and viral load were not.

Conclusions: Publicity about HIV criminalization affects the most vulnerable PLWH, especially foreigners living in precarious conditions who find it difficult to negotiate protection with their main partner. Despite their greater concern, migrants are under-represented among victims and those prosecuted in France. HIV-related cases. Further analyses are needed to understand the reasons explaining their fear. However, the study suggests that criminal risk perception among PLWH reflects more the level of stigma and discrimination they globally experience than the actual risk of prosecution they are exposed to.

TUPEC591
Policy and legal challenges and opportunities for HIV and drug abuse prevention among migrant tourism workers in the Dominican Republic

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Background: The presentation discusses results from a NIDA-funded mixed-method ethnographic study of the health vulnerabilities and social factors contributing to HIV/AIDS and drug abuse among migrant workers in two tourism areas in the Dominican Republic. Prior research by our team has demonstrated a behavioral and epidemiological connection between tourism zones and HIV and drug abuse risk. This project represents the first large-scale mixed-method ethnographic and survey study to determine the social, structural, environmental, and demographic factors that may contribute to “ecologies of vulnerability” within Caribbean tourism zones.

Methods: In Phase 1, the study utilized ethnographic mapping with male tourism migrants, key informant interviews, and in-depth qualitative semi-structured interviews with a theoretical-randomly sampled group of 36 migrant tourism workers (each interviewed twice).

Results: Our research has identified several key structural factors that contribute to vulnerability to HIV, drugs, and other health conditions. Our analysis focuses on understanding the distinct risks and vulnerabilities for deportees in comparison to internal migrants, and delineates that the former group faces a unique and particularly traumatic set of circumstances contributing to drug abuse and HIV risk. Our research with institutional representatives provides some directions for policy and structural interventions to address current gaps in services and policies that would narrow the gap in providing much-needed support for this neglected, highly vulnerable population.

Conclusions: Our analysis provides several structural and policy suggestions that would begin to alleviate some of the health effects among the migrant population working in Dominican tourism areas including:

1. public awareness of the damaging results of the stigmatization of deportees upon return “home”;
2. policy advocacy and community mobilization to change laws that criminalize drug treatment (e.g., methadone);
3. sensitivity training and accountability for authorities who are often known to abuse informal tourism laborers and drug users;
4. greater awareness among policymakers in the US of the invisible linkages between the mass incarceration and deportation of young men in the United States and the vulnerabilities that exist in Caribbean tourism areas that receive millions of tourists annually.

TUPEC592
Gender differences in meeting legal obligations to disclose HIV status within a cohort of HIV-positive illicit drug users in Vancouver

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Background: The Canadian legal position on HIV non-disclosure is among the strictest internationally. In October 2012, the Supreme Court of Canada (SCC) ruled that people living with HIV must disclose their HIV status to sexual partners prior to vaginal intercourse, unless they use a condom and have a low viral load, defined as < 1500 copies/ml.

Methods: Using cross-sectional data from the AIDS Care Cohort to Evaluate Access to Survival Services (ACCESS) a prospective cohort of HIV-positive illicit drug users in Vancouver, we estimated the proportion of participants who would be legally obligated to disclose their HIV status to sexual partners based on the 2012 SCC ruling. Interviewer-administered surveys collected socio-behavioural data, which were linked with clinical data and de-identified. ACCESS participants interviewed since October 2012 and self-reporting vaginal intercourse within six months before interview were included. Participants self-reporting 100% condom use and demonstrating viral load < 1500 copies/ml at every test within six months before the interview were deemed to satisfy the non-disclosure criteria. Multivariable logistic regression identified independent covariates of failing to satisfy the non-disclosure criteria.

Results: Our analytic sample included 176 participants, including 77 (44%) women. The median participant age was 45 (IQR: 40-51), and 42% were in a stable relationship at interview. Within six months before interview, 95% of participants had received ART for ≥1 day. 25% were employed, 12% were homeless, 16% had engaged in sex work, 66% had used injection drugs, and 6% had been incarcerated. Overall, 56% of participants satisfied the criteria for non-disclosure. Independent predictors of failing to satisfy the HIV non-disclosure criteria were female vs. male gender (OR 0.43 [95% CI: 0.22-0.87]), having one recent sexual partner (vs. >1 partners) (OR 0.35 [95% CI: 0.16-0.77]), recent incarceration (OR 0.20 [95% CI: 0.05-0.99]), and being in a stable relationship (OR 0.40 [95% CI: 0.20-0.80]).

Conclusions: Female and recently incarcerated participants were less likely to satisfy the Canadian legal criteria for non-disclosure, and as such are more likely to face a legal obligation to disclose HIV status to sexual partners, irrespective of the challenges to disclosure within the highly criminalized environment in which they seek care.
TUPEC593
Supporting policy-level action for improved health outcomes in Zimbabwe
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Background: Zimbabwe moved swiftly to adopt the 2013 WHO PMTCT regimen of initiating lifelong ART among all HIV-positive pregnant and breastfeeding women (Option B+) in November 2013. The new guidelines increase access to treatment, which requires increased human resource capacity in health systems. ART initiation in Zimbabwe has remained largely doctor-driven. Eighty percent of the country’s pregnant women receive care from nurses, and as such, nurses are key to effective implementation of Option B+. The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) engaged legislators to support policy reforms aimed at changing the scope of practice of nurses to allow them to initiate ART as a task sharing strategy in support of rapid transition to Option B+.

Methods: EGPAF provided technical and financial support to the Ministry of Health & Child Care (MOHCC) in developing a policy brief aimed at Parliamentary legislators. The policy brief simplified the technical narratives of the updated 2013 guidelines and highlighted policy-level reforms promoting nurse-led ART initiation and decentralization of ART to all health facilities. The MOHCC and EGPAF collaborated to hold dialogues with legislators in March and June 2014 using the policy brief to provide further guidance, generate discussion and keep momentum on the importance of nurse-led and decentralized ART.

Results: Nearly 100 legislators and parliamentary staff attended the dialogues, held in March and June 2014. Elimination of mother-to-child transmission of HIV was prioritized on the legislative work plan. Legislators used the brief and dialogues to conduct fact-finding visits to selected central, provincial and district hospitals to review the progress in implementation of Option B+. Results from these discussions were fed into Parliament culminating in a motion - a critical first step towards policy change - moved through the House of Assembly. Members of Parliament used the information to hold community dialogues with their constituents. The Parliamentarians appreciated the simplified policy brief and dialogues in understanding the policy-level action of the WHO 2013 guidelines.

Conclusions: Continued advocacy with legislators from varying backgrounds and with different levels of education is necessary to advance facilitative policy-level action for Option B+ and other HIV services.

Community involvement in biomedical prevention
TUPEC594
Facilitating community-led action for optimal uptake of prevention of mother to child transmission of HIV (PMTCT) services in vulnerable communities: the Elizabeth Glaser Pediatric AIDS Foundation-Zimbabwe community engagement program
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Background: Zimbabwe’s Demographic Health Survey (ZDHS) 2012 shows 65% of births occur in health facilities. The survey highlights strong relationship between uptake of antenatal care (ANC) and place of delivery. These high levels of home deliveries (35%) threaten Zimbabwe’s efforts to eliminate pediatric AIDS, as opportunities are missed to test women and ensure enrollment in prophylaxes. Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) engaged communities in targeted regions to promote actions that address hindrances associated with sub-optimal uptake of PMTCT services.

Methods: Manicaland Province was targeted for support due to high home delivery rates (35.7% of deliveries occur at home here). This rate is likely due to local beliefs that oppose institutional delivery. In 2014, EGPAF facilitated community stakeholder dialogues in five districts in the province. Six Dialogues gathered community residents and leaders (religious and political) within a health facility catchment area to discuss PMTCT build local understanding and promote ownership of the community’s roles in supporting optimal uptake of PMTCT services including institutional delivery. Partnering with other local health organizations, health services such as HIV testing and counseling, CD4 count testing, ANC, and well-baby checks were offered to residents during the dialogues. Aggregate PMTCT cascade data from local health facilities were presented, followed by discussions with different population groups (men, women, community leaders, youths, etc.) on their role to support PMTCT services.

Results: Nearly 4,000 people attended six community dialogues. Community leadership expressed appreciation of the platform to discuss local PMTCT aggregate data and understanding challenges associated with barriers to optimal service access. Local- led actions, based on decisions made during the dialogues included: community leaders in one district committed to building a shelter to provide temporary residence for expectant mothers to avoid the long distances; the local council in the same district allocated land for the shelter and a community business operator committed resources; in another district, the community raised its own resources and organized another community dialogue in a separate ward to address religious objections for facility deliveries.

Conclusions: Community dialogues promoted local-led action to addressing hindrances associated with sub-optimal uptake of PMTCT services.

TUPEC595
Engaging MSM key opinion leaders to create and sustain HIV and STIs services for a trusted community health centre Lagos, Nigeria
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Background: Located in South west Nigeria with a population of 15 million, Lagos State has HIV prevalence rate of MSM at 15.8%. Demand for HIV testing and counseling (HTC) services is low, condom use with both male and female partner is below 50% and self-reported STI symptoms are increasing (IBBSS 2010) with less than 10% of the population accessing such services due to their behaviours being stigmatized and criminalized making them hard to reach. A Trusted Community Health Centre (TCHC) is believed to have the capacity to reach the hard to reach MSM with HIV and STI services through the engagement of Key Opinion Leaders (KOLs).

Methods: Within it’s 2 years of operation, 10 MSM volunteers were selected and trained in December 2012 from different Local Government Areas in Lagos State based on their willingness to serve and having a large friend’s network. Volunteers were trained for 5 days on HIV/AIDS basic facts, prevention, care and support for people living with HIV and benefits of engaging MSM. Pre- and post-test questionnaires were used to assess change in knowledge. MSM specific Behaviour Change Communication (condoms, lubricants, leaflets, picture codes etc.) materials were given upon completion of training to commence work and act as Key Opinion Leaders (KOLs) to create HTC demand for the Community Health Centre using small group discussions, peer education and peer mentoring approach. Ongoing support from the TCHC was provided to the KOLs through regular visits to the mobilization sites and incentives.

Results: 100% volunteers completed the training. Pre and post-test questionnaire showed a 30% increase in knowledge. There was high level of active participation and contributions between the participants and facilitators. A total of 3,714 MSM above age 18 were tested and counselled and 3,221 cases of STIs were diagnosed and treated at the TCHC. There is an increased knowledge of HIV and increased uptake of condoms by the MSM who receive services at the TCHC.

Conclusions: MSM demonstrate higher knowledge acquisition after being trained. MSM as KOLs generate and sustain demand for HIV and STI services for stand- alone health facilities and promote positive health seeking behaviour of other MSM.

Integration of prevention interventions with care/treatment
TUPE7671
Effective use of task shifting in strengthening 4 symptom screening for TB disease among PLHIV in rural clinics in Northern Nigeria
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Background: To support seamless TB screening for the purpose of detecting TB suspects for further patient evaluation, including placing non-TB suspect on INH 300mg for prophylaxis against TB. WHO recommended 4 clinical symptom evaluation as follows: current cough, fever, weight loss, night sweat (adult patients parameters); and history of contact with persons with active TB, failure to thrive, fever, and cough (Pediatric specific) as a standard for clinical screening of TB. However, TB screening among PLHIV remains challenging. To address this, The USAID-funded Pro-ACT project implemented by MSF introduced non-clinicians to complement clinicians in screening PLHIV for TB.
Results: Findings from 11 high volume health facilities showed that 3,805 patients were screened for TB and found to be non-TB suspects before commencing INH 300mg for TB prophylaxis. Of this number, 1,019 have completed 6 months of INH300mg. No patient has been reported to have developed TB following screening and commencement of IPT. This result demonstrates the need for TB-HIV capacity building and support, non-dentists can support TB screening in health facilities, and TB prevention.

Conclusions: 4 symptom screening for TB has proven to be effective in excluding TB for patients declared non-TB suspect before commencement of IPT. The finding also supports TB screening by non-dentists who are provided with adequate skills for TB screening.

TUPED762
Integrating direct provision of ART into TB services to increase ART uptake among TB-HIV co-infected clients in south west Uganda (2010-2014)

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Background: Despite mounting evidence suggesting better health outcomes among TB-HIV co-infected clients receiving antiretroviral therapy (ART), ART coverage among this group, globally, remains subpar. TB-HIV co-infected clients have been identified as an important way to increase the coverage of ART for the TB-HIV co-infected clients.

Methods: HODs of all cadres from 11 high volume facilities at all points of service provision were provided with the necessary skills through trainings, coaching, mentoring and use of TB screening SOPs to be able to screen PLHIV for TB. Patients who are TB suspects based on screening were referred to the laboratory for further evaluation while those found to be non-TB suspects were commenced on INH 300mg. TB screening data collected over a period of 15 months from June 2013 to September 2014 were reviewed.

Results: There has been a remarkable improvement in ART initiation among TB-HIV co-infected clients from the background level of 68% to 78.9% in September 2012.

Conclusions: TB screening on PLHIV has proven to be effective in excluding TB for patients declared non-TB suspect before commencement of IPT. The finding also supports TB screening by non-dentists who are provided with adequate skills for TB screening.

Network of recently infected, HIV+ Network of long-term infected positive controls, HIV+ Total of HIV+ Total # of network participants who have been tested Ratio (% HIV positive)

Screening/seeds* 21 17 38 38 22.9% 2 steps from seeds 60 11 88 44 192 22.9% 3 steps from seeds 109 46 204 90 612 24.0% Total (excluding seeds) 169 57 292 99 604 23.7%

*Many of the seeds were referred from the screening program and are not included as TRIP cases

Methods to improve provider quality, supply and tailoring of services

TUPED764
Are women enrolled in the PMTCT program breastfeeding their infants? Findings from a PMTCT electronic database in Zimbabwe

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Background: There has been a marked improvement in ARRT initiation among TB-HIV co-infected clients in SW Uganda from 2010 to 2014. This can be linked to improved TB-HIV service integration through the scale up of direct ART service provision at TB diagnostic and treatment facilities. Accreditation of TB service facilities to provide ART to co-infected clients is an important way to increase the coverage of ART for the TB-HIV co-infected clients.

Conclusions: There has been a remarkable improvement in ART initiation among TB-HIV co-infected clients in SW Uganda from 2010 to 2014. This can be linked to improved TB-HIV service integration through the scale up of direct ART service provision at TB diagnostic and treatment facilities. Accreditation of TB service facilities to provide ART to co-infected clients is an important way to increase the coverage of ART for the TB-HIV co-infected clients.
the status of implementation of the guidelines regarding breastfeeding, and program implemen-
tation, the Elizabeth Glaser Pediatric AIDS Foundation (EGPFA) captured and analyzed data
from facility registers for women attending antenatal and postnatal care through an electronic
database (EDB) available at 36 representative sites throughout Zimbabwe.

Methods: From January to December 2013, infant feeding data for 338 HIV-infected wom-
en (at birth, six weeks, three, nine and twelve months) were collected from registers at EDB
sites. Analysis examined percentages of women exclusively breastfeeding, mixed feeding or
formula feeding. The objective of the analysis was to assess to what extent women were adher-
ing to infant feeding guidelines as set in the national PMTCT program. Data on HIV-retesting at
18 months for HIV exposed infants was also evaluated.

Results: From January to December 2013, six-week exclusive breastfeeding among HIV-
infected women at these sites remained high at 94%. By three months, 75% were still exclu-
sively breastfeeding; however, the proportion fell to about 21% at the six-month review (fig
1). Completeness of data captured in the registers covered by the EDB varied considerably
from site-to-site and trends after the first six months were not collected. Infant 18-month HIV
tests were only recorded in about 10% of cases; consequently, 15-month mother-to-child HIV
transmission rates could not be analyzed.

Conclusions: Recommendations for six-month exclusive breastfeeding are only adhered
by a fifth of women attending EDB sites in Zimbabwe. There is a need to improve infant feed-
counseling, better monitor long-term breastfeeding patterns; strengthen 18 month infant
feeding re-testing and improve completeness of data recording.

TUPED765
Quality of care and treatment for HIV-positive patients in two rural health
districts in sub-Saharan Africa

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Background: Quality of care is a determinant for access to care, adherence to treatment
as well as retention in care and is essential to ensure good health outcomes and to minimize
transmission, morbidity and mortality. Nevertheless, providing good quality care and treatment
is specifically challenging in health districts with scarce resources. This study assessed
the quality of care and treatment for PLHIV in the phase of rapid scale-up of ART in resource-
limited health districts in Tanzania and Burkina Faso in diverse epidemiological context focusing
on interpersonal, service delivery and process of care related quality.

Methods: A cross-sectional study design was adopted with mixed-methods approach, that
includes:

(i) key informant interviews;
(ii) client survey;
(iii) checklist for patient-provider encounter, health facility infrastructure, medical files; and
(iv) participatory observations.

Demographic information was collected from Demographic Surveillance Systems data. All ART
providing health facilities in the respective districts were included. A quality score with a maxi-
mum score of 5 was constructed to compare performance across facilities in both countries.

Results: None of the health facilities received performance scores higher than 3.5 (3.2-3.5)
indicating an average level of quality. The difference between facilities was not statistically
significant. Four main areas of weakness were:

(a) inappropriate care delivery processes, including lack of adequate physical examinations and
laboratory testing;
(b) incomplete assessment of patient’s readiness for ART eligibility;
(c) insufficient provision of information on ART implications; and
(d) incomplete and unsystematic health record and referral systems.

Conclusions: During the crucial phase of rapid scale up all health facilities included in
this study reported difficulties in coping with an increased demand for ART and 70% of the
health facilities did not meet the World Health Organization’s “four minimum requirements” for
ART provision.

Main challenges encountered included the number and capacity of health workers. Nurses
often provided the largest share of ART consultations, however were less likely to receive ap-
propriate training and capacity building opportunities. Any further expansion of ART provision
requires innovative models of care delivery and sustained capacity building for HCWs.

Disclaimer: The author alone is responsible for the views expressed in this publication
and they do not necessarily represent the decisions, policy or views of the World Health Or-
ganization.

TUPED767
HIV-infected adolescent and caregiver experiences of HIV stigma and discrimination
in Kenya

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Background: There are few data exploring how HIV stigma affects the lives and HIV
 care of those infected or affected by HIV. We sought to better understand how HIV stigma is
experienced by HIV-infected adolescents and caregivers in Kenya.

Methods: We conducted a qualitative study focusing on group discussions (FGD) at 3 HIV
clinics in western Kenya. Separate FGDs were held for HIV-infected adolescents (aged 15-19
years) and for caregivers of HIV-infected children. A trained facilitator led FGD in Kiswahili us-
ing a semi-structured interview guide based on an understanding of HIV-related stigma. FGD
recordings were transcribed, analyzed and investigated using constant comparison, progressive coding, and triangulation to arrive at a contextualized understanding of adolescent and caregiver experiences of HIV stigma.
Results: Forty adolescents (mean age: 13 years) participated in 5 FGD and 53 caregivers (mean age: 40 years) participated in 6 FGD. Most caregivers were the biological mother of an HIV-infected child (51%), aunt or uncle (19%) or biological father (13%). Participants described 4 types of HIV stigma: perceived, internalized, enacted, and courtesy (Table 1, Figure 1). Perceived stigma was the most common type of stigma identified by both adolescents and caregivers and was described as a deep fear of discrimination, specifically in the form of facing isolation and gossip within the community. Fears of loss of social support or damage to relationships were more common than fears of physical forms of stigma (e.g., fear of losing jobs, bullying, abuse, or losing community resources.) Fear of stigma motivated a number of treatment-related behaviors including secrecy about HIV status, not taking medicines in front of others, and hiding medicines, although caregivers alone reported attending distant clinics to avoid recognition. Reports of instances of enacted stigma were rarer than these prominent fears would suggest, and were less common with adolescents than with caregivers.

Conclusions: HIV-infected adolescents and caregivers described an environment characterized by fear of HIV stigma and discrimination in western Kenya. These perspectives offer valuable insight into the experiences of living with HIV in this setting and may inform interventions.

### Table 1: Types of Stigma Described by HIV-Infected

<table>
<thead>
<tr>
<th>Stigma Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internalized Stigma</td>
<td>Stigma directed at oneself</td>
</tr>
<tr>
<td>Enacted Stigma</td>
<td>Accounts of stigma lived in real time</td>
</tr>
<tr>
<td>Perceived Stigma</td>
<td>Fear of future stigma</td>
</tr>
</tbody>
</table>

![Figure 1: Illustrative Descriptions HIV Stigma](image)

**TUPED768**

What factors are critical in improving client satisfaction with PMTCT services in Zimbabwe? Findings from a client satisfaction survey

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**Background**

Quality improvement (QI) in health care aims to improve quality of care by modifying service delivery processes to optimize health services and client satisfaction. In Zimbabwe, client satisfaction with PMTCT services is not well-documented. Through support to the Ministry of Health and Child Care (MOHCC), the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) conducted a survey to assess client satisfaction with PMTCT services.

**Methods**

EGPAF conducted a descriptive cross-sectional survey on client satisfaction with services at 43 rural and urban health facilities across 6 provinces in November 2014. Interviews and focus group discussions were conducted with pregnant and breastfeeding women attending antenatal care (ANC) and postnatal care (PNC) clinics after receiving care. Client satisfaction with PMTCT services was assessed through 2.5 point bipolar Likert scales on care experiences and perceptions such as waiting time and confidentiality during consultation. Availability and functionality of client involvement systems was also assessed. Logistic regression was conducted to determine independent factors associated with client satisfaction. Ethical approval was granted by Medical Research Council of Zimbabwe.

**Results:**

Five hundred and sixty six, (300 ANC and 266, PNC) women were interviewed. Eighty two percent lived within 10km of the health facility. Eighty nine percent of the respondents were satisfied with PMTCT services received on the assessment day. Having had a physical health assessment by a clinician was independently associated with client satisfaction (AOR=2.12, p<0.004). Perceived long waiting periods before receiving services was associated with client dissatisfaction (AOR=0.30, p=0.008). Although not statistically significant, giving out clear instructions to clients was associated with client satisfaction (AOR=2.40, p=0.07). Systems to gather client views and comments (health center committees, comments books and suggestion boxes) were present; however, client awareness of the platforms was low (45%, 5% and 25%, respectively).

**Conclusions:**

Client satisfaction with PMTCT services in Zimbabwe is high. Efforts to further improve client satisfaction should target shortening client waiting time and promoting good medical practice that involves physical examination of clients during consultations. This requires more health staff time, which could be accomplished through task shifting. Clients should be continuously engaged by promoting use of available client feedback systems.

**TUPED769**

Congestion in urban HIV treatment clinics in Lusaka, Zambia: an assessment of factors to inform decongestion solutions

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**Background**

In 2013, Zambia adopted national antiretroviral therapy (ART) guidelines that increased the number of treatment-eligible patients. Concern over the impact of crowding and congestion in Lusaka’s ART clinics on retention rates prompted an assessment to gather evidence on the critical factors contributing to and possible solutions for facility congestion, with particular attention focused on barriers to 3-month refills for stable patients.

**Methods**

In November 2014, eight of the eligible ART clinics were randomly selected to participate in the assessment. ART registry records for 80 stable patients were reviewed and 84 patient exit interviews and 16 key informant interviews with clinicians were conducted. We obtained stockout history from medical store registers and observed patient time spent waiting for and receiving care at each clinic station.

**Results:**

Across sites, between 5% and 70% of stable patients received a 3-month supply of antiretroviral drugs (average 46%). Key informant interviews suggested shortages of staff and poor filing systems as causes of congestion, and inconsistent supply of drugs and the need to frequently return for lab results owing to lab systems challenges as barriers to 3-month prescriptions. From January to October 2014, 3 of 8 facilities experienced at least one stockout of the recommended first-line ART regimen (TDF+3TC+EFV*). Average stockout duration was 2.5 days (IQR 1.6). Most (77.4%) patients reported that long wait times were the primary reason they did not continue receiving care. Patients who only attended the clinic to refil their ARVs from the pharmacy (47.5%) spent an average of 1 hour 34 minutes from triage to departure, while patients coming for a clinical visit spent on average 2 hours 10 minutes. Actual consultation time with a clinician was 5 minutes on average.

**Conclusions:**

A large percentage of patients attended the facilities only to collect a refill from the pharmacy. Although Zambia’s national ART guidelines recommend that stable ART patients receive 3-month prescriptions, we found wide variation in refill practices across sites. We have tailored an intervention using quality improvement officers to troubleshoot challenges and improve refill practices. This work is expected to contribute to clinic decongestion and pave the way for additional service delivery improvements.
TUPE770
Descriptive case study of a quality improvement intervention to implement evidence-based HIV care and improve HIV care and treatment outcomes in 17 British Columbia sites

C. Clarke1, T. Cheng1, K. Reims2, C. Steinbock3, S. Milligan4, M. Thumath5

Abstract:
In high-income countries where highly active antiretroviral therapy (HAART) may be more widely available via established healthcare systems, gaps persist across the HIV continuum of care. In the intervention setting of British Columbia (BC), Canada, only 46.8% of the HIV-diagnosed population were adherent to treatment and achieving virologic suppression in 2010. In December 2010, a quality improvement (QI) initiative was launched to disseminate and implement evidence-based practices for improving HIV care and treatment outcomes.

Methods:
HIV care sites across BC were recruited to participate in a quality improvement initiative: Breaking Through Series Collaborative methodology. Between December 2010 and October 2013, sites learned about and applied evidence for improving HIV care and reported monthly qualitative descriptions of their changes with four numerical care quality indicators. From January 2011 to 2012, two reviewers analyzed reports and assigned implementation scores based on objective criteria (Table 1). Quality indicators were pooled and interpreted using accepted probability-based run charts rules (RCR).

Results:
A total of seventeen teams with a pooled median population of 2,296 HIV-patients in 2011 joined the initiative. In year one, median implementation scores increased from 1.0 (SD=0.38) to 3.3 (SD=0.85) on a scale ranging from 0.5 (no activity) to 5.0 (full implementation of the Chronic Care Model (CCM), all quality indicators at 95%, and spread of changes beyond the initial population). A total of 29% of sites achieved an implementation score of 4.0 or greater, indicative of comprehensive CCM implementation and evidence of improvements. Analyzed by RCR, in quality indicators. Analysis of pooled quality indicators using RCR signaled evidence of improvement for patient engagement in care (median 88.8% to 90.4%), and the proportion of patients on treatment for six months or more and achieving virologic suppression (median 57.3% to 78.4%) (both p<0.05).

Conclusions:
This multi-site QI intervention successfully increased implementation of evidence-based practices to improve HIV care quality outcomes. The overall success of the intervention points to opportunities for spreading this methodology to improve HIV care and treatment outcomes. Scaling-up time-limited interventions such as this have potential to maximize the efficacy and efficiency of publicly-funded healthcare systems across Canada and in other high-income countries.

Disclosure: None

TUPE771
Forecasted demand for ARV medicines in low and middle income countries up to the end of 2018

V. Habiyambere, J. Perriens, B. Dongmo-Ngumfack
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Abstract:
In high-income countries where highly active antiretroviral therapy (HAART) is more widely available via established healthcare systems, gaps persist across the HIV continuum of care. In the intervention setting of British Columbia (BC), Canada, only 46.8% of the HIV-diagnosed population were adherent to treatment and achieving virologic suppression in 2010. In December 2010, a quality improvement (QI) initiative was launched to disseminate and implement evidence-based practices for improving HIV care and treatment outcomes.

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Disclosure: None

TUPE772
The demand for CD4 testing, viral load and early infant diagnostic testing in low and middle income countries will grow strongly between now and 2018

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Abstract:
In high-income countries where highly active antiretroviral therapy (HAART) is more widely available via established healthcare systems, gaps persist across the HIV continuum of care. In the intervention setting of British Columbia (BC), Canada, only 46.8% of the HIV-diagnosed population were adherent to treatment and achieving virologic suppression in 2010. In December 2010, a quality improvement (QI) initiative was launched to disseminate and implement evidence-based practices for improving HIV care and treatment outcomes.

Methods:
HIV care sites across BC were recruited to participate in a quality improvement initiative: Breaking Through Series Collaborative methodology. Between December 2010 and October 2013, sites learned about and applied evidence for improving HIV care and reported monthly qualitative descriptions of their changes with four numerical care quality indicators. From January 2011 to 2012, two reviewers analyzed reports and assigned implementation scores based on objective criteria (Table 1). Quality indicators were pooled and interpreted using accepted probability-based run charts rules (RCR).

Results:
A total of seventeen teams with a pooled median population of 2,296 HIV-patients in 2011 joined the initiative. In year one, median implementation scores increased from 1.0 (SD=0.38) to 3.3 (SD=0.85) on a scale ranging from 0.5 (no activity) to 5.0 (full implementation of the Chronic Care Model (CCM), all quality indicators at 95%, and spread of changes beyond the initial population). A total of 29% of sites achieved an implementation score of 4.0 or greater, indicative of comprehensive CCM implementation and evidence of improvements. Analyzed by RCR, in quality indicators. Analysis of pooled quality indicators using RCR signaled evidence of improvement for patient engagement in care (median 88.8% to 90.4%), and the proportion of patients on treatment for six months or more and achieving virologic suppression (median 57.3% to 78.4%) (both p<0.05).

Conclusions:
This multi-site QI intervention successfully increased implementation of evidence-based practices to improve HIV care quality outcomes. The overall success of the intervention points to opportunities for spreading this methodology to improve HIV care and treatment outcomes. Scaling-up time-limited interventions such as this have potential to maximize the efficacy and efficiency of publicly-funded healthcare systems across Canada and in other high-income countries.
Healthcare workers and volunteers: training, mentoring, retaining, task shifting, safety

TUPE773
Community Lay Cadres’ contributions and over task-shifting in expansion of antiretroviral therapy to rural health centres in Zambia

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TUPE774
Reductions in annual ART costs in Uganda: implications for future ART resource needs and task-shifting

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Background: Data on per-patient ART costs provide information for budgeting, planning, and modeling cost and cost-effectiveness. We estimated the cost per ART visit for three large AIDS treatment organizations in Uganda. Kitovu Mobile (KM) uses a community outreach approach and services are delivered at the community level; Uganda Care (UC) has a mixed model: Standard (UC-S) and Task-Shifted (UC-TS); and TASO uses a hierarchical structure with one headquarter, four regional offices, and 11 service delivery centers all associated with community drug distribution points (CDDPs). Of these three models, KM is considered highly task-shifted, while UC and TASO have a mixture of highly- and minimally- task shifted models.

Methods: Retrospective costs directly incurred by the providers in 2012 were collected. Provider costing data reflected both financial costs of services for ART treatment such as drug and personnel costs; and economic costs such as equipment, training, and construction. The cost per client visit was estimated, as provider records did not account for numbers of unique patients.

Results: The average estimated cost per client visit was $21 for KM, $26 for UC, and $39 for TASO clients. For TASO and UC, personnel and operational costs accounted for approximately 50% of total costs, while drugs and laboratory account for the rest. For KM, drugs and laboratory account for over 60% of the total costs. Given that each patient makes an average of four visits per year, the annual provider ART cost per client ranges from $100 to $160.

Conclusions: Outreach or more task-shifted models cost less to service providers. The analysis also revealed a reduction in annual ART cost compared to findings from previous studies in Uganda and similar contexts. This might be due to increases in number of clients, reductions in drug costs, and the fact that these three organizations are mature. In addition, these three task-shifted models did not compromise service quality (85% reported satisfied) and retention rate (80% at 18 months) based on our separate analysis. Further studies are needed to identify and understand the quality and effectiveness of each model, as well as the economic costs to the clients who receive their services.
TUPE776
HIV training program is effective to increase HIV knowledge among health care workers in Georgia

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Background: Increasing HIV related knowledge to reduce HIV associated stigma is crucial intervention to fight against HIV epidemic. We proposed a study to assess the improvement of HIV knowledge and to reveal its associated factors, among healthcare workers participating in HIV training program. The program provided HIV trainings for healthcare workers to increase HIV knowledge and reduce stigma in Eastern European country of Georgia.

Methods: A total of 1880 health professionals participated in HIV trainings during 2012-2013 years. HIV trainings were provided in 5 regions of Georgia. HIV knowledge was assessed by using identical self administered pretest-posttest survey questionnaires before and after training. Questionnaire included demographic and professional information, as well as multiple choice questions about HIV: diagnostic, transmission, ART treatment and care. We applied linear regression models suggests that age, experience and HIV training sometimes before pretest are significant (p< 0.0001) predictors to increase HIV knowledge after participating in HIV training program.

Results: From 1880 health professionals participating 64 % (1575) were females; median age was 41 (IQR 29, 51). Participants with high medical education and nurses represented 83.1 % (1562) and 16.9 % (318) consecutively. The mean percent of correct answer at pretest was 50.0 %, which was increased to 85.7 % after HIV training in post-test. The difference between mean scores tested with paired t test was statistically significant (p< 0.0001). Multiple linear regression models suggests that age, experience and HIV training sometimes before pretest are significant (p< 0.0001) predictors to increase HIV knowledge after participating in HIV training program.

Conclusions: In conclusion HIV training program among health care workers was effective to increase HIV knowledge. We recommend more training and/or retraining of health professionals, as well as to include HIV training course into Continuing Medical Education for health workers.

TUPE777
Taking lessons learned in the implementation of a clinical mentorship program to increase the confidence of nurses to initiate ART, in support of the roll out of Option B+

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Background: Since inception of the anti-retroviral therapy (ART) program in Zimbabwe in 2004, ART initiation among pregnant women and children has been doctor-led. There is a shortage of doctors in Zimbabwe, particularly in rural settings. Despite decentralization efforts, only 25% (401/1630) of antenatal care (ANC) facilities in Zimbabwe dispensed ART by December 2013. The majority of ANC nurses trained in HIV management working at these sites cited lack of confidence as a key barrier to ART initiation. EGPAF sought to address this gap through implementation of a clinical mentorship program for nurses.

Methods: EGPAF supported clinical mentorship in seven provinces of Zimbabwe from March to September 2013, involving 230 nurses from 103 sites. The trained nurses completed a one-week, practical training on ART initiation and care of HIV and opportunistic infections at ART sites. Following this internship, a multidisciplinary team of mentors (a doctor, nurse, and pharmacy technician) from each district hospital provided onsite mentorship bimonthly for three months. Mentorship included observation of case management and reinforcement of skills, and review of patient monitoring cards and registers. These mentors would also check in with nurses over the phone between visits to answer questions. To compare data, 447 control sites were selected - frequency matched to mentorship sites by number of ANC bookings per quarter, geographic location and availability of CD4 testing. Quarterly mean uptake of ART in ANC was compared between mentorship and control sites for before, during and after mentorship using EGFRF program data.

Results: There was a significant increase in ART initiation among pregnant women at the mentorship sites compared to control sites (p value = 0.048) (Figure 1). A total of 168 children less than 2 years of age were initiated on ART at mentorship sites. Before mentorship all infants and young children were referred to district and central hospitals for ART initiation by doctors.

Conclusions: Clinical mentorship is an effective way of building the confidence of trained nurses to initiate pregnant women and children on ART and can be used to support decentralization and expedite the roll out of Option B+ as recommended in WHO’s 2013 guidelines.
Demand generation for HIV services

TUPED779

Overcoming burden of seasonality in scaling up voluntary medical male circumcision: a case study from Tanzania

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Background: Local beliefs about healing, agricultural and school traditions, and wide-spread preferences for VMMC during “cold” months have plagued the VMMC scale-up and is a major barrier to the target of serving 20 million adults in 14 priority countries. Seasonality causes inefficient use of health workforce and infrastructure. Cost analyses suggest low service utilization in “off seasons” results in the greatest increase in unit price among all factors examined. Research conducted in 2010 in Iringa region of Tanzania indicated very strong client preferences for circumcision during the 3-month long “cost” season, and in the first year of the program 88% of VMMCs were performed during these months. To become more efficient the VMMC program, led by the Government of Tanzania with support from Jhpiego (funding from PEPFAR through USAID), endeavored to overcome the constraints of seasonality.

Methods: Routine VMMC client data in de-identified individual records is collected during clinical services and entered into a database. Data from October 2009 to September 2014 was exported into Excel and analyzed. Programmatic experiences were collected by project staff and documented in annual reports. Key informant interviews were held with eight VMMC providers.

Results: Approaches used to overcome seasonality were:

1. Focus on rural areas where VMMC services would not otherwise available during the preferred season.
2. Collaborate with district and local school officials and parents to allow students to be re-leased for services.
3. Use media messages to expose potential clients to satisfied clients circumcised off-season and promote positive benefits such as shorter lines/more privacy.
4. Train providers to change their attitudes and also to address issue of healing and seasonal-ity with clients.

As a result of these efforts, the percentage of clients served in the winter season decreased from 88% in 2010 to 28% in 2014, while the number of clients served overall increased each year.

Conclusions: Tanzania has provided a pathway of low cost solutions that can be used by other countries faced with the challenge of seasonality. Breaking seasonality will decrease the VMMC unit cost while increasing productivity with similar resources - making the VMMC programs more efficient overall.

Strategies to increase linkage to HIV care

TUPED780

Implementing access to care interventions: structural, organizational and personnel barriers and facilitators

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Background: Early connection to and retention in HIV care is critical to reaching and maintaining viral load suppression but current information indicates that only 19.8% - 43.4% of people who live with HIV (PLWH) are undetectable. Given the recent findings that viral load suppression dramatically reduces the transmissibility of HIV, finding and linking PLWH to care is critical. Yet, we know relatively little about how to effectively implement linkage interventions to reach PLWH who are not in care.

Methods: AIDS United’s Positive Charge (PC) initiative funded five U.S. sites from 2010-2013 to implement linkage to care interventions. Each site implemented evidence-based strategies, including care navigation, case management, motivational interviewing, and addressing structural barriers to care (such as providing transportation or providing same-day appoint-ments). Because the interventions aimed to both engage the individual and increase coordina-tion among service providers to facilitate access to care, each lead agency had at least two local collaborating agencies. Qualitative interviews about the experiences of implementation, including barriers and facilitators, were conducted with 37 staff members from 20 implementing agencies.

Results: Descriptions of implementation barriers and facilitators fell into four major cat-egories: environmental factors; collaboration; staffing; and, role confusion. Environmental factors included organization readiness to implement and lack of service infrastructure in the community. Collaborative factors included the necessity of smooth integration among different programs to enable “warm” handoffs. Ensuring confidentiality of patient information within the service network was of particular concern. Adequate leadership support and staff training were other factors that impacted implementation. Finally, differentially roles of linkage staff and case managers was critical. Successful implementation strategies included developing early relation-ships with collaborating partners, finding ways to share key information among agencies, and using evaluation data to build support among leadership staff.

Conclusions: Given the increased interest in engaging PLWH in care, the findings from this study have potential to greatly inform community-based interventions in the U.S., as linkage and retention in HIV care is now understood to be critical to stemming the epidemic. Ensuring there is a culturally competent system of care that is responsive to PLWH’s needs is a crucial task for the public health system.

TUPED781

Peer navigation in South Africa: addressing stigma and psychosocial barriers to engagement in HIV services

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Background: Engaging patients in medical care and supportive services is essential to HIV treatment and prevention goals. In higher resource settings, peer navigation (PN), the use of HIV-positive individuals to help optimize patients’ utilization of clinical resources, has been effective at improving retention in care. The feasibility of implementing PN in lower resource settings with widespread epidemics is not well understood. In South Africa, prior research has shown that social support enhances medication adherence, but it is unknown whether PN can address barriers to engaging in clinical services.

Methods: We conducted a five-month pilot PN program at four primary health clinics in North West Province, South Africa to promote retention in care, medication adherence, and secondary prevention behaviors (e.g., disclosure, condom use). Upon completion of the pro-gram, in-depth interviews were conducted with five healthcare providers, four HIV-positive peer navigators, and nine patients who were newly diagnosed when PN services were introduced. Interviews explored experiences receiving and providing navigation, program acceptability, and challenges and successes in engaging patients. Interviews were recorded, translated and tran-scribed, and coded and analyzed using Atlas.ti.
Results: Participants felt that PN was valuable in improving retention in care, adherence, and prevention. Its impact was most evident around helping patients disclose, elicit social support, and make prevention decisions. The primary barriers that newly diagnosed patients faced were stigma-related (e.g., difficulty accepting their status, fears about telling others of their infection). Whereas other healthcare providers had little time to address such barriers, navigators helped patients overcome them by adopting multiple roles, including mentor and confidante. Challenges faced by navigators included stigma-related concerns about their own HIV status disclosure and difficulties helping patients become self-sufficient problem solvers. A programmatic challenge is training PNs to engage in dynamic interactions and creative problem solving.

Conclusions: In this setting, a PN model is feasible and acceptable for providers, navigators, and clients. It is critical that peer navigators receive psychosocial support to accept and disclose their own HIV status, and ongoing training to manage patients’ stigma-related barriers and to teach safe disclosure and problem-solving skills. Larger studies are needed to test the approach’s efficacy over the long term.

TUPED782
Implementation of a rapid referral pathway to HIV treatment for gay men and MSM diagnosed with acute HIV-infection in sexual health clinics in British Columbia

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Background: During acute HIV infection (AHI), there is a high risk of onward transmission due to significantly elevated HIV viral load. This intervention was designed to facilitate immediate linkage for acutely infected individuals detected with pooled nucleic acid amplification (NAAT) HIV testing from STI clinics to HIV treatment and support. The objectives of the pilot were to improve retention and engagement in HIV care by linking MSM to care within 48 hours and potentially impact onward transmission.

Methods: Participants were offered the choice of standard of care (passive linkage) or the offer of an immediate same-day referral and accompaniment to an HIV specialist. Participants were also offered referrals to peers receiving navigation, primary care, and social work as appropriate. A retrospective evaluation using quality improvement methods was conducted. This included a chart review to assess linkage to care and qualitative interviews with providers and patients to assess patient satisfaction. Linkage to care was defined as having an HIV viral load load by an HIV treating physician.

Results: Prior to pilot implementation, out of 45 patients diagnosed with HIV, the median linkage to care in 2013 was 21.5 days. After applying the intervention, a total of 19 clients were diagnosed with acute HIV from Jan 1 to Sept 1, 2014 at the STI clinics. Of these, 16 (84%) chose immediate referral and were linked to care in a median of 1.0 days. The median linkage to care for non-acute patients (n=15) was 14.0 days during the same time (p<0.05). The majority of acute patients using the immediate referral pathway expressed a high degree of satisfaction with immediate linkage to care. Clinicians reported high patient interest in immediate treatment.

Conclusions: Immediate linkage from STI services to HIV specialist care, with comprehensive social support to be highly acceptable to MSM diagnosed with acute HIV infection in Vancouver. Important implications exist for partner notification including the offer of post exposure prophylaxis for contacts. Further research is needed to assess the potential impact on HIV prevention and the long-term implications of earlier treatment including adherence.

TUPED783
Factors associated with ART initiation among HIV-infected participants in the Bangkok men who have sex with men cohort study, 2006-2014

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Background: In 2014 Thailand released new antiretroviral treatment (ART) guidelines stating that persons with HIV should initiate ART regardless of CD4+ cell count. We investigated the factors associated with initiating ART among HIV-infected participants in the Bangkok Men Who Have Sex with Men Cohort Study (BMCS).

Methods: Between 2006-2010, we enrolled men into the BMCS and followed them every 4 months for 3-5 years. At each visit, we conducted HIV testing, and collected behavioral data using computer-assisted self-interview. For HIV-infected participants, we provided post-test and ART counseling, follow-up visits with CD4+ cell count monitoring from HIV diagnosis until the last study visit, and referral to a specialized ART service when they were eligible for ART acc.
**TUPED786**

**Preliminary findings from a care facilitation approach to accelerate entry into care after HIV diagnosis from mobile HIV counselling and testing units in South Africa**

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**Background:** Individuals recently diagnosed with HIV need to overcome several individual- and system-level barriers in order to benefit from both the health and prevention goals of early HIV care. Participation in motivational and strengths-based counselling support may assist individuals in developing self-efficacy to overcome these barriers. Here we describe the uptake of a multi-session strengths-based care facilitation programme by participants diagnosed through mobile HIV counselling and testing (HCT) units.

**Methods:** A prospective study in a pragmatic trial in which participants are recruited in two districts in South Africa immediately after testing HIV-positive at mobile HCT units. Participants in this analysis were limited to those randomized to the care arm. Care facilitation was offered, individually or in pairs, at individual-level, within 90 days of HCT and a maximum of five sessions were provided in person at a venue accessible to the participant or telephonically. Up-take was defined as attending at least one session. We describe the proportion of intervention uptake and factors associated with uptake using logistic regression.

**Results:** Between March 2012 and October 2014, 662 participants were assigned to care facilitation. 66% were male, 40% were rural residents, with a median age of 33 years (interquartile range [IQR] 27, 40) and CD4 cell count of 435 cells/μL (IQR; 280, 600). Overall 366 (81%) attended at least one session. The median time to the first session was 21 days (IQR 8, 45), and this was lower among rural compared to urban residents (15 vs. 25 days). 246 (67%) of the participants attended at least one session. The median time to the first session was 21 days (IQR: 8, 45), and this was lower among rural compared to urban residents (15 vs. 25 days). 246 (67%) of the participants attended at least one session. The median time to the first session was 21 days (IQR; 8, 45), and this was lower among rural compared to urban residents (15 vs. 25 days). 246 (67%) of the participants attended at least one session. The median time to the first session was 21 days (IQR; 8, 45), and this was lower among rural compared to urban residents (15 vs. 25 days).

**Conclusion:** These findings suggest the feasibility of a multi-session counselling approach to increase uptake for strengths-based counselling to be an effective component of connecting people with HIV to care.

**TUPED787**

**TB/HIV Care Association’s model to increase linkage to care for sex workers: a peer linked mobile service with point of care CD4 testing and STI syndromic management**

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**Background:** Linkage to care and treatment is crucial for public health impact. Referral challenges exist for all clients, but for sex workers (SW), who are criminalized and stigmatized, this path to health services is a more difficult journey.

**Methods:** TB/HIV Care Association (THCA) is providing a SW peer linked mobile health programme in Ethekwini (Durban), in South Africa. The services include screening for HIV, tuberculosis (TB), and sexually transmitted infections (STIs) with referral care and support. HIV-positive SWs are provided with point of care CD4 testing and WHO staging. TB suspects, who have spumon collected and GeneXpert-positive clients are referred and STI clients referred on site THCA syndromic management. Screened clients are linked to a SW peer navigator and sexualized THCA clinic staff member and provided a referral letter to the clinic. Referral SWs benefit from our algorithms to ensure linkage to care (phone calls, peer visits and navigation) verification with clinic. Successful referral was measured as the proportion of clients with confirmed clinical attendance or who received THCA syndromic management. Service delivery data was analysed from July 2012 to June 2013 (Y1), July 2013 to June 2014 (Y2) and July to September 2014 (Y3).

**Results:** Successful referral for all HIV-positive SWs increased from 33% (247/751) in Y1 to 49% (352/717) in Y2 and 68% (145/213) in Y3. In Y3, only 27% (1027) of clients who refused point of care CD4 testing were successfully referred compared to 72% (91/127) of clients CD4 tested not eligible for ART and 75% (44/59) of clients CD4 tested eligible for ART. Successful referral for TB increased from 39% (94/244) in Y1 to 60% (54/95) in Y2 and for STIs increased from 35% (10/288) in Y1 to 85% (277/328) in Y2.

**Conclusion:** A peer linked, sensitized mobile clinic staff, point of care CD4 testing and STI syndromic management and strengthened referral improved linkage to care for HIV, TB and STIs. This may have an important impact on decreased transmission in the community.

**TUPED788**

**Delays in antiretroviral therapy initiation among HIV-positive individuals: results of a community-based positive living with HIV (POLH) study in Kathmandu, Nepal**

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**Background:** Approximately 5.3 million people living with HIV/AIDS (PLHWA) needing antiretroviral therapy (ART) in low-and-middle income countries had not received it by 2012. Among those who initiated the treatment, high rates of ART initiation during the advanced stages of the disease remain a concern because of increased risk of early mortality and further HIV transmission. Although treatment eligibility has been monitoring during pre-ART care, many PLHWA fail to access regular care after HIV diagnosis or obtaining CD4+ count result. Yet studies exploring ART eligibility among PLHWA at the community level are sparse. This community-based study explored ART eligibility and correlates among PLHWA in Kathmandu, Nepal, where ART coverage was only 23.7% in 2011.

**Methods:** This cross-sectional study was conducted among 326 PLHWA (20-60 years) recruited through the networks of five non-governmental organizations working with PLHWA. Participants’ CD4+ cell counts were tested by the National Public Health Laboratory. Potentially correlates included perceived family support (measured with 10-item scale), depression (measured with Nepali version Beck Depression Inventory-I), illicit drug use, and HIV symptom burden. Correlates of ART eligibility were examined using multivariable logistic regression analysis.

**Results:** We obtained CD4+ count results of 289 participants: 72 of them were ART-naïve. Half of the ART-naïve participants were eligible for ART with CD4+ counts of < 350 cells/mm3. 33.3% of these participants had CD4+ count result < 200 cells/mm3.

**Conclusion:** High proportion of ART-eligible individuals and strong association between low levels of perceived family support and ART-eligibility among our participants suggest that, to improve ART initiation among treatment-eligible individuals, thereby ART coverage in the country, HIV service providers should consider the role and impact of family support in influencing individual decision.

**TUPED789**

**Enhancing community engagement through involvement of community members in delivery of antiretroviral drugs (ARV) to fellow community members: TASO Rukungiri experience**

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**Background:** The AIDS Support Organization (TASO) is the biggest HIV/AIDS care organization caring for PLHIV in Uganda since 1987. To date over 150,000 PLHIV have been supported with psychosocial, medical and social support services. In Uganda the HIV prevalence rate is over 7.3%, meaning that the demand for HIV services is enormously higher yet resources especially human resources for health are limited. TASO employed a strategy of engaging community members mostly those living with HIV (commonly known as Expert clients) to support in service delivery, empower fellow clients in management of own health and reduce frequent clinic visits, and community HIV/AIDS sensitisation.

**Methods:** In one of the 11 branches of TASO, Rukungiri recruited and trained 107 Expert Clients (ECs) in 2010 covering a radius of 100km from the branch offices, caring for atleast 8,000 PLHIV. In addition over 25,000 family members of PLHIV are also supported with routine psychosocial services, economic strengthening and education support for OVCs, support fellow community member in delivery of drugs (ARVs), HIV sensitisation, ART and TB adher-
ence monitoring through Directly Observed Therapy (DOTs) and pill count, follow through with behavioral change management strategies within the same communities and act as referral or contact agents between the health facility (TASO) and community. At quarterly basis all PLHIV in a given area converge and interface with technical staff and also give account of the quality of service provided by their Expert clients.

**Results:**
1. On average each EC reaches 50 PLHIV per month which has increased reach of HIV/AIDS services to would to hard to reach areas in Uganda.
2. Engagement of ECs has reduced operational cost for HIV service delivery in TASO as technical staff interface with PLHIV only on quarterly basis other than monthly basis.
3. ECs have improved HIV/AIDS awareness levels in their communities since they are always within the community moving home to home, counseling and offering paramedical services to fellow members.

**Conclusions:** Engaging communities in service delivery is not only a key driver to achieving community ownership and accountability but also a way to reduce operational cost and demand for human resources for health.

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**TUPED790**

**Bringing community to cure**

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**Background:** Community engagement is essential for successful HIV Cure Research. Individuals with HIV will need to be aware of the potential and risks of HIV cure research in order to make informed decisions about participating in clinical trials. Those with and affected by HIV are needed for advocacy, ethics discussions, and messaging feedback. The defeatHIV Community Advisory Board (dHCAB) is an effective catalyst for community engagement and feedback between HIV cure researchers and the community, as well as for collaboration among different local HIV-related CABS, such as those for CFAR, ACTU, and HVTU. The dHCAB is the local CAB for the defeatHIV Martin Delaney Collaboratory based at Fred Hutchinson Cancer Research Center in Seattle, WA, one of three NIH-supported cure collaboratories.

**Methods:** The objective is to engage communities, including: community forums with HIV cure research leaders; opportunities to meet Timothy Ray Brown; providing multi-cultural food and music at education events; holding community events at different community organizations and venues; visiting agencies to engage them in cure research; tabling at events such as the annual AIDS walk and pride festivals, theater productions, etc; webinars; active use of social media, including Facebook, Twitter and Youtube. Those on the dHCAB have had the opportunity to attend and present at scientific meetings and to provide input to researchers on protocols, informed consent documents, and recruitment.

**Results:** Over 1000 community members have participated in dHCAB events and we have reached thousands more through outreach. The dHCAB currently consists of 12 members. Members range in age from high school to senior citizens and include women, gay and straight men, individuals in recovery, newly diagnosed individuals and long term survivors, African-Americans, Asians, Latinos, and Native Americans. Programs typically bring in dozens to hundreds of participants. The defeatHIV investigators consider the dHCAB a valuable asset and partner and have taken feedback to heart. We have learned about community concerns and provided meaningful pathways for education and dialogue.

**Conclusions:** With creativity, perseverance and respect it is possible to engage the community and researchers in meaningful ways that will advance HIV cure research.

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**TUPED791**

**Implementation of community-based adherence clubs for stable antiretroviral therapy patients**

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**Background:** Community-based models of antiretroviral therapy (ART) delivery have been recommended to support ART expansion and retention in resource-limited settings. However the evidence base for community-based models of care is limited. We describe the implementation of community-based Adherence Clubs (CACs) at a large, public-sector facility in peri-urban Cape Town, South Africa.

**Methods:** Starting in May 2012, stable ART patients were down-referred to CACs. Eligibility was based on self-reported adherence, >12 months on ART, and viral suppression. CACs were facilitated by 4 community health workers (CHWs) and met every 8 weeks for group counseling, a brief symptom screen and distribution of pre-packed ART. The CACs met in community venues for all visits including annual blood collection and clinical consultations. CAC patients could send a patient-nominated treatment supporter (“buddy”) to collect their ART at alternate CAC visits. Patient outcomes during the first 18-months of the programme are described using Kaplan-Meier methods.

**Results:** From June 2012 to December 2013, 74 CACs were established, each with 25-30 patients, providing ART to 2,133 patients (Figure 1). CAC patients were predominately female (71%) and lived within 3km of the facility (70%). During the analysis period, 9 patients in a CAC died (<1%), 53 were up-referred for clinical complications (0.3%) and 573 CAC patients sent a “buddy” to at least one CAC visit (27%). After 12 months in a CAC, 6% of patients were lost to follow-up and fewer than 2% of retained patients experienced viral rebound (>1000 copies/ml).

**Conclusions:** Over a period of 18 months, a community-based model of care was rapidly implemented decentralizing more than 2,000 patients in a high prevalence, resource-limited setting. Key factors contributing to the implementation success were a cohesive multidisciplinary team, policies supporting out-of-facility ART distribution by CHWs and a reliable supply of ART. The primary challenge for this out-of-facility model was ensuring that patients receiving ART within a CAC were viewed as an extension of the facility and part of the responsibility of CHC staff. Further operational research is needed to optimize timing of down-referal after ART initiation and to examine patients’ experiences of community-based ART delivery.

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**TUPED792**

**“Health care workers have changed their bad language”: When the patient's voice is heard**

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**Background:** Elizabeth Glaser Pediatric AIDS Foundation, in collaboration with facility-based and district quality improvement teams (QIT), introduced the Patient’s Voice program to solicit community-level feedback on clinical services in Kikimanjaro Tanzania.

**Methods:** Two high-volume hospitals providing HIV treatment services, who utilize community resource persons (CRPS), QITs, introduced quarterly assessments, including patient satisfaction exit surveys (PSS) administered by district-level QIT members to about 25 patients, and Community Dialogues attended by up to 50 community members, led by the CRPS. For transparent data review and action planning, the program incorporated consumer representation on the facility QIT. These teams were then responsible for implementing improvement projects in response to the issues identified.

**Results:** Since 2013, each site completed four rounds of assessments resulting in 363 community participants and seven completed QIT meetings. The PSS and dialogues revealed different issues at each round and in each facility. In one facility, the main finding from the first round was long waiting time at various service delivery points. Mean waiting time reported on PSS was significantly reduced in subsequent rounds (R1=3.8 hrs, R2=2.4, R3=2.6, R4=3.0, p<.005) after the QIT implemented the following changes: appointment time blocks, two additional drug dispensing windows/stations, and a clock placed in the staff meeting room to encourage timeliness of meetings and breaks. The other facility’s dialogue highlighted poor quality of care at the labor ward, namely that women were required to wash hospital linens after delivery and staff spoke rudely.

The district management addressed the issue with hospital staff, and patients reported in the next round an improvement: “Health care workers have changed their bad language.” Later
TUPED793
A community-led health campaign in a low-resource rural setting in Western Uganda

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Background: Universal HIV testing and counselling is critical for comprehensive test and treatment strategies in prevention and reduction of new infections. Community health campaigns have been proved effective in providing HIV and multi-disease screening in a research setting (SEARCH; NCT01864603). We sought to evaluate the feasibility and cost of a community-led approach to carrying out a multi-disease health campaign using local political and health leadership, in a rural Uganda community.

Methods: In September 2014, community leaders within the geo-political area of the Rwabashkye health center, initiated and led a village-level census and mobilization activities including organized meetings and poster distribution, in advance of implementing a 6-day health campaign conducted in 3 different locations. Local leaders from a neighboring SEARCH community volunteered in an advisory capacity during the planning stages. During the campaign, health staff provided counseling, diagnosis, treatment and referral services at all campaign locations. Lab services included point-of-care screening for HIV, malaria, hypertension and diabetes. Referral for all further care, safe male circumcision, and family planning services was offered. Costing of all supplies purchased and donated was conducted after the health campaign.

Results: 5194 persons were enumerated prior to and 2463 persons attended the health campaign. The mean age in attendance was 25 years with 41.8% male participation. HIV tests were performed in 2119 (85.9%) participants and in 1537 adults (>15 years); 114 (7.42%) tested positive. The community expended $7584 to implement mobilization and campaign activities. The Uganda Ministry of Health (MOH) provided HIV and malaria test kits, some drugs and commodities at a cost of $4431. The SEARCH program provided limited administrative support and one-time capital goods (e.g. tents, chairs, photocopier) at $4738. The total cost per person in attendance was $6.63. Excluding MOH- and SEARCH-provided goods; the cost of conducting this health campaign to the community was $3.07/person.

Conclusions: Rural political and health leaders successfully conducted a health campaign with high HIV testing uptake. The per person cost of a multi-disease health campaign conducted under a research setting in an adjacent community was approximately $13/person compared to $6.33/person for similar services in this community-led health campaign.

TUPED795
Early diagnosis of HIV infections and detection of asymptomatic STI in a community-based organization addressed to MSM

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Background: HIV prevalence and incidence are still increasing in men who have sex with men (MSM). An important factor contributing to this increase are HIV infections not detected, mainly acute infections with high viral loads. Another contributing factor are Sexually Transmitted Infections (STI), which can increase the risk of HIV transmission, being sometimes asymptomatic. A shared project between the HIV vaccine research programme in Catalonia (HIVACAT) and a community centre for the detection of HIV in MSM (BCN Checkpoint), was set up. The objectives were: 1. Early diagnosis of HIV infections and referral to HIV Units; 2. Detection and treatment of asymptomatic STI.

Methods: A cohort of MSM at higher risk of infection was set up. Individuals were selected through a risk-assessment questionnaire. The participants were screened on a quarterly basis for HIV infection, and once a year for other STI: serologies for syphilis, hepatitis A, B and C. PCR for C. trachomatis and N. gonorrhoeae in penis and rectum. In addition, HPV in anus and mouth was screened by PCR, together with an anal cytology. A High Resolution Anuscopy was performed if a dysplasia was detected.

Results: Between December 2009 and October 2012, 267 MSM were recruited, 44 were lost to follow up, and 19 acute HIV infections were diagnosed (incidence: 3.5 per 100 persons/ year). Prevalence of STI at baseline visit were: syphilis 8.2%, C. trachomatis in penis 3.1% (95% CI: 1.5-5.2), in rectum 6.3% (95% CI: 3.9-10), N. gonorrhoeae in penis 2% (95% CI: 0.7-4.7), in rectum 6% (95% CI: 3.6-9.7). HPV in anus 76.2% (95% CI: 69-81.8), in mouth 4% (95% CI: 1.9-7.8). Cytological abnormalities were detected in 41.7% (95% CI: 35-47.9). 1 acute hepatitis C was diagnosed. All individuals with HIV infection were referred to an HIV Unit, within 10 days.

Conclusions: The active collaboration between a community centre and HIV researchers in this project, allows identifying early HIV infections and asymptomatic STI among MSM, ensuring an adequate linkage to health care. The high incidence and prevalence of HIV and STI supports the recommendation of periodical screenings among MSM with sexual activity.

TUPED779
Engaging the community to improve delivery and uptake of TB HIV collaborative services at health facilities: experience from public health facilities in Northern Nigeria

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Background: Nigeria ranks 10th among the 22 high TB burden countries in the world and it is estimated that 210,000 new cases of all forms of TB occurred in the country in 2010, equivalent to 133 per 100,000 population. 90.4% TB cases were notified in 2010 with 41.4% smear positive cases. Globally Nigeria has the highest number of new HIV infections reported each year, and an estimated 3.7% of the population is living with HIV. Delivery and uptake of TB HIV collaborative services had remained low in Nigeria due to poor community awareness, poor access to health facilities and human resources gaps.

Methods: 60 staff and volunteers of 7 community based organizations selected from the 2 states were trained on community TB care and then supported to provide TB HIV services in the health facilities in addition to the community with community-health facility linkages from January to December 2013. Service areas covered were community TB awareness creation, HIV testing and counselling (HTC) for TB cases and suspects, TB screening for persons living with HIV (PLHIV) and TB suspect referral, community-facility and intra-facility referrals and service documentation. After a period of 12 months, routine pre and post intervention secondary data from health care facilities on TB screening for PLHIV, HTC for TB cases and suspects and new TB HIV co-infected cases identified, as measures of service delivery and uptake, were analyzed.

Results: TB screening for PLHIV and HTC for TB patients and suspects increased post-intervention while TB HIV co-infected cases identified and treated remained about the same, as shown in the table.

Conclusions: Community involvement in TB HIV care has the potential to address barriers such as awareness, access and human resources gaps in order to improve delivery and uptake of TB HIV collaborative services at health facilities. This should be promoted in control of TB and HIV.

Table of Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-intervention (January-December 2012)</th>
<th>Post-intervention (January-December 2013)</th>
<th>Percentage increase over same period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of new PLHIV screened for TB at enrollment</td>
<td>22,703</td>
<td>32,884</td>
<td>44.8%</td>
</tr>
<tr>
<td>Number of TB patients and suspects visiting facility counseled and tested for HIV</td>
<td>15,196</td>
<td>19,917</td>
<td>31.1%</td>
</tr>
<tr>
<td>Number of TB patients and suspects positive for HIV</td>
<td>2,249</td>
<td>2,047</td>
<td>-4.5%</td>
</tr>
</tbody>
</table>

TUPED794
Engaging the community to improve delivery and uptake of TB HIV collaborative services at health facilities: experience from public health facilities in Northern Nigeria

A. Indey1, F. Oronsaye, C. Imamhaji, B. Oyedokun, P. Jwarie, E. Medina, A. Olatun, B. Uguja, C. Agada

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Conclusions: Community involvement in TB HIV care has the potential to address barriers such as awareness, access and human resources gaps in order to improve delivery and uptake of TB HIV collaborative services at health facilities. This should be promoted in control of TB and HIV.
TUPEDE796
How can involving women living with HIV strengthen the evidence base of our policies and programmes? A methodological analysis
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Background: Few examples exist of peer-led and -governed analyses of treatment access where women with HIV are central to study design and implementation. A multi-phase global review, to explore barriers and enablers to women accessing HIV care and treatment sought to address this gap, ensuring experiences, realities, needs and priorities of women with HIV in relation to treatment access are better understood, and create a robust model for meaningful involvement.

Methods: The study (literature review; global consultation; and country case studies) was informed by a Global Reference Group (GRG) made up of 14 women with HIV from 11 countries worldwide. The global consultation was designed and implemented by the GRG which comprised women from diverse key populations and age-groups. GRG members conducted a “pre-consultation” among small groups of HIV-positive women, utilising a holistic well-being approach to define key themes informing group discussion (FGD) and interview guides. The GRG coordinator established a closed international email listserv for 19 women with HIV, and moderated an extensive e-discussion. The GRG then contributed to a literature review; led the global consultation (pre-consultation, e-discussion, FGDs and one-to-one interviews); and provided guidance for country case studies run by GRG members. Each review phase built on and was informed by preceding phase(s).

Results: The methodology resulted in a Community Dialogue questionnaire framework which expanded traditional questions regarding treatment access (focusing on initial uptake), towards a more holistic, woman-centred and rights-based “continuity of care” approach. This included attention to quality of care, basic needs including nutrition, peer support and treatment literacy, decision-making and choice around treatment initiation, care and treatment for side-effects and treatment monitoring. The 175 women living with HIV who participated in peer-led FGDs and interviews in Tunisia, Bolivia, Nepal and Cameroon appreciated this holistic approach to women’s health and rights, compared with traditional questions.

Conclusions: Meaningful involvement of women with HIV (where they are intended beneficiaries), in implementation science reviewing service delivery, creates enhanced contextu…

TUPEDE797
Engaging frontline community health workers to provide oral rapid HIV testing to pregnant women in rural India
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Background: Early screening of HIV among pregnant women is an important component of PMTCT. Currently in India, only 20% of the 27 million pregnant women are annually tested for HIV, partly due to shortage of trained health workers and partly due to lack of testing kits. Therefore, training frontline community health workers to provide HIV testing with an non-invasive oral fluid testing such as using FDA-approved OraQuick® could enable significant task shifting and increase early screening of pregnant women in rural areas. The aim of this study was to test the feasibility of structured training of frontline health workers on OraQuick® for HIV screening.

Methods: The frontline community health workers also known as Auxiliary Nurse Midwives (ANM) of all Primary Health Centres, from one block each of Nagpur and Adilabad districts were identified. A two-day training session was used to build their capacity to conduct effective oral rapid HIV testing, and build their knowledge and counselling skills on HIV. Participants were also trained on completing a questionnaire for assessing the feasibility of the kit for its accurate usage in field setting. After training, application of the kit by the health workers and its use in screening was assessed within the maternal health care services. Results: From May to December 2014, 89 ANMs were trained in Nagpur (40) and Adilabad (49) respectively on oral rapid testing, pre and post-test counselling skills, universal precautions and the need to have a confirmatory HIV test irrespective of the screening results. The training also refreshed their knowledge on obstetric care and HIV prevention. Following this, the frontline workers have performed HIV testing of 363 pregnant women using OraQuick®. All test results were confirmed at government run Integrated Testing and Treatment Centres (ICTC), with 100% conformity rate.

Conclusions: Oral fluid rapid HIV testing by community workers for HIV could improve the uptake of HIV testing services among pregnant women in rural India. Our findings provide a foundation for policy advocacy to allow task-shifting of oral fluid rapid HIV testing to frontline community health workers based on further implementation and research outcomes.

Operational challenges in implementing test and treat strategies
TUPEDE798
Feasibility of supervised self-testing using an oral fluid-based HIV rapid testing method among pregnant women in rural India
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1MAMTA Health Institute for Mother and Child, Research Department, New Delhi, India, 2International HIV/AIDS Alliance, Brighton, United Kingdom

Background: Access and utilization of HIV screening among pregnant women in rural India is prevented by inaccessibility of health facilities, lack of point-of-care HIV testing services, HIV-related stigma and discrimination. In addition, invasiveness of HIV testing could be a contributing factor. The aim of this study was to assess the feasibility of a supervised self-testing using FDA-approved OraQuick® a non-invasive Oral Fluid-based HIV Rapid Test. The study was conducted by MAMTA Health Institute for Mother and Child in collaboration with Mahatma Gandhi Institute of Medical Sciences at Kasturba Hospital in Wardha, Nagpur.

Methods: Between October and December, 2014, a random sample of consenting 200 pregnant women were oriented on test procedure, provided with pre-test counselling, and subsequently asked to perform the test by themselves under observation of a trained medical doctor. Post-test counselling and linkage to appropriate care were provided to all participants. All test results were confirmed through method at government-run Integrated HIV testing centers. Participants also completed a self-administered semi-structured questionnaire to assess acceptability and feasibility of self-testing.

Results: Of the 200 participants, 71.5% had never been tested for HIV before. 84% preferred oral-based tests to blood-based HIV testing mainly because it was very easy to use (43%), gave results quickly (27%), non-invasive (22%), among others. In addition, 92.5% participants reported that the instructions given for the test were easy to understand while 7.5% found them difficult. After completion of test, 95.5% were confident that they had performed the test correctly. 96% of participants recommended that the OraQuick® kits should be made available publicly. The HIV test status obtained through oral testing concurred 100% with the ICTC results. Two women were detected HIV positive. However, the band forming (T-line) for HIV positive was not very dark.

Conclusions: Self-testing using oral fluid-based HIV Rapid Test could potentially improve access to HIV testing among pregnant women in rural India. Policy advocacy and further research related to different high-risk groups that could benefit them with preferred supply channels (private, public, community-based) of HIV testing is required in coming days.

TUPEDE799
Increasing ART retention in Cote d’Ivoire through active monitoring and follow-up
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Background: Ensuring HIV-positive clients are retained in ART care programs is a significant challenge for HIV program implementers. Within Elizabeth Glaser Pediatric AIDS Foundation-Cote d’Ivoire (EGFAP-CDI) supported sites, the 12-month ART retention rate was 62% in October-December 2013. Factors that influence patient retention include health systems challenges and the patient’s own perceptions and experiences of ART. EGFAP-CDI’s care and treatment program has been working to address the myriad factors associated with poor adherence. Strategies were implemented to improve patient retention including active monitoring of patients on ART and community follow-up.

Methods: A strategy to monitor and reach out to ART patients was implemented in 27 sites in January 2014 in 4 health regions and 16 health districts. This strategy involved EGFAP-CDI working with sites to develop an electronic list of patients ever initiated on ART. EGFAP field program officers would update this electronic list weekly to insert data on new clients enrolled, clients who had been retained for 6 months and clients who had been retained for 12 months
**Results:** Overall, 12-month retention increased from 62% (N=734) in 2013 to 76% (N=1565) in July-September 2014 in the 27 sites. This increase was observed along with a decrease in the LTFU rate from 28% (N=734) in October-December 2013 to 8% (N=1565) in July-September 2014.

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**Conclusions:** Active monitoring and follow-up of ART patients resulted in increased retention and decreased LTFU in select sites in Cote d’Ivoire, but requires strong human resource commitment and community counselor participation. Next steps include scale-up of this approach in all ART sites supported by EGPANF-CDI and greater engagement from health care workers at facilities.

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**TUPED802**

**Peer-provided HIV counselling and testing for key populations in Cambodia: lessons learnt and implications for service delivery**

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1KHANA, Phnom Penh, Cambodia, 2Independent Consultant, New York, United States,
1International HIV/AIDS Alliance, Hove, United Kingdom

**Background:** Peer-provided testing can potentially increase uptake of HIV testing at the community level. However, this approach has not been widely implemented in Cambodia. In April 2013, KHANA, a local Cambodian organization began the implementation of peer-provided finger-prick testing for key populations. This study explores early outcome and lessons learnt.

**Methods:** Programmatic data related to the intervention was collected. This was complemented by semi-structured interviews (n=29) and focus group discussions (5 sessions; n=27) conducted among beneficiaries, peer providers of finger-prick testing, and key population representatives from implementing organizations.

**Results:** By June 2014, peer-provided testing had been expanded to 18 municipality and provinces, and 391 trained peer providers of testing had conducted 15,000 HIV tests among entertainment workers (EW), men who have sex with men (MSM), transgender people (TG), and people who use or inject drugs (PWUD/PWID). Of the 15,000 HIV tests conducted, 75 were positive. Qualitative findings suggested that key population beneficiaries found that the experience of being counselled and tested by a peer was acceptable and, in some cases, preferable to professional counsellors at VCT centres. Peer providers of HIV testing reported that the training that occurred as part of the project was beneficial in terms of capacity building.

**Conclusions:** Peer-provided finger-prick testing is acceptable among key populations in our study setting, and may contribute to early identification of HIV infection and linkage to care as well as capacity building of community-based peer health workers. However, given that only 75 new HIV cases, that is 0.005%, were found out of the 15,000 tests conducted between March 2013 and March 2014 a better understanding of the HIV prevalence and geographic dynamics is required. This will inform subsequent strategies for reaching key populations.
Conclusions: The need of family planning was high. Staff and partner involvement increased utilization of family planning while particular groups such as sexually active widows, single and divorced women were identified as being in need of targeted interventions.

TUPED804

Missed opportunities to reduce the risk of cardiovascular disease amongst people living with HIV: high prevalence of untreated cardiovascular disease risk factors at an HIV clinic in South Africa

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Background: In South Africa (SA), both HIV and cardiovascular disease (CVD) are prevalent health threats. As people living with HIV (PLWH) live longer on antiretroviral therapy (ART), identifying and managing those with CVD risk factors (CVDRF) and providing prevention services to others will optimize health outcomes. However, there is insufficient information about CVDRF amongst PLWH on ART in SA, and optimal screening strategies have not been identified.

Methods: We conducted a cross-sectional study at an HIV clinic in Free State, SA. 175 PLWH > 30 years, on ART, were screened for CVDRF via questionnaire, physical examination, chart review, total cholesterol and HbA1c. High blood pressure (HBP) was defined as average systolic BP > 140 mmHg and/or diastolic BP > 90 mmHg. Obesity was defined as body mass index ≥ 29. Diabetes was defined as HbA1c ≥ 6.5%. 10-year WHOISH risk stratification was used to define ten-year CVD risk in participants ≥ 40 years.

Results: Of all participants, 10.4% had random total cholesterol >240 mg/dL, 4.1% had diabetes, and 32.2% were obese (40% women, 8.9% men, p < 0.001). Of 110 participants eligible for CVD risk stratification, 96.4% had <10% ten-year risk of a cardiovascular event.

TUPED805

Caries experience in HIV-infected, HIV-perinatally exposed but uninfected and HIV unexposed, uninfected Nigerian children: a comparative study

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Background: Oral health is one of the highest unmet needs of HIV infected children in the developing world. Studies have shown that HIV-infected subjects experience more dental caries and other oral diseases compared to their uninfected counterparts, suggesting a compromised bacterial environment. HIV exposed but uninfected children might also be at a higher risk for such infections. Although HIV infection is associated with well-known oral pathologies, there remains a dearth of comparative studies aimed at determining the association between HIV infection/exposure and early childhood caries. This information will help understand the extent to which the oral microbiome is disrupted by HIV infection or perinatal exposure.

Methods: A cross-sectional study of 3 groups of age-matched children receiving care and treatment at a Nigerian tertiary hospital. The groups comprise of 100 each: - HIV-infected (HI), HIV exposed but uninfected (HEU), HIV unexposed and uninfected (HUU) children aged between 6 and 72 months. Standardized clinical oral examinations were performed by trained dentist-examiners in conjunction with saliva and plaque sample collection to determine microbiome composition.

Results: Overall, the prevalence of caries was 10%. Compared with HUU children, HI children presented with more oral diseases (34% vs.17%) and a higher mean caries index (1.8 vs. 1.2), however there were no significant differences in caries prevalence (16% vs. 11% p<0.31). HI exposure was not associated with dental caries or oral diseases. Caries was associated with age, CD4 counts, socioeconomic status and sugar intake. Preliminary data from the analysis of 10 saliva samples per group suggest that the HI group had a higher diversity index compared to the HEU group.

Conclusions: HIV infected children present with more dental caries than HIV unexposed and uninfected children. Our data suggests that HIV infection might be associated with caries severity. Our study adds to the body of knowledge regarding the association between caries, the oral microbiome and HIV. Further comparative longitudinal studies are required to examine this relationship particularly at advanced stages of HIV infection. This knowledge will help inform the integration of oral health services to the care of pediatric HIV patients particularly in the developing world.
Does the patient experience of healthcare change following the implementation of the integration of HIV care into primary health care clinics? Perspectives from patient surveys in Free State South Africa

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Background: Integration of HIV-care into primary health care (PHC) clinics is a strategy used in South Africa to expand access to antiretroviral therapy (ART) while maximising health system resources. However, how patients at PHC clinics perceive changes in their healthcare after integration is unknown.

Methods: In Free State, South Africa, we administered surveys in two cross-sectional waves ten months apart to patients attending four PHC clinics that were at various stages after PHC clinics began offering ART as part of their PHC services. We measured Quality of Care (QoC) and Satisfaction with Staff (SwS) using validated instruments. We used T-tests, Pearson’s χ² and multiple linear regression to understand changes in QoC and SwS between years of administration. Qualitative questions were collected and thematically coded for dominant themes.

Results: 910 patients/caregivers (2012:n=487, 2013:n=423) participated. Adjusted regression estimates showed no differences in QoC and SwS from 2012 to 2013. QoC was 1.63 points higher (C10.16.10<0.05) for those whose 36-45 compared to 18-25. Those attending clinics for >10 years reported 1.44 points lower QoC (C1.2.79.0.09<0.05) than those coming for 6 months to 1 year. Those coming every 3 months reported a 2.76 point higher QoC (C1.0.15.33<0.05) than those coming at least twice a month. Compared to chronic disease patients, child health attendees reported 2.69 points lower QoC (C1.4.0.09<0.01), ART patients reported 1.67 points lower QoC (C1.3.8.0.26<0.05) and tuberculosis patients reported 3.53 points higher QoC (C1.0.83.23<0.05). Compared to chronic disease attendees, child health attendees reported a 1.77 points lower SwS (C1.2.71.0.33<0.01) while tuberculosis attendees reported a 2.13 higher SwS (C1.74.3.52<0.05). The most common complaint and compliment for staff was long wait time and respectful/friendly staff, respectively.

Conclusions: While the implementation of integration of HIV-care into PHC clinics progressed, we identified no changes to QoC and SwS and conclude that integration was done with concerns for providing high-quality healthcare. However, we observed variations in QoC and SwS reported by participants’ purpose of visit. Further research is needed to understand these disparities in patient QoC and SwS to ensure excellent healthcare for patients attending primary care clinics with integrated HIV-care.

TUPED808

Patterns of disclosure and factors associated with non-disclosing to a spouse or primary sexual partner among TB-HIV patients initiating antiretroviral therapy in Lesotho


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Background: Disclosure of HIV-positive status has important implications for antiretroviral adherence and preventing transmission to sexual partners, but some TB-HIV patients preferentially disclose only their TB diagnosis. We assessed patterns of HIV disclosure and factors associated with non-disclosure among adult TB-HIV patients initiating ART within 8 weeks of TB treatment initiation who enrolled in the Ban TB patients on ART and Retain on Treatment (START) study.

Methods: START is an ongoing cluster-randomized implementation science trial in 12 health facilities in Berea district, Lesotho, evaluating the effectiveness, cost-effectiveness, and acceptability of a combination intervention package (CIP) vs. standard of care to improve early ART initiation, retention, and TB treatment success among TB-HIV patients. Interviewer-administered baseline questionnaires (collected 4/2013-12/2014) were analyzed to describe patterns of HIV disclosure. Factors were assessed for associations with non-disclosure to a spouse/primary partner among married/cohabitating patients using Chi-square, Fisher’s exact, and Wilcoxon rank-sum tests. Variables associated at p<0.2 were included in an initial multivariate logistic regression model; the final model was selected using manual backward stepwise selection.

Results: Among 300 participants with available data, 285 (95%) had disclosed to someone other than healthcare workers. Participants had most commonly disclosed to a spouse or primary partner (74.3%), parent (70.5%) or sibling (81.9%). Among 156 married/cohabitating participants, 128 (82.1%) had disclosed to their spouse/primary partner and 33 (21.2%) knew their partner was HIV-positive. The median age was 37y, 35.9% were female, 55.8% were sole/shared heads of household, and 32.0% reported hazardous/harmful alcohol use. In bivariate analyses, not knowing if a partner was HIV-positive was associated with non-disclosure (p=0.045). On multivariate analysis controlling for age and knowledge of partner HIV-positive status, factors associated with non-disclosing to a spouse/primary partner included female sex (AOR 3.32, 95% CI 1.10-10.07), and self-reported hazardous/harmful alcohol use (AOR 3.64, 95% CI 1.27-10.42).

TUPED807

Who doesn’t disclose their HIV-positive status? Patterns of disclosure and factors associated with non-disclosing to a spouse or primary sexual partner among TB-HIV patients initiating antiretroviral therapy in Lesotho


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TUPED809
Incorporating non-communicable disease screening into community-based HIV counselling and testing in Cape Town, South Africa

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Background: Non-communicable diseases (NCDs) account for 80% of deaths in low and middle income countries. In South Africa hypertension, diabetes mellitus, obesity and hyperlipidaemia are increasing due to on-going lifestyle transition as a consequence of economic development. Prevalence of NCDs amongst in a single site has increased due to previous aging effects of HIV infection on the immune system. The HIV epidemic in South Africa is huge with 12% prevalence. HIV counselling and testing (HCT) is a vital step in HIV prevention and care and is an entry point for NCD screening. This study used routine data to determine whether HIV status, age and gender are associated with NCDs in a population who self-initiate for community-based HCT.

Methods: Five Community HCT sites were established in partnership with non-government organizations, in high disease burden areas around Cape Town. Clients access HCT services at stand-alone centres (fixed sites) or (mobile sites), where services are provided from a mobile van and tents. HIV rapid testing was conducted according to national guidelines. Non-communicable disease screenings include BMI, (≥24 vs < 24), hypertension (high BP vs not high BP) and random blood glucose (≥11.0mmol vs ≤11.0mmol). Comparisons were made using either Chi-square or Fisher's Exact and multivariable logistic regression.

Results: 11,210 clients were screened for HIV (October 2013 to June 2014). 443 clients were diagnosed with HIV (4%); of which 61% were diagnosed at mobile services. A higher proportion of clients with a high BMI (≥24) attended the fixed sites (59% vs 62%; p<0.001). A higher proportion of clients with a high BP (≥140/90 - ≥120/100)attended at the mobile site (73% vs 64%; p<0.001). Elevated glucose (>11.0mmol) was associated with HIV status (0.28 vs 1.86%; p<0.022). Females were more likely than males to have higher BMIs and lower BPs when controlling for age (OR: 5.6; 95% CI (1.1 - 6.2), p<0.001 and OR: 0.7; 95% CI (0.6-0.8), p<0.001, respectively).

Conclusions: Incorporating chronic health screening into a community HCT model can potentially allow for multiple disease screening in a single visit. This model is effective in resource constrained settings by providing an entry point for NCD screening and early case-finding.

TUPED811
Lipid abnormalities in urban and rural patients on ART in Zomba district

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Background: In Africa large populations are ageing with long-term exposure to ART. Antiretroviral drugs may increase risk for cardiovascular conditions, for instance by affecting lipid profiles. Cardiovascular risk factors have therefore become a research priority, but few data about lipid abnormalities from HIV infected Malawians exist.

Methods: Adult patients were enrolled into a cross-sectional study from the HIV clinics at Zomba Central Hospital (urban) and Pirimiti Hospital (rural), both in southern Malawi. Lipidopothy was diagnosed with a validated questionnaire. Non-fasting samples were taken for point-of-care determination of total cholesterol (TC), triglyceride (Tg) and HDL-cholesterol (HDL-c) levels. We used elevated TCHDL-c ratio to signify increased cardiovascular risk.

Results: 854 patients were enrolled, 73% were female, mean age was 43 years, 97% were on ART, with a mean duration of 51 months, 84% were on tenofovir/lamivudine/efavirenz and 69% had previous exposure to stavudine or zidovudine. 16% were overweight (BMI≥25), 28% had elevated waist/hip ratio, 29% had previous diabetes diagnosis and 44% had lipodystrophy. Previous exposure to stavudine and/or zidovudine was higher in those with lipodystrophy (78% vs. 62%; p<0.001). Women were younger and had significantly higher BMI, waisthip ratio and ART duration. Rural patients had significantly lower BMI and ART duration. 16% had elevated TC, 16% reduced HDL-c and 28% had elevated Tg. These abnormalities were generally mild, more common in women and similar in rural and urban patients. Elevated TCHDL-c ratio was rare (4%). Elevated waist/hip ratio, but not age, gender, BMI, lipodystrophy diagnosis, duration of ART or urban/rural location, was significantly associated with elevated TCHDL-c ratio in multivariable analysis.

Conclusions: Lipid abnormalities in ART patients in southern Malawi were generally mild and lipid profiles indicative of increased cardiovascular risk were rare. Prospective studies in ART populations are required to place lipid profiles into context with other cardiovascular risk factors and correlate them with clinical events. Similar to western populations, the waist/hip ratio may be an easily obtainable proxy for increased cardiovascular risk in Malawians on ART.
TUPE812
The impact of integrating HIV and sexual reproductive health services on health and healthcare-seeking behavior of female entertainment workers in Cambodia

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Background: In Cambodia, despite great successes in the fight against HIV and AIDS, challenges remain to eliminating new HIV infections and addressing sexual reproductive health (SRH) issues in key populations including female entertainment workers (FEWs). To address these issues, the Sustainable Action against HIV and AIDS in Communities (SAHACOM) project has been implemented since late 2009 using a community-based approach to integrate HIV and SRH services. This study evaluates the impacts of the SAHACOM project on SRH risks and care seeking behaviors among FEWs in Cambodia.

Methods: A mid-term and end-line comparison design was used. Mid-term data were collected in April 2012, and end-line data were collected in March 2014. A two-stage cluster sampling method was used to randomly select 595 women at mid-term and 567 women at end-line for face-to-face interviews.

Results: Compared to women at mid-term, women at end-line were significantly less likely to report having sexual intercourse in exchange for money or gifts (OR= 2.6, 95% CI= 1.5-4.5). Regarding sexually transmitted infections (STIs), women at end-line were significantly less likely to report having an STI symptom in the past three months (OR=2.2, 95% CI= 1.8-2.8) and more likely to seek treatment for the most recent symptom (OR=2.8, 95% CI= 1.8-4.3). Furthermore, women at end-line were significantly more likely to be currently using a contraceptive method (OR= 1.3, 95% CI= 1.1-1.7) and less likely to report having an induced abortion (OR= 1.6, 95% CI= 1.1-1.9) during the time working as a FEW.

Conclusions: The overall findings indicate that the SAHACOM project is effective in reducing SRH risks and improving access to SRH care services among FEWs in Cambodia. However, several unfavorable findings merit attention.

TUPE813
A cost-finding study of cervical cancer screening methods integrated into HIV care in Nairobi, Kenya

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Background: Integration of cervical cancer screening into HIV clinics may be an efficient method for decreasing the burden of cervical cancer in low- and middle-income countries. As countries contemplate adopting this practice, choice of screening method - Pap smear, visual inspection with acetic acid (VIA), human papillomavirus (HPV) testing - will be of key importance, and costs should be considered in the decision-making process. The purpose of this study was to determine per screening costs of each method in an integrated setting.

Methods: A micro-costing study was conducted at Coptic Hope Center for Infectious Diseases and Kenyatta National Hospital in Nairobi, Kenya from August to October 2014. We assessed direct medical costs (e.g., supplies, provider visits) and direct non-medical costs (e.g., transportation) of each testing method via interviews with administrative, clinical, and laboratory staff. To determine indirect costs (e.g., patient, caregiver costs), we conducted a time-and-motion survey and patient interviews with 148 women receiving cervical cancer screening (Pap or VIA) and supplementary interviews with patients receiving treatment for pre-cancerous lesions and cervical cancer. As HPV testing is not frequently used, indirect costs for HPV testing were extrapolated from Pap smear data and direct costs were calculated based on clinical and administrative interviews, and on standard operating procedures for processing HPV laboratory tests.

Results: VIA was the least expensive method ($11.17 per screen), followed by Pap smear ($11.32 per screen) and HPV testing ($24.19 per screen). Pre-screen direct medical costs - particularly supplies, equipment and lab costs - were the main cost drivers (VIA: $5.87; Pap: $11.28; HPV testing: $20.16). Direct non-medical costs and indirect costs were similar across methods (direct non-medical: $2.65-$2.84 per screen; indirect: $2.19-$2.65 per screen).

Conclusions: These findings provide estimates of cervical cancer screening costs integrated into care in an HIV clinic in Kenya that are more comprehensive and more up-to-date than currently exist in the literature. In addition to informing policy makers on the costs of different cervical cancer screening methods, these findings may also be used in future cost-effectiveness analyses to assess the incremental cost per clinical outcome (e.g., in terms of reduced of mortality and morbidity).

TUPE814
Integrating HIV care and treatment services within a methadone clinic in Dar es Salaam, Tanzania: a formative research study

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Background: Timely antiretroviral therapy (ART) initiation is a vital component of effective HIV prevention, care and treatment. Yet people who inject drugs (PWID) are less likely to receive ART than non-drug users. Methadone clinics provide a unique setting to deliver comprehensive HIV care and treatment to PWID disproportionately burdened by HIV. This formative research will inform the development of an implementation model for the effective integration of HIV care and treatment within methadone services in Dar es Salaam, Tanzania.

Methods: Semi-structured in-depth interviews were conducted with 12 providers and 20 PWID-positive clients (10 women, 10 men) at a methadone clinic in Dar es Salaam in January 2015. We used a grounded theory approach to identify barriers to ART initiation among eligible methadone clients and examine perceptions of integrating HIV care and treatment within methadone services.
Results: Participants identified several factors that impede timely ART initiation for metha- done clients: delays in receiving CD4 results from the off-site laboratory, inconsistent ARV avail- ability, and stigma, which operates at three levels: individual, social/familial, and institutional. At the individual level, internalized stigma was perceived as a barrier to following up on CD4 results and taking prescribed ARVs. Due to the double stigma of illicit drug use and HIV, metha- done clients often lack social and family support to start treatment. At the institutional level, par- ticipants reported that methadone clients face discrimination at off-site HIV clinics. Participants favored integrating HIV care and treatment services within the methadone clinic with on-site point-of-care (POC) CD4 screening and HIV treatment specialists. Perceived benefits of an integrated model included: reduced stigma; lower burden on existing HIV clinics; less time spent by providers escorting clients to off-site HIV clinics and obtaining CD4 results; and more timely ART initiation. Perceived challenges included: added provider workload; lack of HIV treat- ment, limited staff capacity; and limited space at the methadone clinic to house a CD4 machine.

Conclusions: Using a human-centered design framework, we seek to develop a func- tional model of methadone and ART integration. On-site POC CD4 screening coupled with trained HIV specialists can help reduce barriers to timely initiation of ART for HIV-positive methadone clients.

TUPED815
Early exits from the opioid substitution treatment (OST) in Ukraine: reasons and possible explanation
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Background: Retention in OST is essential individual and population levels indicator. Those who leave the program early in treatment (< 30 days) may require specific attention to prevent treatment drop out.

Methods: Using uniquely coded individual level monitoring data from OST program in Ukraine (157 sites in all regions), reasons for discharge were investigated among those who enrolled (N = 4,239) and discharged (N=1,098, 26%), during July 1st 2012 - September 30th 2013 (14 months). Discharge reasons of those left OST site during first 30 days - early exits (N= 460, 42%), were compared to those who left later - exits (N= 638, 58 %) using bivariate analy- sis. Poisson regression, with robust variance estimates was utilized for identifying associations between program indicators and type of exit.

Results: Among early exits such reasons as death (6.3% vs 9.9%), own will (17.8% vs 39.2%) imprisonment (3% vs 8.9%) and administrative discharge (10.4% vs 16.5%) have been less prevalent at p < 0.001. However, change of OST site has been more prevalent among early exits (58.9% vs 19.6%, p< 0.001). Multivariate analysis showed that recommended WHO dosages (PR 0.26, 95%CI 0.12 -0.41) and being at integrated care sites (PR 0.39, 95% CI 0.21- 0.57) were associated with less chances of leaving the program within first 30 days of treatment adjusted for type of treatment drug and HIV status.

Conclusions: At initial stages of OST comprehensive services and dosages play an important role in early retention of patients, possibly preventing patients from changing the treatment site.

TUPED816
Accelerated HIV/TB service integration into primary care clinics and programmatic outcomes in rural Swaziland
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Background: Swaziland is hardest hit by the dual HIV/TB epidemic. HIV and TB services were vertical and constrained by a human resource crisis. In 2007, the Ministry of Health and Medecins Sans Frontieres (Operational Centre Geneva), Mbabane, Swaziland, 2Ministry of Health, NTC-P, Marzi, Swaziland, Ministry of Health, SNAP, Mbabane, Swaziland, 3ICF International HIV/AIDS Alliance in Ukraine, Treatment, Kyiv, Ukraine, 4ICF, International HIV/AIDS Alliance in Ukraine, Treatment, Kyiv, Ukraine

Methods: We reviewed available programme records and analysed routine HIV and TB programme data from the rural Shiselweni region between 2008/2009 and 2012. Frequency statistics and proportions were used to assess level of scale-up, integration and outcomes.

Results: Within 2 years (2009-2010), HIV/TB care was integrated and decentralized from 3 secondary care facilities to 22 rural health care facilities. Annual HTC increased from 17,587 in 2003 to 36,974 in 2012, and HIV positivity decreased from 26% to 13%; PHC performed 46% of all HTC in 2009 and 57% in 2012. Out of 4915 HIV+ cases in 2012, 57% were diagnosed at PHC. In 2008, all ART care was provided in secondary facilities, and in 2012, 56% of ART patients were fol- lowed at PHC. ART coverage increased from an estimated 30% in 2008 to universal treatment coverage (>90%) in 2012, and 6-month retention in care improved from 82% to 83% during the same period. More than 74% of HIV patients were co-infected with TB in all reporting periods. Out of 2,819 patients with TB treated in 2009, 11% did not know their HIV status compared to 2% in 2012. TB treatment initiation at PHC increased from 4% (n=121) in 2009 to 54% (n=608) in 2012. Among HIV co-infected cases, treatment success for bacteriologically-confirmed TB increased from 64% in 2009 to 75% in 2012, and ART uptake from 41% to 82%.

Conclusions: HIV/TB service integration was feasible and achieved good programmatic outcomes in this rural setting with high HIV/TB prevalence. Integration was made possible through task-shifting and involvement of lay health cadre. These outcomes should encourage decision makers to integrate HIV services in other resource constrained settings.

TUPED817
Baseline assessment on FP service utilization among eligible HIV-positive women in Amhara, Tigray, Oromia, SNNPR and Addis Ababa
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Background: NNPFWE is a specialized Network of PLHN+ association aimed to support positive women associations and regional networks across the country. The aim of this baseline assessment is to address key gaps, including preventing vertical transmission of HIV and poor sexual reproductive service uptake among HIV-positive people, through peer support, community led social & behavioral change communications, male in- volvement and increasing community to facility referral linkage. The use and continued use of FP and PMTCT services for women living with HIV is extremely low in Ethiopia when compared globally; only 24% of women, who were in need of PMTCT services in 2012, were able to access services.

Methods: Baseline assessment was conducted in four regions (Amhara, Oromia, Tigray and SNNP) and one city administration (Addis Ababa) from August 4-22, 2014 using quantita- tive and qualitative data collection methods. A total of 402 HIV positive women were inter- viewed.

Results: The mean of age at first birth was 18.62 years. Despite the fact that 15.3% of mothers gave birth to HIV positive children which is indicative of need for strong work on PMTCT, 20.5 % of the study subjects increased from 17.5% in 2009 to 75% in 2012, and ART uptake from 41% to 82%.

Conclusions: It is essential that access to family planning services is increased, to enable all HIV-positive women to “make informed reproductive choices”. Such improvements can occur through integration of family planning and HIV services. Thus, integrated service will increase the proportion of HIV-positive women who are aware of their status and will educate them about the benefits of contraceptive use as a means of preventing mother-to-child transmission.

TUPED818
The favorable value of targeting an alcohol intervention to persons living with HIV/AIDS in Kenya
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Background: Unhealthy alcohol consumption is both prevalent and is an important risk factor for HIV acquisition and progression in Kenya. Cognitive behavioral therapy (CBT) based interventions addressing unhealthy alcohol consumption in Kenya have shown promising results, increasing abstinence and decreasing risky sex. We sought to determine the value and impact of targeting this intervention to HIV-infected individuals enrolled in HIV care and treat- ment programs in Kenya.

Methods: We developed a computer simulation to inform HIV prevention decisions in East Africa across a wide range of possible interventions. Unhealthy alcohol use was modeled as increasing the risk of: (a) condom nonuse (RR 1.29) (b) ART non-adherence (RR 2.33) and (c) sexually transmitted infection (STI) prevalence (RR 1.72).

CGBT was assumed to decrease unhealthy alcohol consumption by 45% and cost $5 per person/ year. We compared 3 intervention targeting strategies - (1) all HIV infected persons (2) pre-ART patients or (3) patients receiving ART.
We compared these targeting strategies to a hypothetical scenario where an alcohol interven-
tion was delivered to all adults regardless of HIV status. Time horizon of simulation is 20 years.

**Results:** CBT aimed at HIV infected patients in Kenya could prevent 18,000 new infections over the 20 year time horizon. This would add 46,000 QALYs, yielding an incremental cost-
effectiveness ratio (ICER) of $600/QALY (see Table). Targeting only to the pre-ART HIV infected patients results in 15,000 infections averted, and the addition of 21,000 QALYs, but would cost saving. As a comparison expanding ART access to all HIV infected individuals with a CD4 ≤ 500 cells/mm³ results in the prevention of 100,000 new HIV infections, the addition of 250,000 QALYs, yielding an ICER of $1,650/QALY. The value of CBT and its prioritization was strongly influenced by its estimated cost.

![Graph showing a comparison of different strategies for HIV prevention.](image)

**Conclusions:** We demonstrate the improved value (at the overall clinical impact) of targeting the CBT intervention amongst the HIV infected community and those within who are already engaged in care and who may be hazardous alcohol users. Our results highlight the favorable value and cost-effectiveness of alcohol focused interventions in Kenya as a means to improve HIV related outcomes and population health.

**TUPED819**

Parents' views and acceptability of early infant male circumcision (EIMC) integrated into maternal child health (MCH) services in Iringa, Tanzania

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**Background:** Evidence suggests that EIMC is less expensive, safer, easier to perform, and heals more quickly than adult male circumcision. Current WHO guidelines recommend that EIMC, integrated into MCH services, is acceptable among most parents in sub-Saharan Africa and an AIDS-defining disease. Despite efforts to integrate cervical can-
cer screening into HIV care, screening rates remain low. Studies focused on women have identified lack of spouse support as a barrier to screening, but little is known about men's perspectives. This study explores HIV-positive men's knowledge and perception of cervical cancer and the potential for male partner support for cervical cancer screening in Kenya.

**Methods:** We conducted 15 in-depth-interviews and 3 focus-group-discussions with part-
ticipants of HIV-positive women and HIV-positive men. Participants were recruited at Coptic Hope Center for Infectious Diseases, an HIV treatment clinic, in Nairobi, Kenya between November and December 2014. Interviews were audiotaped, transcribed and a baseline codebook was validated through a grounded theory approach. Extensive in-text memos assured reliability of coding, and a preliminary comparative analysis between transcriptions was performed to as-
sure validity of the findings.

**Results:** White knowledge of cervical cancer was limited, participants understood general concepts of screening for early detection and disease prevention and felt that cervical cancer screening was important. Many participants used HIV-related terminology (e.g. knowing one's "status") to describe the need for screening. Participants reported men as decision-makers in the family with significant influence over healthcare seeking behavior of their female partners. They reported that they were amenable to learning about women's health to make more in-
formed decisions to support the health of their partners. Participants identified a lack of knowl-
edge among men about cervical cancer and stigma associated with promiscuity and HIV/sexu-
ally transmitted infections as major barriers to male partner support.

**Conclusions:** HIV-positive men in Kenya appear to appreciate the importance of cervi-
cal cancer screening for disease-prevention in this preliminary analysis. This perspective is likely influenced by their exposure to health information from their HIV-related care. Cervical cancer awareness efforts in Kenya should target men as well as women, since men may act as gatekeepers to women's access to healthcare. HIV clinics and their messages of HIV preven-
tion may help HIV-positive men better understand cervical disease, and could be leveraged to promote male partner support in cervical cancer screening.

**TUPED820**

Can male partners play a role in cervical cancer screening? The knowledge and attitudes of HIV-positive men towards cervical cancer screening in Kenya


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**Background:** Cervical cancer is a leading cause of cancer deaths among women in sub-Saharan Africa and an AIDS-defining disease. Despite efforts to integrate cervi-
cal cancer screening into HIV care, screening rates remain low. Studies focused on women have identified lack of spouse support as a barrier to screening, but little is known about men's perspectives. This study explores HIV-positive men's knowledge and perception of cervical cancer and the potential for male partner support for cervical cancer screening in Kenya.

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tion may help HIV-positive men better understand cervical disease, and could be leveraged to promote male partner support in cervical cancer screening.
MMT sites (45%), long waiting time (7%), lack of information on health care services (2%), and others (47%). 64% clients supported the satellite model which integrates MMT into commune health stations that may improve the convenience of use.

**Conclusions:** It is feasible to implement co-payment MMT services in Vietnam. Integrating and co-locating MMT with other general health care facilities, decentralizing to commune level are highly preferred and could be considered to improve the efficiency of MMT services.

**TUPE822 Impact of peer nutritional counseling on ART patients' food insecurity and nutritional outcomes: a pilot study in Honduras**

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**Background:** Food insecurity and poor nutrition are key barriers to antiretroviral (ART) adherence, particularly in resource-poor settings. Culturally and locally-appropriate and sustainable interventions that provide nutrition counseling for people on ART and of diverse nutritional statuses are needed, particularly given rates of overweight and obesity among people living with HIV (PLHIV).

**Methods:** As part of scale-up of a pilot intervention that used professional nutritionists, we recruited and trained 17 lay peer workers from 14 government-run HIV clinics in Honduras to deliver peer nutritional counseling using a highly interactive curriculum that was developed after extensive formative research on locally available foods and dietary patterns among PLHIV. At baseline and 2 month follow-up assessments, interventions included: 1) in-person surveys to collect data on household food insecurity (15-item scale), nutritional knowledge (13-item scale), dietary intake and diversity (number of meals and type and number of food groups consumed in past 24 hours), and 2) anthropometric measures (body mass index or BMI, mid-upper arm and waist circumferences). We used multivariable linear regression analysis to examine the effects of integration on food insecurity score and the various nutritional outcomes while controlling for baseline characteristics (gender, education, and work status) and clinic-level clustering.

**Results:** Of 482 participants, we had complete data on 354 (76%), of which 62% was female, median age was 39, 34% reported having paid work, 52% had completed primary school, 34% was overweight or obese, and 73% reported moderate or severe food insecurity. Between baseline and follow-up, household food insecurity showed a significant decrease among all participants (n=356, β=0.47, p< .05) and among those with children under 18 (n=303, β=1.16, p<.01), while nutritional knowledge and dietary intake and dietary diversity also significantly improved, (β=0.08, p< .001; β=0.30, p< .001; and β=0.15, p< .001, respectively). Nutritional status (BMI, mid-arm and waist circumferences) showed no significant changes, but the brief follow-up period may not have been sufficient to detect changes.

**Conclusions:** Peer-delivered nutritional counseling intervention for PLHIV can improve dietary quality and reduce food insecurity among a population of diverse nutritional statuses. Future research should examine if such an intervention can improve adherence among people on ART.

**TUPE823 Integrating HIV and reproductive health services to increase consistent condom use for HIV prevention: a multicentre, non-randomized trial**

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**Background:** Condom use has generally been below optimum in HIV-affected countries and uptake for HIV prevention remains challenging. Published evidence suggests that integration of HIV and reproductive health services can address the structural/service challenges and improve condom uptake.

However, effective HIV prevention requires consistent condom-use, beyond just condom uptake. This study assessed the effectiveness of integrating HIV and reproductive health services on consistent condom-use in women of reproductive age in generalised HIV epidemic settings.

**Methods:** We assessed the effect of integrated HIV and reproductive health services on consistent condom-use in 3660 women (≥15 years old) in Kenya and Swaziland. Repeated condom-use measures were taken on each woman at enrolment and at 6, 18 and 24 months after enrolment. Both countries implemented integration in all health facilities nationwide; therefore we assessed consistent condom-use using both the original-design intervention/control contrast, as well as an individual-level exposure-to-integration index binarized into ‘high integration’ and ‘low integration’. Assessment was performed in the combined study population and different sub-populations: PNC and FP clients, HIV-positive and HIV-negative clients, single and married clients. We fitted a series of 3-level random intercept mixed-effects logistic models. Propensity score analysis was used to correct for potential selection bias due to non-randomized design of the study.

**Results:** In the combined population, the odds for consistent condom use in the high integration group were almost twice those in the low integration group (OR: 1.80; 95%CI: 1.31, 2.48), with propensity for consistent condom-use increasing with increase in exposure to integrated services. No difference in consistent condom-use was found between women in intervention and control groups (OR: 1.50; 95%CI: 0.52, 7.08). Consistent condom-use had higher odds among HIV-positive than HIV-negative women, especially among HIV-positive women exposed to high integration (OR: 2.26; 95%CI: 1.05, 5.01). Married women were less likely to report consistent condom-use than single women; however, married women exposed to high integration were more likely to practice consistent condom-use than those exposed to low integration (OR: 1.96; 95%CI: 1.33, 2.88).

**Conclusions:** Integration of HIV and reproductive health services can produce significant increases in consistent condom-use among women attending public health services in generalised HIV-epidemic settings.

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**TUPE824 The impact of integrated reproductive health and HIV services on HIV testing uptake: results from a cohort study among family planning clients in Kenya**

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**Background:** Integrating HIV testing and counseling (HTC) into reproductive health services is a policy priority in Kenya, where only one third of adults are aware of their HIV status. Developing effective models of care to deliver HTC is critical, and family planning (FP) clients are an important target group as they are sexually active and usually not current condom users.

**Methods:** We assessed the impact of integrated FP-HIV services on HIV testing rates among FP clients (N=862) using a non-randomized cohort design within 6 intervention and 6 comparison facilities in Central Province, Kenya. Participants were interviewed at four time points over two years. Due to intervention fidelity issues, we assessed clients' exposure to integration in four ways: (i) design group (clinics received training and resources for HTC); (ii) woman's reported receipt of both RH and HIV services at recruitment visit (i0); (iii) a functional measure of facility integration (‘index’), at i0, (iv) a woman's cumulative exposure to functionally integrated care across different clinic visits over the two-year cohort. Those who achieved HIV testing goals were reported 2 HIV tests over the year period; or one test among those who sero-converted. Measures of effect were assessed using conditional logistic regression models accounting for clustering at facility level.

**Results:** HIV testing generally increased over the cohort period, from 28% at i0 to 86% after 2 years. Figure 1 shows testing uptake according to exposure group. While crude analysis showed that receipt of integrated care at recruitment visit increased testing uptake, the only exposure that demonstrated long-term impact in multivariable analysis was a woman's cumulative exposure to integrated care over the two year study period. Those with a high level of exposure to integrated facilities, as measured by the ‘index’, were three times more likely to achieve testing goals compared to those with low exposure (aOR 2.94, 95%CI 1.73-4.8).
Integration of HIV services with other development programmes

TUPED826
An integrated treatment model for opioid addiction to enhance HIV prevention and treatment in Vietnam

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Methods: Open-ended interviews with 56 providers conducted in 2010 and 2012. Data were analysed by degree of facility integration to compare results from “high functioning” and “low functioning” clinics.

Results: Analysis of Client Flow data revealed a ‘capacity-delivery’ gap across all clinics, even those highly functioning: there is a large gap between the % days on which integrated care was accessed (i.e. capacity to deliver integrated care) and the % visits/consultations actually receiving integrated care (i.e. functional delivery of integrated care).

Conclusions: Achieving successful service integration requires attention not only to staffing numbers and training (the usual focus of “success” in health systems and services), but also to the variety and challenge in their work and better job satisfaction through increased client-satisfaction and “low functioning” clinics.

**Background:** In Vietnam, the main source of HIV infection is injection drug use. About 46% of opioid users are estimated to be HIV-positive. 13,000 opioid users are currently receiving methadone treatment, 26% of them are HIV-positive but only 70% received HIV treatment.

**Funding:** NIH/NIDA grant number R37 DA019829 (Strathdee, PI), Open Society Foundations Latin America Program grant OR2013-1132 (Strathdee, PI), and UCSD CFAR International Pilot Grant (NAID P30 AI036214 (Magis and Beletsky, PI).
TUPE828
Community-led integrated service delivery
‘war rooms’ game changing the fight against
HIV/AIDS and TB: case study of the Operation
Sukuma Sakhe model in KwaZulu-Natal, South
Africa

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Background: KwaZulu-Natal is South Africa’s second largest province - home to 10.2
million (20% of the population). It has an adult HIV prevalence of 27.9%, compared to 18.8
nationally. More than 67% live below the poverty line, 5.7% are illiterate, 2.8% have no ac-
cess to safe water and 25.2% are unemployed. These socio-economic determinants negatively
impact health outcomes, especially HIV/AIDS, TB and maternal and child mortality. In 2009,
the KwaZulu-Natal government rolled out Operation Sukuma Sakhe (Lets Build Together), an
integrated model of service delivery to fight poverty, HIV and TB infections in poor communities
using community-led service delivery “war rooms”. The model was implemented with technical
support from BroadReach Healthcare and has been acknowledged by UNAIDS and govern-
ment as a best practice model.

Methods: Communities, supported by dedicated teams of community health workers, plan
and direct service delivery to where it is needed through the war rooms. This forms the
foundation of integrated service delivery planning at ward, district, and provincial levels. Each
household is seen for its integrated needs and a basket of services is provided in an integrated
fashion. Services include supporting HCT, TB screening, default tracer, condom distribution
and promotion, child wellbeing, early pregnancy booking, medicines distribution, community-
based care services and addressing social issues obtaining vital documents and accessing
social grants.

Results: Data from OSS “war rooms” and linked health facilities show positive trends for
several indicators since the introduction of CCGs. Table 1 presents data for 2010-2014 from
Ugu district (population 740,000) where OSS was implemented in the district in 2011 and sup-
ported by trained CCGs from 2012. In 2014 CCGs in Ugu served almost 370,000 households;
performed around 358,000 household visits in 2013 increasing to 472,000 in 2014, with almost
90,000 visits resulting in referral to a facility over the two years.

Conclusions: The implementation of OSS suggests that poorly resourced communities
can play a significant role in improving health outcomes including HIV/AIDS and TB. Commu-
nity-led health interventions directly impact facility-based interventions and investing in com-
muty structures can be a cost-effective approach towards healthcare delivery in communities
and improvement of overall health outcomes.

TUPE829
Strengthening EMTCT & EID program
performance through mobile technologies
in Uganda

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Background: In Uganda, health facility in-charges submit EMTCT data from health facili-
ties to the Ministry of Health (MOH) operated District Health Information System monthly. The
reports do not capture data on pregnant women receiving HIV counseling and testing at their
first ANC visit, the proportion of pregnant women with known HIV positive results at the first
ANC, the total of missed appointments within the ANC, or adequate ARV and test kit stock out.
In response, the MOH and CDC-funded META project rolled out a weekly mobile phone
test message (SMS) reporting system in February 2013 supported by midwives working at
health facility level. Baylor-Uganda is mandated by CDC to coordinate weekly PMTCT SMS re-
porting at 375 public health facilities in 23 districts and to update a weekly early infant diagnosis
(EIFD) dashboard for real time reporting of infants’ DNA PCR results.

Methods: The purposive sampling technique was used to select midwives with mobile
phone contacts. A total of 1179 midwives from 275 health facilities were trained on how to
submit data on 9 PMTCT indicators using their mobile phones. The midwives then submit their
health facility PMTCT data for the previous week to a toll free SMS number and automatically
receive SMS feedback.

Results: Through intensified monitoring and follow up through biweekly SMS and phone
call reminders, inclusion of multiple users per facility, engagement of district health officers,
and weekly and monthly feedback to stakeholders (to inform evidence-based decision making),
the overall reporting rate increased by over 4%. The average weekly SMS reporting rate for
January-March 2014 was 69% and increased to 100% from October-December 2014. The
stock out of ARVs and test kits reduced from 47 facilities to 2 and of test kits from 68 to 5. 98%
of EID results returned to the facility on time and were provided to caregivers, and all positive
infants were stated on ART timely. There was also a significant reduction in mothers missing
appointments from 187 in October 2013 to 27 in October 2014.

Conclusions: Mobile technologies that enhance the timeliness of data collection and
reporting and inform decision making are essential to virtual EMTCT.

TUPE830
Community-owned electronic repository: improving
data access and uptake to develop
evidence-informed policies and programs

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Background: Country-specific HIV-related strategic data are often inaccessible to end-
users such as programmers and policymakers. Jamaican stakeholders including program
developers, advocates and policymakers report obstacles in accessing data on the political,
social, economic and legal aspects of the HIV epidemic. This leads to overlap in local research
initiatives and less-effective responses. Civil society organizations report challenges in under-
standing the technical jargon used in framing research findings and recommendations.
To address these concerns, the University of the West Indies’ HIV and AIDS Response Pro-
gramme developed a user-friendly online electronic repository aimed at improving stakehold-
ers’ access to and efficient use of local strategic data to inform program design and implemen-
tation, advocacy, and policy development in Jamaica.

Methods: Local ownership by potential users was achieved through a participatory ap-
proach, including stakeholder meetings with nongovernmental organizations, academia, and
government representatives; inclusion of stakeholders in a steering committee; and beta test-
ing, which provided preliminary feedback.
Content was identified by searching academic databases and local materials obtained from
partners. Annotations of select publication types were also included. The general criteria used
to include material in the repository were: publications from 2000 onward; a focus on Jamaica,
not excluding the wider Caribbean; and information on all aspects of sexual health and HIV
prevention, treatment, care, and support.
Development of a searchable website allowed for basic and advanced search features to in-
crease access.

Results: This repository has become the primary Jamaican mechanism through which local
and regional research is collated and accessed. The user-friendly summaries of research make
it possible to better inform local HIV-related program design and implementation, advocacy,
and policy development. Meaningful involvement of end-users throughout the process has in-
creased their interest and capacity to use the data.
**Conclusions:** The response received from beta testing and launch has been very positive and supportive of this intervention. Users emphasized the benefit of gaining access to centralized information and learning about existing program data to avoid duplication. Phase 2 of this intervention focuses on the development of a mechanism through which all local stakeholders routinely feed their research material into the repository, ensuring sustainability.

**Results:** Only two out of twenty NGOs complied with all the seven stages of WHO model. 95.0% carried out implementation involving target audience and 85.0% conducted outcome evaluation of the materials. 80.0% pre-tested materials, 65.0% conceptualized communication messages while 25.0% of the NGOs involved target audience in the production process. Only 40.0% project coordinators had training on BCC. Weak technical capacity in BCC material development was a major challenge reported by the project coordinators.

**Conclusions:** Poor skills in Behaviour Change Communication material development observed. Training and supportive supervision are needed to enhance the skills of project coordinators in the development of behavioural change communication materials.

**TUPED831**

**Overcoming barriers to opening supervised injection services in the United States**

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**Backgrounds:** Supervised injection services (SIS) are an effective, evidence-based HIV prevention intervention not available in the United States because of the current legal and political approaches to people who use drugs. SIS are settings where people can inject or consume drugs under clinical supervision and can receive health care, counseling, and referrals to health and social services, including drug treatment. They have been extensively studied and evaluated and are effective at addressing a number of health and safety outcomes. SIS are the next step beyond syringe access to end HIV and HCV transmission among people who use drugs.

**Methods:** In Vancouver, it has been shown to be cost-effective in reducing new HIV cases. It has reduced the overdose rate in its neighborhood by 35%. Overall, the evaluation found no community or health-related harms and a large number of benefits.

**Results:** The legal and policy analysis reveals a number of contested legal barriers to opening an SIS. The largest barriers among key stakeholders and supported officials remain stigma, fear of controversy, and lack of understanding of the legal environment, exacerbated by a low level of concern about the key population of people who inject drugs. Communities across the U.S. are developing strategies to address those barriers, including additional research, building community pressure, and working directly with grassroots community organizations to open SIS out of view of legal authorities.

**Conclusions:** This is a global best practice that could bring public health benefits to the United States. Policy makers and elected officials as well as public health leaders need to be educated about legal and health realities and the benefits of SIS. Political opinion needs to shift to allow the US to fully implement SIS as an effective HIV intervention.

**TUPED832**

**Process evaluation of behavioural change communication materials developed and utilized for HIV prevention by non-governmental organizations in Oyo State, Nigeria**

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**Backgrounds:** Public health education is a strategy for controlling the spread of HIV. An important component is the effective utilization of Behavioural Change Communication (BCC) materials. Forty Non-Governmental Organizations supported by the Oyo State World Bank-assisted HIV and AIDS programme produced BCC materials targeting audiences. However, the process evaluation of the development of the materials was not systematically conducted. This study was therefore designed to assess the level of adherence by these NGOs to basic WHO standards in the process of development of the materials.

**Methods:** The study was a descriptive cross-sectional survey. Balloting was used to select 20 out of the 40 supported NGOs. The NGOs were categorized into five equal groups based on target audience that is; Female Sex Workers, Mission Birth Attendants, In-school Youth, Women and People Living with HIV. Checklists were used to assess compliance with each of the following seven stages of educational materials development in line with the WHO model: Needs Assessment (NA); message conceptualization; design; pre-testing; production procedure; implementation and outcome evaluation. In-depth Interviews (IDIs) were conducted for the twenty NGO project coordinators while one Focus Group Discussion (FGD) was conducted among each of the five target groups. Descriptive statistics was used to analyze quantitative data while the FGD and IDI data were transcribed and analyzed using thematical approach.

**Conclusions:** The response received from beta testing and launch has been very positive and supportive of this intervention. Users emphasized the benefit of gaining access to centralized information and learning about existing program data to avoid duplication. Phase 2 of this intervention focuses on the development of a mechanism through which all local stakeholders routinely feed their research material into the repository, ensuring sustainability.

**Results:** Only two out of twenty NGOs complied with all the seven stages of WHO model. 95.0% carried out implementation involving target audience and 85.0% conducted outcome evaluation of the materials. 80.0% pre-tested materials, 65.0% conceptualized communication messages while 25.0% of the NGOs involved target audience in the production process. Only 40.0% project coordinators had training on BCC. Weak technical capacity in BCC material development was a major challenge reported by the project coordinators.

**Conclusions:** Poor skills in Behaviour Change Communication material development observed. Training and supportive supervision are needed to enhance the skills of project coordinators in the development of behavioural change communication materials.

**TUPED833**

**Preliminary reliability and validity results for measures of intergenerational disjuncture that may reflect pathways between social structural change and HIV outbreaks**

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**Background:** HIV/AIDS researchers have called for new measurements of pathways by which HIV outbreaks or epidemics may be affected by structural interventions or by “big events” like wars, civil unrest or transitions. One potential pathway is intergenerational disjuncture, in which youth become alienated or the degree to which their behavior is controlled by the norms of older generations is reduced; or conversely, in which older adults become alienated from youth.

We have recently developed preliminary pathways measures assessed at the individual level, including scales for intergenerational disjunction for younger (IGD-Y) and older (IGD-O) adults through mixed methods research in New York City. Items for these scales tapped into aspects of disjuncture, e.g., “The older generation’s ideas about prioritizing sacrifice over fun just don’t work for me and my generation.”

**Methods:** We collected data from people who inject drugs and homosexuals living in high poverty areas by referral from a large study using respondent driven sampling, and by participant referrals during 2012-2014. We analyzed data from 92 younger (ages 18-24) and 443 older adults (ages 25-67) using Cronbach’s alpha reliability analysis, and Pearson’s correlations with criterion validator variables reflecting risk behaviors in the last month.

**Results:** The sample was 45% female, 38% Hispanic ethnicity, and 62% Black/African American race. 93% had annual incomes below $15,000. Alpha was 0.82 for the 10-item IGD-Y scale, and 0.88 for the 9-item IGD-O scale. IGD-Y was significantly (p < 0.05) positively correlated with having participated in sex work (r = 0.56), attended group sex events (r = 0.42), injected drugs (r = 0.49), and smoked crack (r = 0.53). IGD-O was modestly negatively associated with validators, correlating significantly with having attended group sex events (r = 0.11), and used marijuana (r = 0.24).

**Conclusions:** Preliminary IGD-Y and IGD-O scales show evidence of good reliability and validity. The pattern of associations suggests disapproval of youth risk behaviors by older adults, and perception of this disapproval by youth. Research in international settings is needed to assess whether these measures are reliable and valid in other contexts, and to see whether structural interventions that reduce intergenerational disjuncture can reduce HIV transmission.

**TUPED834**

**Targeting eMTCT efforts using geospatial analysis of mother to child HIV transmission in Zimbabwe**

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**Background:** UNAIDS’ goal for “virtual elimination” of mother-to-child transmission (eMTCT) is within reach for many low- and middle-income countries, including Zimbabwe. We evaluated the potential for geospatial analysis to support targeting and prioritization of enhanced PMTCT activities.

**Methods:** We analyzed 2012 cross-sectional survey data from the evaluation of Zimbabwe’s accelerated PMTCT program. Using multi-stage cluster sampling, women were randomly selected from catchment areas of 157 randomly selected health facilities offering PMTCT services in five provinces. Eligible women were ≥16 years old and biological mothers of infants (alive or deceased) born 9-18 months before the interview. We aggregated individual-level data within each catchment area to estimate: 1) the MTCT rate, and 2) the estimated number of HIV-infected infants. These data were linked to GPS coordinates of each facility and displayed on a map. We hypothesized that high MTCT rates indicate areas where the PMTCT cascade re-
quires strengthening, whereas catchment areas with large numbers of infected infants indicate
locations at the highest priority for HIV prevention, enhancing infant ART training and delivery,
and strengthening the ART supply chain.

Results: Overall, 1107 (12.9%) of 8,586 women surveyed were HIV-infected, and among these
women, 8.8% of their HIV-exposed infants were HIV-infected. MTCT differed significantly
by catchment area (median: 0%, mean: 11%, interquartile range (IQR): 0-50%), Figure, Panel
A). Areas with higher MTCT rates were distributed across the five provinces with no discernible
geographic clustering. The estimated number of HIV-infected infants 9-18 months of age also
varied by catchment area (median: 0, mean: 1.7, IQR: 0-10.5, Figure, Panel B); areas with
the highest burden of HIV-infected infants were clustered in Harare as well as Matebeleland
South and Manicaland, provinces with the highest prevalence of HIV-infected antenatal care
attendees.

Conclusions: Although MTCT is declining in Zimbabwe, geospatial visualization of local
MTCT rates and the number of pediatric infections indicate variability distributed across several
regions of Zimbabwe. The few catchment areas with both high MTCT rates and a high burden
of HIV-infected infants (clustered in Harare, Matebeleland South, and Manicaland) should be
the highest priority for intensifying HIV prevention and PMTCT services to achieve and maintain
eMTCT.

TUPED835
Improved HIV testing uptake, food security and reduced violence among orphans and vulnerable
children in Zambia: the impact of using baseline data to define program scope

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Background: The United States Agency of International Development awarded a high-
value, 5-year agreement in Zambia to improve the wellbeing of people living with HIV/AIDS
and orphans and vulnerable children called STEPS OVC (Sustainability through Economic
Strengthening, Prevention and Support to OVC, Youth and Other Vulnerable Populations). To
measure and maximize program impact, we evaluated beneficiary outcomes at the beginning
and end of the project. In this paper we discuss the impact of programmatic activities, resulting
from the collection and use of baseline outcomes data, on orphans and vulnerable children.

Methods: We applied a quasi-experimental pre-test/post-test study design, randomly
sampling 2,099 orphans and vulnerable children aged 11-17 years from program rosters to
participate in a household survey in a maximum variation sample of nine districts in 2011 and
again in 2014. Outcome measures included HIV testing uptake, sexual behavior, experience
of violence, food security. Ethics approval was obtained in the US and Zambia.

Results: The response rate was 86% at baseline (N=1,868) and 86% at endline (N=1,813).
At baseline high food insecurity, abuse, and low HIV testing uptake was documented, as well
as low condom use among sexually-active adolescents (aged 13-17). The program considered
these data using MEASUREMENT Evaluation's Framework for Linking Data to Action, and shifted its
workplan to ensure fulfillment of these immediate and priority needs, particularly through eco-
nomic strengthening programming. At endline, outcomes among children had improved signifi-
cantly. Considering the last four weeks, children surveyed were less likely to report having
a whole day and night without food (33% to 25%), having gone to bed hungry (38% to 51%),
and having eaten a smaller meal than needed (87.5% to 62%). At endline children reported
less reported physical violence in the last 6 months (69% to 21%), increased condom use (64%
to 49%), and they were more likely to report having had an HIV test (21% to 28%). We found
no differences in HIV/AIDS knowledge or age of sexual debut between baseline and endline.

Conclusions: Understanding the priority needs of a population is critical to ensuring impact. Interventions to improve the utility of data collection and data use will be discussed.

TUPED836
Households that choose to participate in community savings groups are better off
than households that do not: findings from an evaluation in Zambia and implications
for programming

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Background: HIV-infected households suffer from more income/asset loss, and children
living in HIV-infected households often receive less or less-nutritious food, drop out of school
to work, and/or do not receive health services. Community savings groups can mitigate these
effects of HIV/AIDS on people living with HIV/AIDS and orphans and vulnerable children. This
paper presents analyses of midline data from a larger evaluation of Savings and Internal Lend-
ing Communities (SILC), a user-owned, self-managed savings and credit group. Community
members self-select into SILC group, we sought to determine the characteristics of self-selec-
tors and how these compared to those of the general population.

Methods: Data are from a three-year, longitudinal, quasi-experimental study with interven-
tion and comparison groups, aiming to determine the impact of SILC on child and household
welfare. The study applies a multi-stage cluster sampling approach comparing 1,000 SILC
households in 32 SILC wards with 1,000 SILC households in 32 non-SILC wards. We collected
data from five population groups in each household: head of household, primary caregiver, SILC par-
ticipant (intervention wards), children aged 0-9 years, and children aged 10-17 years. Outcome
measures include expenditures, assets, food security and dietary diversity, and self-efficacy.
Midline data were collected during the hunger season (February 2014). Ethics approval was
obtained in the US and Zambia.

Results: The response rate was 97.5% (N=1,923 households). Overall, households, re-
pondents, and children in the SILC household group were better off compared to those in the
comparison group. SILC households reported higher expenditures, higher dietary diver-
sity scores, and were less likely to report moderate to severe hunger than households in the
comparison group. Caregivers in the SILC household group were more likely than those in the
comparison group to report self-esteem and general, parental, and financial self-efficacy.
Children in the SILC household group reported higher dietary diversity and less hunger. Differ-
ces between groups persisted even when controlling for level of exposure to SILC (length of time 
included).

Conclusions: Community savings groups are an important HIV/AIDS mitigation strategy,
but they target a particular sub-population. Programs need to profile their beneficiary popula-
tions appropriately and implement targeted strategies to mitigate the impact of HIV/AIDS ef-
Equally.

TUPED838
Utilization of Google Earth to georeference survey data among people who inject drugs:
strategic application for HIV research

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Background: integration of geospatial data in behavioral HIV and human rights re-
search has become increasingly widespread in the last two decades. In survey-based research,
these data have been typically gathered through initial identification of physical address or
street intersection datapoints on paper maps, followed by a manual translation to geospatial
coordinates for analysis. This methodology is limited by cartographic imperfections, confusion
over address nomenclature, and human error. Studies targeting migrants, refugees, and others
who may lack particularized local geographical familiarity are especially impacted. We sought
to overcome these challenges in the context of a large longitudinal study on HIV risk among
people who inject drugs (PWID) in Tijuana, Mexico.

Methods: We integrated Google Earth and Google Street View into structured interview
protocols. When asked for location information relevant to a specific interview item (e.g. most
recent incident of physical abuse by police), respondents were able to pinpoint the exact posi-
tion of the encounter by virtually navigating to this location with the assistance of the interviewer.
Latitude and longitude coordinates were synced into the intake interview database for use in multi-
variable and spatio-temporal modeling of HIV risk.

Results: Between 2010-2013, we recruited 737 PWID in Tijuana at baseline. Only 37% of
our sample was native to Tijuana, underscores high levels of PWID migration. Areas frequent-
ded by our study population are poorly covered by formal maps and/or liminal locations where

Latitude and longitude coordinates were synched into the interview database for use in multi-

a street address would have been difficult to determine (e.g. informal deportee encampments along the US-Mexico border). These geospatial data are now being used to enhance investigations of structural determinants of HIV and other infectious disease. This includes modeling of PWID experience of police assault and patterns of encounters and arrests in the immediate proximity to drug treatment facilities.

Conclusions: Integrating low- or no-cost real-time virtual navigation as part of data collection, especially among HIV risk groups vulnerable to spatial dispersion or migration is a powerful and low-threshold approach that can add important insights to investigations of the structural production of HIV risk. Implications for future applications are discussed.

**TUPE839**

**Efficiency of facility-based HTC and its determinants: results from the ORPHEA study in Kenya, Rwanda, South Africa and Zambia**

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**Background:** HIV testing and counseling (HTC) is a critical component of almost all HIV prevention, care, and treatment services. Understanding cost variation and the key determinants of efficiency of facility-based HTC within and across countries is critical to more effectively scaling up this intervention.

**Methods:** The data for this analysis come from the “Optimizing the Response in Prevention: HIV Efficiency in Africa” (ORPHEA) study - a facility-based study of the costs and technical efficiency of HIV interventions conducted in Kenya, Rwanda, South Africa, and Zambia between 2011 and 2013. The relationship between average unit cost and unit number of clients (scale of production) was assessed for two outputs in the HTC service cascade: clients tested and clients HIV positive. The log of cost per client tested and cost per client HIV positive were regressed on scale of production adjusting for service quality and management variables that measure governance, accountability, supervision, monitoring, and incentives.

**Results:** We found that a 10% increase in production scale correlates with a decrease of 5.8% in the average cost per client tested (p< 0.001). Hospitals that produce HTC show, on average, double the cost per client tested compared to smaller facilities such as health centers (p< 0.001). Regarding average cost per client tested and HIV-positive, scale of production and the facilities’ positivity rate explain lower average costs variability, however the latter has a much stronger negative effect. Supervisions and funding linked to performance were strong predictors of average costs variability.

**Conclusions:** The relationship between unit cost and scale underscores the need to focus scaling up in sites with sufficient demand for services. Scale of HTC services production can increase overall efficiency, as well as targeting strategies to detect HIV-positive individuals. Hospitals tend to have a greater HTC average cost, explained by higher fixed costs and a low scale of production, making this setting of provision less efficient than the health center model. Monitoring and supervision are relevant factors that contribute to increase efficiency in contrast to incentives for performance. These results bring up the need to design an incentives scheme linked to increase the detection of HIV-positive clients.

**TUPE840**

**Efficiency of VMMC and its determinants: results from the ORPHEA study in Kenya, Rwanda, South Africa, and Zambia**

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**Background:** While VMMC programs have made significant progress since their inception, as the levels of coverage increase they face important challenges to reach their goals, including availability of resources. Scaling up VMMC coverage to achieve national targets will require that countries deliver the highest achievable quality of service at the lowest feasible cost.

**Methods:** The data for this analysis come from the “Optimizing the Response in Prevention: HIV Efficiency in Africa” (ORPHEA) study - a facility-based study of the costs and technical efficiency of HIV interventions conducted in Kenya, Rwanda, South Africa, and Zambia between 2011 and 2013. Quality was measured through patient exit interviews. The log of cost per VMMC client and a quality variable (bounded between 0 and 1) were analyzed as outcomes in a simultaneous regression model, including as covariates the scale of production of VMMC clients (p=0.02). Facilities that shift tasks away from doctors produce VMMC at half the cost of facilities that employ doctors (p=0.005), however this characteristic does not have effect on quality (p=0.629). The degree of financial monitoring also shows an inverse association with average costs.

**Conclusions:** The large differences in unit cost found across facilities suggest high levels of inefficiency in the provision of VMMC. Implementation and management characteristics are important variables to explain the variability of the cost per VMMC, and are less relevant to explain quality. Health centers producing VMMC services with nurses determines better costs efficiency while maintaining the same levels of quality. Beyond scale, there is considerable scope to increase efficiency in the production of VMMC services through reallocation of health inputs.
WEAA0101
Comparison of HIV-1 envelope specific IgA and IgG antiviral ability to prevent HIV-1 infection: additive, inhibitory and synergistic effects
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Background: Despite the crucial role of IgA in mucosal immunity, very little is known about how IgG and IgA isotypes interact to prevent HIV-1 infection. This gap in the current knowledge was highlighted in the HIV-1 RV144 vaccine trial in which specific monoclonic (mIgA) mitigated IgG effector functions and correlated with increased risk of HIV-1 acquisition. Both IgG and dimeric (dIgA) are present in the female and male genital tracts, which are the main site of viral entry. However, the ratio of IgG to IgA varies between compartments. In this study, we compared the antiviral properties of IgG and IgA antibodies with the same epitope specificity at ratios found in genital secretions. Subsequently, we investigated whether the combination of antibody recognising discrete epitopes but from the same isologue resulted in improved antiviral activities.

Methods: CH31, b12, 2FS and 7B2 mAbs binding to soluble HIV-1 gp120 Enve and kinetics parameters of these interactions were determined by competitive enzyme-linked immunosorbent assay and Bio-Layer Interferometry (BLI). HIV-1 Env virus was captured by the panel of mAbs was quantified by p24 ELISA, antibody mediated viral aggregation (AMVA) was determined using Nanoparticle Tracking Analysis (NTA) and neutralisation activity by TZM-bl neutralisation assay.

Results: We demonstrated that IgGs captured significantly more virions than IgAs and this was correlated with higher association rate constants whereas dIgA presented the ability to mediate viral aggregation. Strikingly, the combination of dIgA and IgG recognising the same epitope did not elicit any additive effects. In contrast, IgG prevented dIgA binding to HIV-1gp120Env and its ability to capture and aggregate HIV-1 viruses. However, mixtures of IGAs or dIgA recognising distinct epitopes but from the same isologue resulted in synergistic effects with higher proportions of captured viruses; antibody mediated viral aggregates and neutralisation activities.

Conclusions: This study compared the ability of IgG and dIgA to prevent HIV-1 infection with respect to the ratio IgG and dIgA found in genital secretions. Collectively, these results suggest that the combination of antibody targeting different epitopes provides enhanced general antiviral activities. Nonetheless, antibody binding to the same epitope but of different isotypes may lead to competition and inhibition of antiviral functions.

WEAA0102
Anti-V3/glycan and anti-MPER neutralizing antibodies, but not anti-V2/glycan-site antibodies are strongly associated with higher anti-HIV-1 neutralization breadth and potency
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Background: Previous candidate HIV vaccines have failed to either induce wide-cover- age neutralizing antibodies or substantially protecting vaccines. Therefore, current efforts focus on novel approaches never before successfully used in vaccine design, including modeling epitopes. Candidate immunogen models identified by broadly neutralizing antibodies include the membrane proximal external region (MPER, recognized by 4E10, 2FS and 10E8 monoclonal mAbs (mAbs)), V3/glycans (typhoid by PTG121-128 mAbs) and the V2/glycan site (initially defined by PG9 and PG16 mAbs). Anti-MPER and anti-V3/glycan antibodies are often autoreactive or polyreactive, and this is thought to pose both direct and indirect barriers to achieving neutralization breadth.

Recent evidence shows that antibodies with moderate neutralization breadth are frequently attainable, with 50% of sera from chronically-infected individuals neutralizing 25% of a large, diverse set of viruses. Such moderately neutralizing antibodies may be more attainable in vaccines. Despite these findings, there is little systematic information addressing which specificities are preferentially targeted among such commonly found, moderately broad neutralizing sera.

Methods: We explored associations between neutralization breadth and potency and presence of neutralizing antibodies targeting MPER, V3/glycan site and V3/glycans in sera from 177 antiretroviral therapy-naive HIV-1-infected (>1yr) individuals recruited in Cape Town, South Africa.

Results: Recognition of both MPER and V3/glycans was associated with increased breadth and potency. MPER-recognizing sera neutralized 4.62 more panel viruses than MPER-negative sera (95% prediction interval (PI) 4.41, 5.20), and V3/glycan-recognizing sera neutralized 3.24 more panel viruses than V3/glycan-negative sera (95% PI 3.15, 3.52). In contrast, V2/glycan site-recognizing sera neutralized only 0.38 more panel viruses (95% PI 0.20, 0.45) than V2/ glycan site-negative sera and no association between V2/glycan site recognition and breadth or potency was observed.

Table: Summary of effects of neutralizing antibodies targeting MPER, V2/glycan site and V3/glycan in sera from 177 antiretroviral therapy-naive HIV-1-infected (>1yr) individuals.

<table>
<thead>
<tr>
<th>Category</th>
<th>Less broad (Geo Mean ID50 &lt; 125)</th>
<th>Potently neutralizing (Geo mean D50 &gt; 225)</th>
<th>Relative Risk (95% CI)</th>
<th>p value (X)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-MPER neg</td>
<td>124 20</td>
<td>1.00 (reference)</td>
<td>122 22</td>
<td>1.00 (reference)</td>
</tr>
<tr>
<td>Anti-MPER pos</td>
<td>24 9</td>
<td>1.50 (0.42, 2.47)</td>
<td>13</td>
<td>1.00 (reference)</td>
</tr>
<tr>
<td>Anti-V2 glycan site neg</td>
<td>63 21</td>
<td>1.00 (reference)</td>
<td>62 10</td>
<td>1.00 (reference)</td>
</tr>
<tr>
<td>Anti-V2 glycan site pos</td>
<td>29 5</td>
<td>0.59 (0.24, 1.42)</td>
<td>27 7</td>
<td>0.79 (0.37, 1.77)</td>
</tr>
<tr>
<td>Anti-V3 glycan neg</td>
<td>75 17</td>
<td>1.00 (reference)</td>
<td>73</td>
<td>1.00 (reference)</td>
</tr>
<tr>
<td>Anti-V3 glycan pos</td>
<td>12 9</td>
<td>2.32 (1.21, 4.46)</td>
<td>12</td>
<td>2.08 (1.10, 3.92)</td>
</tr>
</tbody>
</table>

(Broad/Potent neutralization and target recognized)

Conclusions: Despite autoreactivity of many neutralizing antibodies recognizing MPER and V3/glycans, antibodies to these sites are major contributors to neutralization breadth and potency in this cohort. This suggests that the autoreactivity effect is not critical and that the MPER and V3/glycans should remain high priority vaccine candidates. The V2/glycan site result is surprising because broadly neutralizing antibodies to this site have been repeatedly observed. It may therefore be appropriate to focus on developing immungens based upon the MPER and V3/glycans.

WEAA0103
Impact of HLA-B*35 alleles on HIV disease outcome in Mexico and Central America
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Background: The HLA-B*35:01/02/03/08/14/16/17/20/43 were classified as PY, and B*35:02/03/12 as Px. Ranking HLA-B*35 alleles have been classified into two groups, PY and Px, based on residues 223, 224 and 228. Despite these findings, there is little systematic information addressing which specificities are preferentially targeted among such commonly found, moderately broad neutralizing sera.

Methods: We explored associations between neutralization breadth and potency and presence of neutralizing antibodies targeting MPER, V3/glycan site and V3/glycans in sera from 177 antiretroviral therapy-naive HIV-1-infected (>1yr) individuals recruited in Cape Town, South Africa.

Results: Recognition of both MPER and V3/glycans was associated with increased breadth and potency. MPER-recognizing sera neutralized 4.62 more panel viruses than MPER-negative sera (95% prediction interval (PI) 4.41, 5.20), and V3/glycan-recognizing sera neutralized 3.24 more panel viruses than V3/glycan-negative sera (95% PI 3.15, 3.52). In contrast, V2/glycan site-recognizing sera neutralized only 0.38 more panel viruses (95% PI 0.20, 0.45) than V2/ glycan site-negative sera and no association between V2/glycan site recognition and breadth or potency was observed.
WEAA0104
Type-1 programmed dendritic cells induce primary CTL capable of effectively targeting the HIV-1 reservoir

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Abstract:

Background: The "kick and kill" strategy for the cure of chronic HIV-1 infection involves unmasking cells harboring the latent viral reservoir followed by their immune elimination. We hypothesize that a broad priming of de novo rather than memory HIV-1-specific CTL will be required to effectively target the autologous HIV-1 reservoir, and that this "kick" can be best achieved using specifically programmed type-1 dendritic cells (DC1).

Methods: Mature, IL-12p70 producing DC1 were generated using a combination of either TNFα, IL-1β, poly IC, IFNγ, IL-4, or CD40L and IL-23. Mature, IL-12 deficient DC were generated using either a combination of TNFα, IL-1β, IL-6, PD-8, or CD40L alone. CD8+ T cells were purified from lymph nodes of recently infected and, both naive (primary) and memory CD8+ T cells were isolated from HIV-1 infected Multicenter AIDS Cohort Study participants who were on virus-suppressive cART for several years. These cells were stimulated with autologous DC cells were isolated from HIV-1 infected Multicenter AIDS Cohort Study participants who were on virus-suppressive cART for several years. These cells were stimulated with autologous DC

Results: DC1 proved far superior to the IL-12-deficient dendritic cells for inducing primary CTL responses in both infected and uninfected donors. Importantly, DC1 required CD40L "help" at the onset of priming cultures for successful CTL induction and expansion. Both primary and memory CD8+ T cells each responded to distinct autologous HIV-1 Gag peptides with robust IFNγ production. However, a broader targeting of known MHC class I-restricted epitopes was achieved by the primary CTL responders than the memory cells. Importantly, despite substantial IFNγ production by both T cell subsets, the primary CD8+ T cells were significantly superior to restimulated memory T cells in eradicating HIV-1 infected CD4+ T cells. The primary CD8+ T cells were significantly superior to restimulated memory T cells in eradicating HIV-1 infected CD4+ T cells. The primary CD8+ T cells were significantly superior to restimulated memory T cells in eradicating HIV-1 infected CD4+ T cells.

Conclusions: We demonstrate that naive T cells from HIV-1 infected persons on ART have the repertoire and ability to be primed by high IL-12p70-producing DC1 to effectively target the HIV-1 reservoir, while memory CTL responses are suboptimal. These findings highlight the importance of directing HIV-1 curative strategies towards the induction of de novo rather than memory HIV-1-specific CTL responses.

WEAA0105
Molecular determinants of HIV-1 permissiveness and persistence in gut-homing CD4+ T cells expressing the Th17 marker CCR6

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Abstract:

Background: HIV-infected CD4+ T-cells are enriched in gut-associated lymphoid tissues (GALT). The integrins a4β7 and a7β8 mediate imprinting for gut-homing, and their expression is induced by retinoic acid (RA), a vitamin A metabolite produced by GALT dendritic cells. We previously demonstrated that CD4+ T-cells expressing the Th17 marker CCR6 are permissive to HIV in vitro, harbor replication-competent HIV reservoirs in ART-treated subjects, and that RA selectively increases HIV replication in these cells. To identify new molecular determinants of HIV permissiveness/persistence, we performed a genome-wide transcriptional analysis in RA-treated CCR6+ versus CCR6- T-cells.

Methods: CD4+ T-cells were sorted from PBMCs by negative selection using magnetic beads (Miltenyi). Memory (CD45RA-) CCR6+ and CCR6- T-cells were sorted by flow cytometry (BDFACS). Cells were stimulated via CD3/CD28 and cultivated in the presence or absence of RA (10nM) for 4 days. Total RNA was extracted for microarrays analysis (HT 124v BeadChip). Illumina; >46,000 probe sets per chip). Validation of microarrays were performed by real-time PCR and/or flow cytometry. HIV-DNA integration was measured by nested real-time PCR.

Results: Among 15,303 "present" cells, 1,538 and 1,285 probe sets were modulated by RA in CCR6+ and CCR6- T-cells, respectively (p-value < 0.05; fold change cut-off 1.5). Gene Set Variation Analysis (GSVA), Ingenuity Pathway Analysis (IPA), and Gene Ontology tools were used to identify pathways/individual transcripts specifically induced by RA in CCR6+ versus CCR6- T-cells. This signature included an increased expression of gut homing markers (a4β7, CCR6), HIV-1 coreceptors (CCR5, CXCR4), and also pathways linked to the regulation of T-cell activation (CD38, Cdk5, MAPK4), glutamate metabolism (Glut1, Glut3), cell cycle (GADD45G), HIV replication via CCR5 expression (KLF2), and multidrug resistance (MDR1/ABCB1). In addition, the transcription of RA-treated CCR6+ T-cells showed decreased expression of known HIV-1 resistance factors (PRR gag, CCL3, CCL4L1).

Conclusions: Our studies demonstrate that RA-mediated imprinting for gut-homing is associated with HIV permissiveness in CCR6+ but not CCR6- T-cells and reveal molecular mechanisms underlying these differences. These findings will orient the discovery of new therapeutic strategies aimed at limiting HIV permissiveness, and subsequently the size of HIV reservoirs, specifically in gut-homing Th17 cells.
WEAB01 Primary HIV Infection: ART at the Start

WEAB0101
Long-term early antiretroviral therapy limits the HIV-1 reservoir size as compared to later treatment initiation but not to levels found in long-term non-progressors

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Background: Early initiation of long-term antiretroviral therapy (ART) may lead to viral control after treatment discontinuation. Recent evidence indicates that ART initiated within seroconversion limits the HIV-1 reservoir size. Insight into the reservoir in patients with different timings of ART as well as those who can control HIV-1 without treatment should further inform new treatment strategies.

Methods: A cross-sectional study of HIV-1 reservoir size (total and integrated HIV-1 DNA) and dynamics (2-LTR circles and cell-associated HIV-1 unspliced RNA (usRNA)) was performed in peripheral blood mononuclear cells (PBMCs) in 84 HIV-1 infected patients from 4 clinical centers (London, UK and Ghent, BE): long-term treated patients with ART formed in 25 Recent SRCV on ART; n=25) or chronic infection (Chronic ART; n=32), cohorts in 2 clinical centers (London, UK and Ghent, BE): long-term treated patients with ART formed in 25 Recent SRCV on ART; n=25) or chronic infection (Chronic ART; n=32), long-term non-progressors (LTNP; n=17) and ART-naive recent seroconverters (Recent SRCV; n=10). Total HIV-1 DNA, 2-LTR and usRNA were measured by ddPCR and integrated HIV-1 initiated during seroconversion (SRCV on ART; n=25) or chronic infection (Chronic ART; n=32), long-term non-progressors (LTNP; n=17) and ART-naive recent seroconverters (Recent SRCV; n=10).

Results: Median total HIV-1 DNA copies were: 92, 48, 137 and 1901 c/10^6 PBMCs in SRCV on ART, LTNP, Chronic ART and Recent SRCV, respectively. Significantly lower levels of total (p<0.041) and integrated HIV-1 DNA (p<0.003) were detected in early compared to chronically treated patients, however these were higher than those found in LTNP (Fig 1a, 1b). Interestingly, similar levels of integrated HIV-1 DNA were found in Recent SRCV compared to the Chronic ART cohort (p=0.104), confirming very fast seeding of the reservoir (Fig 1b). Levels of usRNA were significantly lower in early compared to chronically treated cohort (p<0.007), indicating a lower transcriptional activity in early treated patients and similar to LTNP (p=0.015). Furthermore, early treated patients exhibited a higher CD4/CD8 ratio compared to chronically treated patients (p<0.009), suggesting lower levels of residual immune activation.

Conclusions: Our data demonstrate that long-term early treated patients have smaller reservoir size as compared to patients treated during chronic infection, however not reaching levels found in LTNP. Interestingly, the reservoir dynamics in terms of 2-LTR and usRNA as well as the CD4/CD8 ratio in early treated patients are comparable to LTNP.

WEAB0102
High rates of non-reactive HIV serology after antiretroviral therapy initiated in acute HIV infection

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Background: Non-reactive HIV serology may be a marker of low HIV viral burden. We examined the evolution of HIV antibody in a cohort of individuals treated during acute HIV infection (AH).

Methods: Between April 2009 and December 2014, adults attending voluntary HIV testing in Bangkok, Thailand, were screened for AH by either pooled nucleic acid testing (NAT) of 4th generation immunoenzyme assay (4G IA) non-reactive samples or by 3rd (3G) or 2nd generation (2G) enzyme immunoassay (EIA) of 4G IA reactive samples. Immediate antiretroviral therapy (ART) was offered. Western blot and p24 quantification were performed for Fiebig staging. HIV serology at baseline, weeks 12 and 24 were performed.

Results: 233 Thai adults were enrolled from 130,164 samples screened, 3 individuals did not initiate ART and were excluded from analysis. The median age of the volunteers was 27 years and 95% were male. Median time from history of HIV exposure to enrollment was 18 days and median time from enrollment to ART initiation was 1 day.

Non-reactivity to HIV enzyme immunoassay (N[%])

<table>
<thead>
<tr>
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<th>Week 12 (N=150)</th>
<th>Week 24 (N=135)</th>
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<tr>
<td>2nd generation EIA</td>
<td>207 (100)</td>
<td>51 (34)*</td>
<td>53 (39)*</td>
</tr>
<tr>
<td>3rd generation EIA</td>
<td>99 (48)</td>
<td>5 (3)*</td>
<td>7 (5)*</td>
</tr>
<tr>
<td>4th generation IA</td>
<td>43 (21)</td>
<td>30 (20)</td>
<td>24 (18)</td>
</tr>
</tbody>
</table>

*pMcNemar’s test, p<0.001, compared to baseline [Note: No significant difference between week 12 and week 24]

Table 1: Non-reactivity to enzyme immunoassay
WEAO103
Twenty-four weeks is too short to assess virological success in primary HIV infection treatment

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Background: The goal of HAART, in established HIV infection, is to obtain virological success (plasma HIV-RNA level <40 copies/mL) associated with CD4 increase at 24 weeks of treatment (W24). Therefore, we analysed whether such W24 end-point is also pertinent for patients treated for primary HIV infection (PHI).

Methods: We conducted a 10-year retrospective analysis of the immuno-virological response in 55 adults receiving HAART within 3 months after diagnosis of PHI. Genotypic resistance test results were performed before HAART and at W24 for patients with virological failure (VF) as well as HAART plasma concentrations.

Results: Patients were mostly men (n=48, 87%), White European (n=50, 91%), MSM (n=29, 52%) and mean age 35.9 years. At baseline, mean pVL was 2.610^6 copies/mL (8.10^5 -10^7) and mean CD4 count 473/mm^3 (77-1003). Patients were mostly infected with subtype B (n=30, 54%). Due to the evolution of treatment recommendations over the 10-year study period, 9 different combinations of HAART were used, including mostly TDF/FTC (n=38, 69%) and a protease inhibitor as third agent (n=40, 89%). At W24, 44/55 (80%) patients had pVL<40 copies/mL whereas 11/55 (20%) had low residual pVL (45-391 copies/mL: median: 155). In these latter patients, we observed neither mutation associated with resistance nor inefficient drug concentration. VF was correlated in univariate analysis with a significantly higher mean baseline pVL (p=0.03) and a significantly lower mean baseline CD4 (p=0.04) compared to patients with undetectable pVL at W24. There was no relationship between the mutation VF and age, ethnicity, sex, source of contamination, HAART combination or VF at W24.

Conclusions: Our results show that 24 weeks is too short to achieve virological success in patients with high pre-treatment pVL associated with low CD4 count. These data highlight that the usual W24 end-point to conclude virological success may not be appropriate in PHI.

WEAO104
HIV transmitted drug resistance declined from 2009 to 2014 among acutely infected MSM in Bangkok, Thailand

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Background: Rates of transmitted drug resistance (TDR) have been reported to be 11-21% in the USA and Europe, where baseline genotype resistance testing prior to antiretroviral therapy (ART) is routine. In resource limited settings, baseline resistance testing is not the standard of care, but TDR data can ensure that first-line treatment regimens used in national HIV treatment programs remain effective.

Methods: The RV254/SEARCH10 cohort has enrolled patients with acute HIV infection from the largest HIV testing and counseling center in Thailand since 2009. Patients have baseline genotype testing prior to initiating ART: TRUGENE HIV-1 (Siemens Healthcare Diagnostics, Australia) was used for the first 66 patients and a validated in-house method for the remaining. Mutations were categorized following the World Health Organization surveillance drug resistance mutation (SDRM) list. Prevalence of resistance was calculated by dividing the number of subjects with mutations by the number enrolled during each time period. Change in prevalence over time was assessed by chi-square test for trend. Time periods were combined into 2-year blocks for analysis.

Results: Genotype resistance test results were available from 184 of the first 186 subjects enrolled in the study; virus from 2 patients could not be amplified. Median age was 28 years, 96% were male, and 92% were men who have sex with men (MSM). Median time (inter-quartile range, IQR) from HIV exposure to diagnosis was 18 (14-24) days. Median (IQR) HIV RNA was 5.7 (5.1-6.7) log_10 copies/mL and was not significantly different between patients with and without resistance mutations. Median (IQR) CD4 was 352 (260-466) cells/mm^3. Prevalence rates for resistance mutations are shown in the table. Overall TDR was 7.1%, declining from 12.5% in 2009-2011 to 4% in 2013-2014, although the change was not statistically significant (p=0.07). The mutations most commonly found were the M46I (n=3), K103N (n=2), Y181C (n=2), and M184V (n=2). The prevalence of these mutations was significantly lower in 2013-2014 compared to 2009-2010 (p<0.05). There was no relationship between the rates of transmission and the resistance mutation prevalences over time.

Conclusions: TDR does not appear to be increasing among MSM in Thailand and may be declining. Routine genotype testing prior to initiating ART may not currently be necessary in this population, but surveillance for TDR should continue to monitor for any future changes.

WEAC01 Female Sex Workers: Insights for Intervention

WEAC0101
Social cohesion among sex workers has an independent effect on reduced client condom refusal in a Canadian setting

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Background: Despite substantial evidence in low and middle-income settings that community empowerment and collectionization can be a powerful determinant of successful HIV prevention, there is limited understanding of the impact of connectedness among sex workers on HIV risk in the global north. This study longitudinally modeled the impact of social cohesion on client condom refusal among street- and off-street sex workers in Vancouver, Canada.

Methods: Longitudinal data were drawn from an open prospective cohort of female (trans*- inclusive) sex workers, AESHA (An Evaluation of Sex Workers Health Access), in Metro Vancouver (2010-2013). Participants were recruited through outreach to outdoor locations and hidden indoor and online venues and completed bi-annual interview questionnaires and HIV/STI testing by a project nurse. Lippman and colleagues’ Social Cohesion Scale measured community connectedness (i.e., perception of mutual aid, trust, support) among sex workers. Bivariate and multivariable logistic regression using generalized estimating equations (GEE) were used to examine the independent effect of social cohesion on client condom refusal over three-years follow-up.

Results: Of 654 sex workers, one-third (n=221) reported client condom refusal over three-years follow-up. On average, a medium level of social cohesion was reported; median social cohesion scores were 24 (IQR 20-25, range4-45). In the final multivariable confounder model, for every one point increase in the social cohesion score, the odds of client condom refusal decreased by 3%, (adjusted odds ratio=0.97; 95% CI: 0.95-0.99) after adjusting for age, injection drug use, and place of solicitation.

[Table: Total 2009-2010 2011-2012 2013-2014 p
N enrolled 184 32 52 100
Any resistance 13 (7.1) 4 (12.5) 5 (9.6) 4 (4.0) 0.07
N with RT genotype 183 32 51 100
NRTI mutations 6 (3.3) 2 (6.3) 2 (3.9) 2 (2.0) 0.23
NNRTI mutations 4 (2.2) 3 (9.4) 1 (2.0) 0 (0.0) 0.03
N with PR genotype 180 32 50 98
PI mutations 6 (3.3) 1 (3.1) 3 (6.0) 2 (2.0) 0.52

[Transmitted drug resistance among MSM in Bangkok]
Conclusions: This is the first study to examine the independent effect of social cohesion on client condom refusal among sex workers in the global north. Findings suggest that community collectivization and sex worker-led empowerment efforts can have a direct protective effect on HIV risk reduction and shifting social norms among clients in the sex industry. Given public health and human rights concerns around new Canadian laws introduced this year to further criminalize sex workers’ ability to work together (C-36), these findings highlight the urgent need for legal reforms and a structural framework that better promotes sex workers’ ability to more formally collectivize, including sex worker-led efforts in the HIV response.

WEAC0102

Understanding the financial lives of female sex workers: implications for economic strengthening interventions for HIV prevention

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Background: Many women’s decisions about whether and how to participate in sex work are driven by financial considerations. Despite the importance of economic factors in structural interventions for HIV prevention, data on the financial practices of female sex workers (FSWs) on which to base economic strengthening programs for HIV risk reduction are limited.

Methods: We collected qualitative data in Abidjan, Côte d’Ivoire, through structured participant observation activities conducted with 72 FSWs during non-working hours. Detailed notes were taken as FSWs discussed their expenditures, income-generation, and saving and borrowing strategies. We also collected quantitative financial diary data from a sub-sample (n=33) of FSWs. Women who kept financial diaries did so for six weeks, meeting weekly with researchers to systematically discuss and record all financial transactions. Participatory observation notes were coded and analyzed using qualitative thematic analysis. Data from financial diaries were analyzed using descriptive statistics.

Results: All women in our sample reported sex work as their primary source of income; many supplemented their income with cash gifts and modest loans from clients, family, or peers. FSWs’ food, clothing, and transportation costs accounted for the highest amounts of relatively-fixed spending. Around one-quarter of all expenses were related to costs of sex work (e.g., “work” clothing, beauty care, personal hygiene products, right to work payments, police pay-offs, etc.). Qualitatively, both income and expenditures were reported to fluctuate monthly (e.g., around payday), seasonally (e.g., around holidays), and unexpectedly (e.g., illness or financial shocks). FSWs described saving money in their homes, through social ties, or through formal systems (mobile money or banks), to help manage expenditures. They also reported increasing their sex work activities (e.g., traveling to other areas, offering sex for goods) to formal systems (mobile money or banks), to help manage expenditures. They also reported increasing their sex work activities (e.g., traveling to other areas, offering sex for goods) to

Conclusions: Economic strengthening interventions have, in theory, great potential to lower FSW’s risks of HIV by lessening the financial drivers of sex work. Our findings offer a rare glimpse into the earning, spending, saving, and borrowing practices of FSWs, providing evidence on which to base decisions about how best to design and implement economic strengthening elements of HIV prevention for FSWs.

WEAC0103

High utilization of health services and low ART uptake among female sex workers (FSW) in three South African cities: results from the South Africa health monitoring study (SAHMS-FSW)

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Background: The 2012-16 South Africa HIV National Strategic Plan calls for integrated mobile HIV and point-of-care CD4 testing. We describe HIV seroprevalence, HIV status awareness, and ART use in FSWs.

Methods: We recruited 764 FSW in Johannesburg, 550 in Cape Town and 766 in Durban using respondent-driven sampling (RDS) to take behavioral surveys, access voluntary counseling and testing and provide blood samples for HIV and syphilis surveillance. Serological testing followed national standards. We used RDSAT (version 7.1) to estimate population-adjusted prevalence for HIV, syphilis, selected behavioral and programmatic indicators, and SPSS (version 18.0) for multivariate logistic regressions with selected RDS-adjusted behavioral and programmatic indicators to identify site-specific significant associations with HIV-infection. We reported adjusted odds ratios (aOR) and 95% Confidence Intervals (95%CI) in Table 1: Predictors of HIV - South African Health Monitoring Study, 2014, and current ART utilization in Table 1.

Results: HIV prevalence was 71.8% (95%CI 65.6%-81.2%), 39.7% (95%CI 30.1%-49.8%), and 53.5% (95%CI 37.5%-65.5%) in Johannesburg, Cape Town, and Durban respectively. After controlling for age, consistent condom use, and hazardous drinking, brothel-based FSW had significantly higher odds of HIV-infection in Cape Town (aOR 2.1, 95%CI 1.5-3.1) and Durban (aOR 2.3, 95%CI 1.4-3.9); those working both brothels and streets in Johannesburg were more likely to be HIV-positive (3.0, 95%CI 1.2-7.9). Those accessing healthcare in Johannesburg and Durban (aOR 1.4, 95%CI 1.2-1.6 and 1.3, 95%CI 1.1-1.4, respectively), and ANC services in Cape Town and Durban (aOR 1.8, 95%CI 1.1-2.4 and 1.8, 95%CI 1.1-3.2, respectively), were significantly more likely to be HIV-positive. However, uptake of ART remains low among FSWs.

Conclusions: Although FSW accessing healthcare services are more likely to be HIV-positive, current ART utilization demonstrates a substantial gap to be addressed as South Africa begins implementing universal treatment. Identification and expansion of effective outreach models are needed to increase utilization of ART, as well as effectively target prevention services for HIV-negative FSW. Health outreach strategies must account for behavioral and structural factors in specific sex-work environments.

WEAC0104

Closing the gap: Integrating mobile HIV testing and point-of-care CD4 testing for timely identification of HIV-infected and ART-eligible venue-based female sex workers in Lilongwe, Malawi

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Background: Female sex workers (FSW) are a hard-to-reach key population in sub-Saharan Africa with high HIV prevalence, infrequent access to HIV care services, and low uptake of antiretroviral therapy (ART). We describe HIV seroprevalence, HIV status awareness, and ART eligibility and use for venue-based FSW in Lilongwe, Malawi who received integrated mobile HIV and point-of-care (POC) CD4 testing.

<table>
<thead>
<tr>
<th></th>
<th>Johannesburg</th>
<th>Cape Town</th>
<th>Durban</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venue of Sex Work (Street Based vs Reference)</td>
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<td>95% CI</td>
<td>aOR</td>
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<td>Street and Brothel Based Only</td>
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<td>1.15-7.89</td>
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<tr>
<td>Health Care Utilization</td>
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<td>1.16-1.56</td>
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<td>ANC Utilization</td>
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<td>0.17-0.47</td>
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<td>1.08-5.12</td>
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<tr>
<td>UAI with Non-Paying Partner</td>
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<td>---</td>
</tr>
<tr>
<td>Age</td>
<td>1.13</td>
<td>1.08-1.18</td>
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</tbody>
</table>

[Table 1]
Methods: From July through August 2014, FSW were recruited using venue-based sampling. 200 FSW, age 18+ years, who reported exchanging money for sex in the past 12 months participated in a biological and behavioral survey to evaluate HIV testing, care, and treatment history. Seropositive FSW, identified using HIV rapid testing, received rapid Alere Pima CD4 counts. Eligibility for ART followed the Malawi national guidelines (CD4 ≤350 cells/mm³, currently pregnant or breastfeeding, or any pregnancy after July 2011 following Option B+ policy). Proportions were estimated for HIV serorelevance, self-reported previous HIV diagnosis, ART-eligibility based on national guidelines, and self-reported ART use.

Results: HIV serorelevance was 69% (n=138); 20% (n=27) were newly diagnosed and 80% (n=111) were previously diagnosed. Among those newly diagnosed, 63% (n=17) were identified as ART-eligible (median CD4: 305; IQR: 237-427). Among those who were previously diagnosed, 85% (n=72) were currently on ART, 22% (n=24) were currently ART-eligible but not on ART (median CD4: 391; IQR: 261-474), and 13% (n=15) were ART-ineligible and not on ART. The most commonly reported reason among previously diagnosed and ART-eligible FSW for not being on ART was a prior high CD4 count (17%, n=4).

Conclusions: This study is one of the first to integrate mobile HIV and POC CD4 testing to identify HIV-infected and ART-eligible venue-based FSW in Malawi. The majority of newly diagnosed FSW were immediately identified as ART-eligible. A substantial proportion of previously diagnosed FSW were ART-eligible but not on ART, with many having a prior high CD4 count. Large-scale integration of frequent HIV and POC CD4 testing for timely identification of HIV-infected and ART-eligible FSW is urgently needed to improve health outcomes for FSW and decrease HIV transmission in sub-Saharan Africa.

WEAC0105
Injection drug use among female sex workers in Iran: findings of the first national bio-behavioural study
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Background: While the prevalence of HIV among female sex workers (FSW) in Iran is approximately 4.5%, FSW who have ever injected drugs are believed to have a significantly higher HIV prevalence. This study tries to assess the determinants of injection drug use among FSW through Iran’s first and only national bio-behavioural surveillance survey.

Methods: This survey was conducted in 2010, by recruiting 827 FSW through facility-based sampling from 21 sites in 14 cities in Iran. Data was collected through face-to-face interviews using a pilot-tested standardized risk assessment questionnaire. All analyses were weighted based on the response rate and adjusted for the clustering effect of the sampling sites. A predictive multivariable logistic regression model was constructed to investigate the determinants of injection drug use among FSW in Iran.

Results: Mean age of participants was 32, 50% had primary school education, 36% (95% CI: 68.5-74.6) had ever used drugs and 14.6% (95% CI: 12.2-16.9) had ever injected drugs. The most frequently injected drugs were methadone, crystal methamphetamine, and crack. Among those who had ever injected drugs, 38.6% reported that they had a drug injection during the previous month and the prevalence of HIV was 11.2% (95% CI: 5.4 to 21.5). In the multivariable model, history of HIV testing (AOR= 1.79, 95% CI: 1.19-2.9), duration of sex work (AOR=1.08, 95% CI: 1.04-1.12), drug use before sex in the past month (AOR=2.70, 95% CI: 1.79-4.10), and alcohol use before sex in the past month (AOR=2.07, 95% CI: 1.35-3.17) were significant predictors of injection drug use.

Conclusions: The prevalence of injection drug use among FSWs in Iran is concerning which calls for special attention to be paid to FSWs who inject drugs. As selling sex to cover drug habit expenses is a likely practice among female drug users, a part of harm reduction programs for drug users should try to target this population in order to reduce their sex work practices.

WEAC0106LB
Engagement in the HIV care cascade and predictors of uptake of antiretroviral therapy among female sex workers in Port Elizabeth, South Africa
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Background: Female sex workers (FSW) are 13-times more likely to be living with HIV than other reproductive-aged women. Data on FSW engagement in the HIV care cascade are limited, but suggest high rates of drop-off prior to viral suppression, with substantial drop-offs at HIV diagnosis.

Methods: FSW ≥18 years were recruited through respondent driven sampling into a cross-sectional study in Port Elizabeth, South Africa. Socio-demographics, reproductive, behavioral and healthcare history were assessed through interview-administered questionnaires. All FSW were tested for HIV and CD4 counts were assessed among women living with HIV. Engagement in the HIV care cascade is described, and predictors of self-reported antiretroviral therapy (ART) uptake among treatment-eligible, previously diagnosed FSW estimated using robust Poisson regression. As ART eligibility thresholds changed from ≤350 to ≤500 cells/mm³ during the study period, eligibility was determined based on CD4 count and current guidelines at time of study participation.

Results: Between October 2014-April 2015, 410 FSW participated in study activities. Overall, 261/410 (63.7%) were living with HIV. Prior history of HIV testing and diagnosis were relatively high (≥50%), however self-reported ART coverage among HIV-positive FSW was just 39% (Figure 1).

After adjusting for time since HIV diagnosis, women who had intimate partners and had not disclosed their HIV status to them were over 50% less likely to be on ART than FSW not in relationships (Table 1). Mothers and women with fewer clients per month were also statistically significantly less likely to be on treatment than non-mothers or FSW with more clients in the adjusted analyses.

<table>
<thead>
<tr>
<th>Predictor</th>
<th>OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR (95% CI)</th>
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<td>Age</td>
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<tr>
<td>18-29</td>
<td>0.78</td>
<td>[0.60-1.02]</td>
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<td>0.87</td>
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<td>20-29</td>
<td>1.00</td>
<td>[0.80-1.24]</td>
<td>0.918</td>
<td>1.03</td>
</tr>
<tr>
<td>30 or more</td>
<td>1.24</td>
<td>[1.08-1.41]</td>
<td>0.074</td>
<td>1.29</td>
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<th>Number of clients past 30 days</th>
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<th>p-value</th>
<th>Adjusted OR (95% CI)</th>
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</thead>
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<td>0-10</td>
<td>REF</td>
<td>0.074</td>
<td>REF</td>
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</tr>
<tr>
<td>11 or more</td>
<td>1.42</td>
<td>[1.38-1.57]</td>
<td>0.074</td>
<td>1.29</td>
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<table>
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<th>Adjusted OR (95% CI)</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>No paying intimate partner</td>
<td>REF</td>
<td>--</td>
<td>REF</td>
<td>--</td>
</tr>
<tr>
<td>Disclosed to some or all intimate partners</td>
<td>0.87</td>
<td>[0.69-1.10]</td>
<td>0.188</td>
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</tr>
<tr>
<td>Has not disclosed to intimate partners</td>
<td>0.41</td>
<td>[0.34-0.47]</td>
<td>0.036</td>
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<tr>
<th>Mother</th>
<th>OR (95% CI)</th>
<th>p-value</th>
<th>Adjusted OR (95% CI)</th>
<th>p-value</th>
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<tr>
<td>Yes</td>
<td>0.82</td>
<td>[0.62-1.08]</td>
<td>0.156</td>
<td>0.76</td>
</tr>
</tbody>
</table>

(1) Univariate analyses also assessed age, race, education, mobility, violence and depression. The adjusted model includes variables statistically significant at p<0.20 in univariate analyses, including variables listed, age, and time since HIV diagnosis.

[Predictors of ART use among ART-eligible FSW]

Among treatment eligible FSW not on ART, 15/61 (26.2%) had previously been initiated but were no longer taking ART.
WEAD001 Implementation Strategies to Optimize HIV Care Continuum

WEAD0101
Community-based adherence clubs improve outcomes for stable antiretroviral therapy patients: findings from Gugulethu, South Africa

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Background: There are few data on patient outcomes from community-based models to deliver antiretroviral therapy (ART), with previous research focused on models for home-based delivery. We describe outcomes of ART patients decentralized to community-based Adherence Clubs (CACs) and compare outcomes with patients managed within a facility-based model.

Methods: This analysis included 8,150 adults initiating ART from 2002-2012 at a public clinic in Gugulethu, South Africa followed until the end of 2013. From June 2012, stable patients (ART >12 months, suppressed viral load) were referred to CACs. Kaplan-Meier methods estimated time to outcomes among CACs stratified by gender and age (15-24 years of age and older patients: >25 years of age). LTFU was compared between CACs and facility-based care using proportional hazards models with time-varying covariates and inverse probability weights of CAC participation.

Results: Of the 2,113 patients (68.8% female, 7.4% youth) decentralized to a CAC, 94% were retained on ART after 12-months. After the first CAC visit, LTFU among CAC patients was 5.6% and 6.4% at 12-months (Figure 1A) and viral rebound 2.2% and 1.5% (Figure 1C), for men and women respectively. LTFU was higher in CACs among youth compared to older patients (Figure 1B). Youth were twice as likely to be LTFU (adjusted hazard ratio) aHR: 2.17, 95%CI: 1.26-3.73) and experience viral rebound (aHR 2.24, 95%CI 1.00-5.04) in a CAC compared to older patients. Overall, CAC participation reduced LTFU by 67% (aHR: 0.33, 95%CI 0.27-0.40) compared to facility-based care, and this reduction persisted when stratified by patient demographic and clinical characteristics. Patients initiating ART most recently, in 2010 or 2011, had a 90% reduction in LTFU among CAC compared to facility-based care (95%CI: 0.05-0.21). Youth were the only sub-set of patients that did not have a significant decrease in risk of LTFU in CACs compared to the CHC (aHR 0.68, 95%CI: 0.37-1.22).

Conclusions: Community-based Adherence Clubs appear to be associated with a decreased risk of LTFU compared to facility-based care. More research is needed on how to expand the role of community-based ART services and what components of these delivery models support long-term retention.

WEAD0102
Sustained viral suppression in persons living with HIV/AIDS receiving HAART in Peru

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Background: Successful treatment for HIV infection requires sustained viral suppression (SVD). Patients with undetectable HIV-RNA levels have a significantly lower risk of clinical disease progression. At and community level viral suppression is important to reduce HIV transmission and the emergence of resistant strains. The study aimed to analyze the frequency and duration of viral suppression (VS) in the first cohort of people living with HIV/AIDS (PLHIVA) under treatment.

Methods: We retrospectively evaluated data from all PLHIVA uninsured adults who initiated HAART through the National Program during 2004-2006 and followed-up until 2012. Patients with complete records in the National Laboratory Reporting System Data Base were included. The duration of VS was analyzed using survival analysis (Kaplan-Meier) in PLHIVA who achieved viral suppression. Survival time was measured between the first control with viral load < 400 copies/ml until the presence of first interruption or failure of viral suppression (FSV) with viral load> 400 copies/ml Persons lost to follow up and those without FSV were censored. R Software 3.0.3 was used.

Results: During the study period a total of 6,629 PLHIVA had access to health care settings for initial evaluation and only 5,462 received HAART. Of these, 4,530 (88%) achieved VS for variable time (responders) and 612 never presented VS (non-responders). Cumulative survival rate was analyzed in responders: 91.1% maintained VS up to 1 year, 84.6% up to 2 years, 80.2% to 3 years, 77.1% to 4 years, 74.1% to 5 years and 70.1% to 6 years. According to survival analysis, Kaplan-Meier curves presented lower duration of VS in young adult patients, females, persons in prisons and those who don’t follow-up their CD4 above baseline. No differences were observed with baseline CD4 and viral load (p>0.05).

Conclusions: This findings suggest that VS as a program indicator is feasible and useful for monitoring care health settings and ranking them like a control quality measure. VS could also be included as another parameter in cascade of treatment measures.

WEAD0103
Entry into care following universal home-based HIV testing in rural KwaZulu-Natal, South Africa: the ANRS TasP 12249 cluster-randomised trial

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Background: In a Universal Test and Treat (UTT) strategy, entry into care soon after HIV diagnosis is crucial to achieve optimal population-antiretroviral treatment (ART) coverage. We evaluated the rate of, and factors associated with, entry into care following home-based HIV testing in a cluster-randomised trial of the effect of immediate ART on HIV incidence in rural KwaZulu-Natal, South Africa.

Methods: From March 2012 to May 2014, individuals ≥16 years in ten (2 x 5) clusters who achieved positive were offered TasP trial clinics and were offered universal and immediate ART (intervention clusters) or according to national guidelines (control clusters). Entry into care was defined as attending a TasP clinic within three months of referral among adults not actively in HIV care (no visit to local HIV programme within past 13 months). Associated factors were identified separately by sex, using multivariable logistic regression.

Results: Overall, 1,205 adults (72.6% women) not actively in HIV care were referred to a TasP clinic. Of these, 425 (33.6%) attended a TasP clinic within three months (no difference between trial arms): 32.5% of women, 36.7% of men. Participants who ever visited the local HIV programme (n=360) were more likely to enter into care than those who didn’t women: adjusted Odd-Ratio (aOR) 1.76, 95% Confidence Interval [1.26-2.45]; men: 2.67 [1.18-3.64]. In women (n=375), those less likely to attend a TasP clinic within three months had completed some sec-
Assessing the HIV care continuum in The Caribbean, Central and South America network for HIV epidemiology (CCASNet): progress in clinical retention, cART use, and viral suppression

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Background: Retention, combination antiretroviral therapy (cART) use, and viral suppression are key stages in the HIV Care Continuum associated with delayed disease progression and reduced transmission. We assessed trends in these indicators within the large and diverse CCASNet cohort over a decade.

Methods: Adults from CCASNet clinical cohorts in Argentina, Brazil, Chile, Haiti, Honduras, Mexico, and Peru contributed data from first visit between 2003 and 2012 until final visit, death, or the end of 2012. Retention was ≥2 HIV care visits in a year >90 days apart. cART use was prescription of a regimen of ≥3 active antiretroviral agents in a year. Viral suppression was HIV-1 RNA < 200 copies/mL at last measurement in the year. cART use and viral suppression denominators were subjects with ≥1 visit in the year. Multivariable modified Poisson regression models were used to assess temporal trends and predict percentages meeting each indicator in each year, adjusting for age, sex, HIV transmission mode, cohort, calendar year, and total time in care.

Results: Among 18,799 individuals contributing to retention analyses, 14,380 to cART use analyses, and 13,330 to viral suppression analyses, there were differences between those meeting indicator definitions vs. not by most characteristics (Table).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Not Retained</th>
<th>Retaineda</th>
<th>p-value</th>
<th>Not on cARTb</th>
<th>On cART</th>
<th>p-value</th>
<th>Not Virally Suppressedc</th>
<th>Virally Suppressedc</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Total</td>
<td>22,385</td>
<td>87,171</td>
<td>&lt;0.01</td>
<td>11,565</td>
<td>57,312</td>
<td>&lt;0.01</td>
<td>19,389</td>
<td>41,271</td>
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<td>Age (Years)</td>
<td>≥39</td>
<td>33.1 (4.39)</td>
<td></td>
<td>33.1 (4.39)</td>
<td></td>
<td></td>
<td>33.1 (4.39)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male Sex</td>
<td>14,238</td>
<td>25.1</td>
<td>0.01</td>
<td>21.0 (39.3)</td>
<td>35.5 (42.4)</td>
<td>&lt;0.01</td>
<td>13,493</td>
<td>29.981</td>
<td>&lt;0.01</td>
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<tr>
<td>Female Sex</td>
<td>8,148</td>
<td>24.8</td>
<td>0.01</td>
<td>24.8 (79.3)</td>
<td>34.6 (82.6)</td>
<td>&lt;0.01</td>
<td>8,148</td>
<td>11,290</td>
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<td>MSM HIV risk</td>
<td>7,050</td>
<td>27.6</td>
<td>0.01</td>
<td>22.0 (81.6)</td>
<td>22.2 (81.6)</td>
<td>&lt;0.01</td>
<td>7,050</td>
<td>16,489</td>
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<tr>
<td>DUV HIV risk</td>
<td>820.0</td>
<td>52.7</td>
<td>0.01</td>
<td>42.3 (47.3)</td>
<td>349 (29.3)</td>
<td>0.01</td>
<td>820.0</td>
<td>842 (70.7)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hetero HIV risk</td>
<td>8,443</td>
<td>26.8</td>
<td>0.01</td>
<td>26.8 (73.2)</td>
<td>26.8 (73.2)</td>
<td>0.01</td>
<td>8,443</td>
<td>17,044</td>
<td>&lt;0.01</td>
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<tr>
<td>Other/Unk HIV risk</td>
<td>6,073</td>
<td>18.1</td>
<td>0.01</td>
<td>18.1 (82.5)</td>
<td>18.1 (82.5)</td>
<td>0.01</td>
<td>6,073</td>
<td>8,795</td>
<td>&lt;0.01</td>
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<tr>
<td>Individual Years in Care</td>
<td>7.4 (9.49)</td>
<td>7.4 (9.49)</td>
<td>&lt;0.01</td>
<td>6.5 (3.8)</td>
<td>8.8 (10)</td>
<td>&lt;0.01</td>
<td>6.4 (9.4)</td>
<td>8.5 (10)</td>
<td>&lt;0.01</td>
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</tbody>
</table>

*Person-years contributed and characteristics*

There were significant improvements in the indicators from 2003 to 2012: from 63% to 80% retained, 74% to 91% using cART, and 53% to 82% virally suppressed (p< 0.05, each). Predicted values from adjusted models revealed similar trends (Figure).
WEAD0202
Moving towards targeted HIV testing in older children at risk of vertically transmitted HIV
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Presenting author email: tbandason@btrti.co.zw

Background: WHO recommends PITC to all in high-burden countries. Symptom screening algorithms have been used widely for other diseases like tuberculosis. Prompt identification of undiagnosed HIV infection remains a priority in Southern Africa. We previously proposed a simple algorithm where a child is asked to respond to any of the four questions, namely, whether child a) has previously been admitted to hospital, b) has had recurring skin problems, c) is a single or double orphan d) has experienced poor health in the past 3 months which can be asked by any cadre at primary care level for screening older children at risk of HIV infection and requiring an HIV test. The objective of this study was to validate the performance of this algorithm in a primary care setting.

Methods: All previously untested children, aged 6 to 15 years attending 7 selected Primary Health Care Clinics of Harare, Zimbabwe with parental/caregiver consent were tested for HIV infection and asked to respond to four algorithm questions. Each positive response was scored as one.

Results: 6,102 (74%) children with median age 9 (IQR 7 to 11) years, 3,138 (51%) male consented to an HIV test. HIV prevalence was 4.8% (95% CI 4.2-5.3) and positivity increased successively as the score increased with those who scored zero, 553,830 (1%); scored one, 110,819 (7%); scored two 4048916%; scored three 268627%; scored four 10163%
A child with a score of one or more had 8 times odds (95% CI 1-0.15) of testing HIV positive with a sensitivity of 80% (95% CI 75-85), specificity of 66% (95% CI 64-67). Sensitivity was higher in those aged 10 years or more (86% vs 70%, p=0.001). Overall, we needed to test 11 children to identify one HIV positive.

Conclusions: The algorithm maintained its integrity and demonstrated that it is a sensitive tool screening older children at risk of HIV infection. The algorithm can be used by lower cadre healthcare workers and can help prioritize limited resources.

WEAD0201
Targeted HIV testing in home or clinic for older children of HIV-infected adults in care increases pediatric HIV testing rates and reveals high prevalence of previously undiagnosed HIV infection
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Background: Health systems offer infant HIV testing as part of prevention of mother-to-child HIV transmission (PMTCT) programs, but are not built systematically to diagnose HIV infection in older children before symptomatic illness. Offering HIV-infected adults attending HIV treatment programs targeted testing in home or clinic may increase early diagnosis of pediatric HIV.

Methods: HIV-infected parents attending HIV care clinic at Kenyatta National Hospital (KNH) in Nairobi, Kenya were asked about their children’s HIV status. Adults with untested children aged ≥12 years old chosen to test children either at home (HBT) or in a clinic (CBT). Multinomial relative risk regression was used to identify cofactors of testing acceptance.

Results: During the 9-month period when targeted testing was routinely offered, approximately 4 times as many children were tested per month as in the previous 10-month period (13.6 vs 3.5 per month; RR: 3.9, 95%CI: 2.6-5.5).
Among 116 enrolled adults, 22 (20%) chose HBT and had 46 children tested, 48 (41%) chose CBT and had 58 children tested, and 45 (39%) did not complete testing. More adults chose CBT than HBT (p=0.003), but more children were tested per adult by HBT (2.0 vs 1.2, p=0.001). HIV prevalence among 104 tested children was 8% overall; 6 infected children were identified by CBT and 2 by HBT (median age: 8 years (IQR 2-11)).
Compared to adults who chose CBT, adults who chose HBT were more likely to have higher income, more education, be male, have a partner, have an unemployed partner, and have a partner known to be HIV negative (p<0.05), while adults who did not test their children were more likely to have higher income and have a partner who was known to be HIV negative or of unknown HIV status (p<0.05). In multivariate analyses, income and partner status remained significantly associated with testing choice.

Conclusions: Targeting HIV-infected parents in care increased the rate of pediatric testing and found high prevalence of pediatric HIV. CBT was preferred over HBT at this urban referral hospital. Efforts to increase pediatric HIV testing and to understand parental characteristics are important to provide timely diagnosis and linkage to care.
WEAD0204
Immunization practice and vaccine safety perception in centres caring for children with perinatally acquired HIV: results from the Pediatric European Network for Treatment of AIDS survey


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Methods: An online questionnaire regarding vaccination practices in HIV-infected children was completed by investigators from the PENTA network. Data were collected between November 2013 and March 2014.

Results: 88 experts in the management of pediatric HIV-infection from 46 different units looking after 2465 patients completed the questionnaire. The majority of units (72%) did not perform routine childhood immunizations in HIV centres. Vaccination histories were incomplete for 40% of the studied population. Influenza, pneumococcal conjugate vaccine and human papilloma vaccine immunizations are widely administered (93%, 89% and 83% of units respectively). Varicella and Rotavirus vaccinations are less recommended (61% and 24% of the units respectively). Monitoring of vaccine responses is performed in 72% of centers. Serology appears to be the most feasible assay among the different centers (90%), mostly performed with immune-enzymatic assays.

Conclusions: Vaccination practices for perinatally HIV-infected children still vary widely between countries. A crucial issue is the incomplete adherence to varicella vaccine. Indeed only in few countries varicella vaccination is universally recommended for children at national. More efforts should be made to standardize mandatory and recommended vaccinations, as well as to guide timing of serological assays. The majority of units carry out immuno-enzymatic tests to evaluate specific antibody levels. However, methods vary with different cut-offs of protection and units of measurement employed. Moreover, especially in high risk groups (eg. children who started late HAART or performed vaccinations before treatment), researches on the development of novel methods to assess protective immunity and accurate correlates of protection are needed. The ultimate goal will be to design individualized vaccine schedules, developed on therapeutic and immunological features of individual patients, optimizing the chances of them gaining robust long-term vaccine induced protection.

Background: Although rates of pregnancy and HIV infection are high among Kenyan adolescent women, their engagement in PMTCT services is poorly characterized. We hypothesized that adolescent women show lower engagement in the PMTCT cascade than adult women, from antenatal care (ANC) attendance to HIV testing and antiretroviral (ARV) uptake.

Methods: We conducted a nationally representative cross-sectional survey of mothers attending 120 maternal child health clinics selected by probability-proportionate-to-size-sampling in Kenya in July-December 2013, with a secondary survey oversampling HIV-positive mothers in 30 clinics. Self-report questionnaires verified by clinic booklets recorded ANC attendance, HIV testing, ARV use and maternal characteristics. Data were compared between adolescent (age < 20) and adult mothers. Differences in maternal characteristics were assessed by Chi-square test. Logistic regression was used to analyze ANC attendance and HIV testing among all women and ARV uptake among HIV-positive women.

Results: Among 2521 mothers surveyed, 278 (12.8%) were adolescents. Adolescents were less likely than adults to have above primary education (25.0% vs. 42.9%, p < 0.001), intended pregnancy (40.5% vs. 58.9%, p < 0.001), and a current partner (73.1% vs. 90.9%, p < 0.001). Overall, 2471 (97.8%) reported attending ≥1 ANC visit. Among 1859 women with verified ANC visits, 898 (44.7%) attended ≥4 visits. Adolescents were less likely than adults to attend ≥4 ANC visits (35.2% vs. 45.6%, OR[95%CI]=0.63[0.49-0.80]). This effect remained significant after adjusting for education, primigravida, pregnancy intention and HIV status (OR[95%CI]=0.60[0.48-0.75]). Among 2388 women who attended ≥1 ANC visit and were not known to be HIV-positive prior to pregnancy, 2298 (95.1%) received HIV testing during pregnancy. Testing rates were not significantly different between adolescents and adults. Among 288 HIV-positive women who attended ≥1 ANC visit and were not on HAART prior to pregnancy, 20 (6.9%) were adolescents, and 243 (84.4%) used any ARVs for PMTCT. Adolescents were less likely to use ARVs than adults (65.0% vs. 85.8%, OR[95%CI]=0.31[0.22-0.41]).

Conclusions: Adolescent mothers showed poorer ANC attendance and lower uptake of ARVs for PMTCT. This calls for further study on barriers to ANC and PMTCT services among adolescent women and development of targeted interventions to improve uptake and retention of this vulnerable population through the PMTCT cascade.
WEA0301

Health resource use pattern analysis to inform targeted interventions alongside the HIV cascade of care and optimize the effect of treatment as prevention

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1BC Centre for Excellence in HIV/AIDS, Vancouver, Canada, 2University of British Columbia, Division of AIDS, Faculty of Medicine, Vancouver, Canada, 3Simon Fraser University, Faculty of Health Sciences, Burnaby, Canada

Presenting author email: ekrebs@ceufen.ubc.ca

Background: Identifying patterns of health resource utilization (HRU) of people living with HIV/AIDS (PLHIV) can allow for comparison of their effects on longer-term health outcomes and costs. Further, identification of patterns associated with greater risk of attrition between stages of the cascade of care can help in the development of targeted interventions to effectively increase patient retention.

Methods: We conducted a population-level analysis of HRU for individuals having received a CD4 test after HIV diagnosis. All individuals 18 years or older in British-Columbia in the modern HAART-era (post-September 2006) were included. Using linked comprehensive administrative health databases in a probabilistic model-based clustering analysis with 14 HRU measures, we estimated parameters by maximum likelihood using the expectation maximization (EM) algorithm. Individuals with estimated parameters maximizing the probability of belonging to a similar HRU cluster were classified with each other, and the optimal number of clusters was estimated by the Bayesian Information Criterion. The analysis was conducted across CD4 count stratification (>200cells/mm3; <200 cells/mm3).

Results: Our study included 841 individuals with at least 1 year follow-up (median age 40, 21% female) and with a CD4 count obtained between September 1, 2006 and March 31, 2011. Individuals with CD4 200 were clustered into 2 HRU patterns. The high cost cluster (N=68, mean $18,169[$321,432]), driven by lengthy HIV-related emergency hospitalizations stays (76.5% with >7days); had costs more than double the low cost cluster (N=147; $6,811[$9,392]). Individuals with CD4 200 were best classified in 4 clusters. The high cost cluster (N=74; $15,831[$19,180]) was characterized by non-HIV ER hospitalizations (100%≥1day, 55.4%>7days) and high prevalence of mental health issues. The second highest cost cluster (N=60; $5,058[$5,152]) was characterized by short-term non-HIV elective hospitalizations (43.8%≥1day). The two lower cost clusters both had no hospitalizations; the higher (N=425; $3,378[$6,454]) with much more frequent physician visits and medication use than the lower (N=240; $1,291[$1,699]).

Conclusions: Even within relatively homogeneous cohorts in terms of disease progress at time of linkage to HIV care, individuals were found to have heterogeneous HRU patterns. Identifying classes of individuals according to HRU can help inform clinical response, as well as the design of public health interventions to optimize HIV care.

WEA0302

Optimizing HIV/AIDS resources in Armenia: increasing ART investment and examining seasonal labour migrant programs

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Background: HIV prevalence is declining in all key affected populations in Armenia (people who inject drugs, men who have sex with men, prisoners, and female sex workers); however, there are increases among labour groups who seasonally migrate to countries of higher HIV prevalence. We conducted a modeling study to assess the impact of optimizing the national strategic plan to minimize HIV incidence and AIDS-related deaths by 2020. We determined optimal funding levels for all programs to best achieve the strategic plan, and in particular, examined the outcomes required for migrant programs to warrant increased investment. Methods: We used the Optima model to perform epidemiological and economic analyses. Demographic, epidemiological, behavioral, and HIV program cost data were obtained for Armenia from 2000 to 2014 and used to inform the model. Through internal and external consultations, assumptions were generated on what coverage levels among targeted populations could be attained for different interventions, as well as their expected outcomes. A sensitivity analysis on migrant HIV testing and counselling programs was conducted around assumptions based on observed data.

Results: According to Optima's optimization algorithm, shifts in funding allocations are required to minimize incidence and deaths by 2020. The largest emphasis should be on antiretroviral therapy (ART), as optimal allocations nearly doubled the investment in treatment from 17% to 24% of the total budget. It is projected to avert almost 25% of new infections and 50% of AIDS-related deaths by 2020 compared to levels if 2013 spending were maintained. We show that funding for seasonal migrant programs should be maintained through to 2020 at 5% of the total budget. Sensitivity analysis demonstrated that these programs are cost-effective to fund if the coverage threshold for HIV testing and counselling for seasonal migrants, as illustrated in Figure 1B, can be achieved.

Conclusions: Optimization of HIV/AIDS investment in Armenia could significantly reduce HIV incidence and AIDS-related deaths by 2020, particularly by focusing more on antiretroviral therapy. We have also identified thresholds for program performance, prior to their scale-up, which can be used to evaluate whether they should be scaled-up or down in the future.
scoring. The regression design employed a generalized linear mixed model with both fixed and random effects, fitted using the seemingly-unrelated regression (SUR) technique.

Results: PBF resulted in positive impacts on MCH, PMTCT, and pediatric HIV program outcomes. The majority of the 18 indicators responded to PBF (77% North and 66% South), with at least half of the indicators demonstrating a statistically significant increase in average output of more than 50% relative to baseline. Most adult HIV (excluding pregnant women) initiation and retention indicators did not respond to PBF. On average, it took 6 quarters of implementation for PBF to take effect, and impact was generally sustained thereafter. Indicators were not sensitive to price, but rather inversely correlated to the level of effort associated with marginal output. No negative impacts on incentivized indicators nor spillover effects on non-incentivized indicators were observed.

Conclusions: The PBF program in Mozambique has shown to produce large, sustained increases in the provision of PMTCT, pediatric HIV, and MCH and should be considered as a powerful alternative to traditional input-based financing.

WEAD0304
The estimated need of second-line antiretroviral therapy in sub-Saharan Africa 2015-2030: mathematical modelling study

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Background: At the end of 2013, about 300,000 patients were on second-line antiretroviral therapy (ART) in sub-Saharan Africa. The need for second-line ART may increase substantially with increasing duration of patients on ART and roll-out of viral load monitoring. We aimed to estimate the need of second-line ART in sub-Saharan Africa between 2015 and 2030 under various scenarios.

Methods: We developed a mathematical simulation model of HIV progression on ART to project second-line needs up to 2030 for individual countries. The model allows the user to vary key input parameters, including annual numbers of patients starting ART, delay in switching after detection of treatment failure, possibility of treatment interruptions, background mortality, and monitoring strategies. We applied the model to all countries in sub-Saharan Africa assuming twelve scenarios that combine different future ART scale-up scenarios (accelerated until universal coverage, stable, no future scale-up), monitoring (routine viral load monitoring in all or only selected countries), and retention and switching (including or excluding possibility of treatment drop-out and delayed switching). The input parameters were chosen to fit the numbers of patients on first- and second-line ART in 2015-2013 to observed estimates.

WEAD0305
Kenya private health sector HIV care services costing using the management accounting system for hospitals (MASH) framework

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Background: The private sector is a key HIV service provider in Kenya, but few data on the cost of private service provision are available. The lack of cost data has inhibited the design of reimbursement mechanisms and health insurance packages, as well as policy decisions on private sector financing. This study estimated unit costs for private sector HIV services disaggregated by facility type and level, as a contribution to ongoing efforts to implement health insurance products covering HIV services.

Methods: Cost and service volume data were collected from 149 private sector facilities in 2013 as part of a nationwide systematic sampling of public and private healthcare costing study supported by GIZ, the USAID-funded Strengthening Health Outcomes Through the Private Sector (SHOPS) Project Kenya, and the Ministry of Health. The MASH (Management Accounting System for Hospitals) tool was used to analyze data. Multiple facilities were eliminated due to lack of complete data with only 60 used.

Results: Average unit costs per inpatient day and per outpatient visit were generated by sector and facility levels 2-4 (as defined by Kenya Norms and Standards 2006). HIV specific unit costs estimated included for HIV counseling and testing (HCT) services and provision of ART. The authors estimated operational costs, but were unable to estimate capital costs following lack of data. Average outpatient visits ranged from Ksh. 699 to 1,036 in level 2 and level 4 respectively. ART visit costs ranged from Ksh. 1,575 to 3,960 across the facilities sampled. HCT visit services ranged from Ksh. 537 to 1,151 across level 2 and 4 facilities respectively.

Conclusions: The study contributed to health financing policy discussions in the provision and financing of HIV services in Kenya. Data generated was presented to insurers and providers who expressed intentions of using it for decision making. Possible applications include design of HIV care inclusive insurance products and advising reimbursement decisions regarding the same. Providers offering HIV services can also use it to benchmark their efficiency. Due to poor record keeping in most facilities only 60 of the 149 facilities had enough data for analysis—hence the need to support facilities improve on data keeping.

<table>
<thead>
<tr>
<th>Future scale-up of ART initiation</th>
<th>Treatment interruptions and switching</th>
<th>2020</th>
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<tr>
<td></td>
<td>Universal routine viral load monitoring</td>
<td>Targeted or routine viral load monitoring depending on country</td>
<td>Universal routine viral load monitoring</td>
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<td>1st-line</td>
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<td>Accelerated scale-up</td>
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<td>16,272,600</td>
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<td>Stable scale-up</td>
<td>Interactions included, delayed switching</td>
<td>Interactions included, delayed switching</td>
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<td>12,598,600</td>
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[Table]
The PEPFAR COPs allocation database: a comprehensive database to monitor PEPFAR spending, increase data transparency, and improve civil society engagement in country operational plans

B. Honermann, G. Millett, K. Lindsey, S. Wijayarathne, J. Sherwood, J. MacAllister
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**Background:** $29.5 billion has been allocated by PEPFAR from 2007 to 2014 through the annual country operational plan (COP) process. COPs serve as a planning tool for activities of US government and in-country partners funded by PEPFAR. Historically, utilizing data from COPs has been difficult due to their inflexible PDF/RTF format hindering the ability to query and manipulate data, create graphical representations of the financial data, or identify trends in PEPFAR allocations over time. As PEPFAR moves toward greater civil society engagement during COPs’ development, it is increasingly important that COPs’ data are readily accessible, categorizable, and interpretable for civil society organizations (CSOs).

**Methods:** Utilizing standard open source tools, amfAR - funded by MAC AIDS - created a navigable database and website of all allocation data contained in published COPs from 2007 through 2014. Data are categorized and can be graphically represented and disaggregated by year, primary partner, host country, strategic area, budget code, and organizational type of recipient. Text narratives of individual budgetary mechanisms captured directly from the COPs are also included in the database and provide users with detailed information for specific allocations. In addition, epidemiological profiles and PEPFAR targets are available by country to provide context for the public health impact of investments.

**Results:** From 2007 through 2014, $29.5 billion was allocated through the COPs process. By organizational type, the primary recipients of PEPFAR funds were NGOs ($8.3 billion), private contractors ($5.4 billion), and universities ($3.5 billion). Another $5.5 billion was not allocated to an identifiable partner or program. Trends varied substantially by country. In Rwanda, resources shifted dramatically to Rwandan government agencies (from 7.6% of PEPFAR resources in 2011 to 34.2% of PEPFAR resources in 2013). Comparatively, PEPFAR 2013 host government funding was lower for Kenya (10.72%), Malawi (3.66%), Nigeria (2.64%), and South Africa (0.8%).

**Conclusions:** amfAR’s COPs database provides corresponding financial and graphical information about progress toward country ownership, and gives the most granular view to date of PEPFAR budgets. The database will be an invaluable tool to help CSOs and others digest and utilize PEPFAR budgetary information. The database is available at http://copsdata.amfar.org
Wednesday 21 July

Oral Poster Discussions

WEPTA0101

Evolution of neutralizing antibodies in HIV-1 subtype C infection

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Background: The development of a preventative HIV-1 vaccine will most likely require induction of broadly neutralizing antibodies (BCN). Neutralizing antibodies develop in almost all HIV-1 infected individuals, however they develop months following HIV-1 infection and they are strain-specific. The development of BCN antibodies occurs only in 20-30% of HIV-1 infected individuals. However, the mechanism that leads to the development of BCN is unknown and not all epitopes have been identified. The aim of the study was to evaluate pathways and mechanisms that lead to the development of broadly neutralizing antibodies.

Methods: Twenty individuals with acute HIV-1 infection were identified and followed longitudinally for 3 years in Durban, KwaZulu-Natal. A panel of 16 viruses (6 subtype A, 6B and 6C) was used to screen the patients for neutralizing antibodies at 2-3 years post-infection using the TZM-bl neutralization assay. The patients that developed broadly neutralizing antibodies were followed up longitudinally at 8, 10, 14, 16, 18, 11, 88, 100, 124, 150, 200 weeks to determine the timing of emergence of the BCNs. Specificity of BCNs was determined using single point mutations at 3 years post-infection.

Results: Three out of 20 individuals (AS3-268, AS2-1037, AS2-358) developed broadly neutralizing antibodies. AS3-268 developed potent BCN activity peaking at 3 years post-infection and it targets N276A glycan on the CD4 binding site of gp120. AS2-1037 developed potent broadly neutralizing activity at 2 years post-infection and it targets N332A glycan on the V3 loop of gp120. AS2-358 developed BCN peaking at 2 years post-infection and it did not map to any known specific epitope.

Conclusions: Broadly neutralizing antibodies could be detected at approximately 1 year post-infection and they targeted different epitopes on the viral envelope. Work is currently in progress to assess the maturation of breadth and to assess antibody-virus co-evolution.

WEPTA0102

HLA-B*58:02-specific benefit of MRKAd5 Gag/Pol/Env vaccine in an African population

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Background: The MRKAd5 Gag/Pol/Env vaccine was introduced to the HIV vaccine field recently. However, the efficacy of this vaccine in countries where the predominant subtype B has been shown to be suboptimal. In a previous publication, we showed that a vaccine incorporating HLA-B*58:02 specific epitopes was preferred in people expressing HLA-B*58:02, an African HLA allele strongly associated with rapid progression in natural HIV infection. HLA-B*58:02 vaccinees showed a lower viral set point and slower time to CD4<350 cells/ml compared with non-HLA-B*58:02 vaccinees.

Methods: Two African populations were in the construction of the MRKAd5 vaccine. The MRKAd5 vaccination study was conducted in South Africa and Botswana. In South Africa, vaccinees (n=89) and placebo recipients (n=76) were followed longitudinally to 180 weeks to determine prophylactic effect of the MRKAd5 vaccine. In Botswana, vaccinees (n=43) and placebo recipients (n=39) were followed up to 180 weeks to determine therapeutic effect of the MRKAd5 vaccine. The vaccines in South Africa and Botswana included the vaccine incorporating HLA-B*58:02 specific epitopes and the vaccine not incorporating HLA-B*58:02 specific epitopes.

Results: Vaccinees (n=89) and placebo recipients (n=76) were followed up longitudinally at 8, 10, 14, 16, 18, 11, 88, 100, 124, 150, 200 weeks to determine the timing of emergence of the BCNs. Specificity of BCNs was determined using single point mutations at 3 years post-infection.

Conclusions: Broadly neutralizing antibodies could be detected at approximately 1 year post-infection and they targeted different epitopes on the viral envelope. Work is currently in progress to assess the maturation of breadth and to assess antibody-virus co-evolution.

WEPTA0103

HIV-1 subtype C is significantly more infectious than other subtypes

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Background: HIV-1 subtype C accounts for about 50% of the global HIV-1 infections. It is the predominant subtype in India, Ethiopia and countries in southern Africa. However, virological and epidemiological attributes to this unique epidemiological pattern have not yet been fully defined.

Methods: A total of 207 HIV-1 positive plasma or established strains were cultured and expanded to higher titer stocks by culturing in PBMCs from HIV-1 negative donors. Near full-length genome (NFLG) sequences were obtained by amplifying two overlapping half genomes. The newly obtained sequences were aligned to the HIV-1 whole genome reference sequences for subtyping. Virus genome copy numbers, tissue culture infection doses (TCID) and p24 concentrations were determined for virus stocks and compared via linear regression among major subtypes. Mann-Whitney U tests were used for the infectivity comparisons at the alpha 0.05 level.

Results: Analysis of NFLG sequences showed that these viruses belonged to subtype A1 (16), subtype B (48), subtype C (53), subtype D (10), CRF01_AE (12), other subtypes and CRFs (F1, F2 G, CRF02, and CRF02; each with ≤8 sequences) and URFs (45). Only subtypes with >10 NFLG sequences were subjected to further analysis. No biologically relevant differences (≥a 0.5 log10 difference) among all compared subtypes were observed for three measurements: virion genome copy numbers, TCID, and p24 concentrations. The only exception was that the TCID of subtype C was 0.51 log higher than that of CRF01 (p=0.04). The infectivity per viral genome (TCID/CRC/PCR) copy was the highest for subtype C (0.0042 TCID/CRC/PCR copy) and was significantly higher than those of all four compared subtypes (A1, B, D and CRF01, AE: p<0.0001, p<0.01 and p<0.05, respectively). The p24RNA copy ratios of subtypes C and B (0.13 and 0.12 pg/p24 RNA copy, respectively) were the highest and were significantly higher than those of subtypes A1 and D (p<0.05), but similar to that of CRF01_AE.

Conclusions: The high infectivity of HIV-1 subtype C may give it more replication advantages and allow it to disseminate faster in HIV-1 infected populations in some geographic areas compared to other subtypes. High infectivity may play a critical role in the global epidemic of subtype C.
WEFDA0105
Characterization of HIV-1C gp120 in recently and chronically infected individuals in Botswana
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Background: Viral diversity provides a major challenge in the development of a vaccine against HIV-1. A potential target for HIV-1 vaccines is gp120 envelope protein, which is involved in viral entry and is a target of the host immune system. It has been shown that Envelope characteristics have a role to play in disease progression. However some studies have demonstrated conflicting results. In this study, we aim to analyze HIV-1 gp120 characteristics, specifically, potential N-glycosylation sites, amino acid sequence length and net electric charge in cell associated and cell free RNA derived from recently and chronically infected individuals in Botswana.

Methods: This was a retrospective study using stored samples collected from treatment naive HIV-1 infected cohorts at Botswana Harvard AIDS Institute Partnership, representing non B subtypes and circulating recombinant forms of HIV-1 circulating in Gabon. A panel of 250 HIV-positive and 250 HIV-negative plasmas was prospectively collected, and were identified similarly. For the major subtype CRF_02AG, sensitivity and specificity were 91.5% and 100%, respectively. For the major subtype CRF_02AG, sensitivity and specificity were 91.5% and 100%, respectively. For the major subtype CRF_02AG, sensitivity and specificity were 91.5% and 100%, respectively. Among 250 HIV-infected and 250 HIV-negative plasmas, 250 plasma samples were identified similarly.

Results: There was a significant increase in amino acid sequence length of V2 (p< 0.027) and V4 (p=0.009) in proviral DNA as compared to the recent stage of infection. Similar changes were also observed in cell free RNA in V4 (p=0.0074). In addition, the number of potential N-linked glycosylation sites in proviral DNA was significantly increased in chronic infection in V4 (p=0.0253). No significant changes in net electric charges were observed. There was an association between viral load and V4 region (p< 0.001). All samples were classified as subtype C.

Conclusions: The increase in amino acid sequence length and potential N-glycosylation sites in the V2 and V4 region may be essential in disease progression. The changes observed in V2 and V4 warrant further investigation. A dear understanding of envelope characteristics is important for development and design of new vaccine and therapeutics.

WEFDA0104
Functional differences in the viral accessory protein Nef between major HIV-1 subtypes
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Background: The HIV-1 accessory protein Nef is essential for HIV-1 pathogenesis and progression to AIDS. By hijacking the cellular trafficking machinery Nef is able to alter T cell activation, increase viral replication and permit viral immune evasion via downregulation of the cell-surface receptors CD28, CD4 and MHC-I respectively. However, only recently have these functions been studied outside of laboratory-adapted strains of HIV-1. This proposal aims to investigate how the high degree of HIV-1 genetic diversity impacts Nef function.

Methods: An HIV-1 based lentiviral expression system was used to express Nef proteins from 10 group M subtypes (A1, A2, B, C, F1, F2, G, H, J and K) in the context of an HIV-1 infection. T cell lines were infected with pseudoviruses encoding Nef proteins and analyzed for surface levels of CD28 and MHC-I using fluorescent antibody staining and flow cytometry. Alternatively, CD4 cell surface levels were measured by transfecting CD4+ HEK cells with expression plasmids encoding Nef-GFP fusion proteins followed by fluorescent antibody staining and flow cytometry. Nef expression was determined by a combination of western blot analysis and flow cytometry to measure fluorescent Nef proteins.

Results: Our results demonstrate that MHC-I, CD28 and CD4 are differentially downregulated between HIV-1 subtypes. Notably, subtype C Nef, the most common subtype globally, was significantly less efficient at downregulating MHC-I and CD28 when compared to the laboratory strain NL-4.3. Subtype G Nef, found predominantly in Central and West Africa, was significantly less efficient at downregulating all three cell surface receptors. Differences in downregulation efficiency for all three receptors were attributed to variations in Nef protein expression.

Conclusions: This study represents a comprehensive analysis of Nef function among 10 HIV-1 subtypes and adds to the growing evidence that HIV-1 genetic diversity impacts viral protein function. Due to the pathogenic role Nef plays in HIV-1 infection, these results may help explain recent studies that show differences in disease progression in individuals infected with different HIV-1 subtypes. Finally, these findings support further study of all major HIV-1 subtypes and emphasize the need to consider subtype differences when developing alternative treatment options.

WEFDA0106LB
Early loss of splenic Tfh cells in SIV-infected rhesus macaques
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Background: Follicular T helper cells (Tfh), a subset of CD4 T lymphocytes, are essential for B cell activation and provide help to B cells in the production of antigen-specific antibodies. Although several studies have analyzed the dynamics of Tfh cells in the context of AIDS by analyzing peripheral blood and LNs of HIV-infected patients, paradoxically, none of these studies in HIV/SIV infection have addressed the role of Tfh cells in the primary organ of B cell activation, the spleen.

Methods: To address these questions we have infected rhesus macaques with SIVmac251 (20/AIDS). Animals were sacrificed at different time points post infection and lymphoid organs were recovered. Tfh cells (CD4+CXCR5+) and CD4+ T cell subsets were monitored by flow cytometry. Concomitantly B cell subsets were also analyzed. CD4 T cell subsets were sorted and SIV DNA was quantified by RT-PCR.

Results: Herein, we demonstrated for the first time that the percentages and numbers of splenic Tfh cells decrease early during the acute phase in macaques infected with SIV. This profound loss and abnormal differentiation of Tfh is also associated with the loss of memory B cell subsets. Moreover, SIV DNA is detected in splenic Tfh cells early after infection. Finally, our results showed at the chronic stage that the frequency of splenic Tfh and memory B cells are higher in slow-progression compared to rapid progressors RMs.

Conclusions: Altogether, our results demonstrate the drastic depletion of splenic memory B cells which might be related to the loss of fully matured Tfh cells.

WEFD0101
Reliability of rapid HIV-1/HIV-2 INSTI® on plasma and capillary blood for diagnosis of non B subtypes and circulating recombinant forms of HIV-1 circulating in Gabon
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Background: Point-of-care or “rapid” serologic assays for HIV are widely used in resource-limited settings. Their evaluation in the field carried out independently of the manufacturer is crucial to assess their capability to accurately detect non B subtypes or circulating recombinant forms of HIV-1 (CRF). Our objective was to evaluate the HIV-1/HIV-2 INSTI® test (distributed by Nephrotec, Rungis, France) for the diagnosis of non B subtypes and CRF of HIV-1 circulating in Gabon, a country of wide genetic diversity.

Methods: A panel of 250 HIV-positive and 250 HIV-negative plasmas was prospectively collected after informed consent in adult patients attending the Laboratoire National de Référence des IST et du SIDA, Libreville, as recommended by the WHO (Service delivery approaches to HIV testing and counselling: A strategic policy framework; 2012). The reference HIV serology consisted of Immunocomb II HIV&1 BS01 (Innerv Medical Innovations, Yavne, Israel) as screening test followed by confirmatory Western blot (New Lav Blot I, Bio-Rad, Marnes-la-Coquette, France). All HIV-positive plasma were furthermore subjected to HIV genotyping by pol nested PCR, amplicons sequencing, and analysis of resulting FASTA sequences by Genotyping software from NCBI. A subgroup of 1 out of 10 patients were also tested in parallel with finger-stick whole blood INSTI® test.

Results: All HIV-1 belong to HIV-1 group M with broad HIV-1 genetic diversity as assessed by pol sequences [CRF02_AG (53%), CRF14 (18%), CRF15 (12%), CRF01_AE (8%), A1 (4%), G (2%), K (2%), B (1%)]. Among 250 HIV-infected and 250 HIV-negative plasmas, 250 and 249, respectively, were positive or negative by INSTI® test. Thus, INSTI® test sensitivity and specificity were 100% and 99.6%, respectively; positive and negative predictive values in Gabon were 91.5% and 100%, respectively. For the major subtype CRF_02AG, sensitivity and specificity were 100%. Finally, all 50 patients tested in parallel using plasma and capillary blood and were identified similarly.

Conclusions: HIV-1/HIV-2 INSTI® test is highly reliable for the detection of various non B HIV-1 subtypes, both in plasma and capillary blood, and it fulfills the WHO criteria for HIV test prequalification. The rapid INSTI® test could be useful for HIV screening in Gabon, as well as in other sub-Saharan African countries.
WEHD0102 Evaluation of the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative version 2 assay on whole blood using specimens with unknown ARV exposure

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Background: Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Qualitative version 2 (TaqMan v2 qual) has recently been released for testing of dried blood spot (DBS) for infants and plasma for adults that are antiretroviral (ARV) naïve; however, ARV status of patients is often unknown. This study evaluated the use of whole blood (WB) for HIV-1 detection using TaqMan v2 qual.

Methods: 133 samples (125 EDTA, 8 Virology Quality Assurance [VQA] WB) were used with known HIV-1 status (positive n=75; negative n=58) as per Roche Amplicor HIV-1 DNA PCR assay v1.5 (Roche v1.5). EDTA samples were split: 1ml plasma, 100ul WB and 1ml DBS. Samples were processed using TaqMan v2 qual according to manufacturer’s instructions and results compared to Roche v1.5.

Sensitivity and specificity were determined for each sample type and compared to EDTA plasma viral load. Seven WB samples (HIV-1 positive n=4; HIV-1 negative n=3) were evaluated for reproducibility and precision using the TaqMan v2 qual.

Results: Of the 89 Roche v1.5 HIV-1 positive samples, 68 were detected using TaqMan v2 qual DBS or WB, whereas only 60 were detected using TaqMan v2 qual plasma. HIV-1 positive samples missed had either a viral load of not detected or <20 RNA copies/ml. The TaqMan v2 qual plasma samples missed 13% of HIV-1 positive samples. No false positives were observed across the three different matrices evaluated. Of the 8 VQA WB samples tested on TaqMan v2 qual and Roche v1.5, 100% concordance was observed (n=6 HIV-1 positive; n=2 HIV-1 negative). Diagnostic sensitivity and specificity are detailed in the table below. Reproducibility and precision was 100% for all samples tested.

Conclusions: TaqMan v2 qual using DBS or WB had the highest sensitivity when compared to Roche v1.5 (98.5%). Plasma samples on TaqMan v2 qual missed 13% of HIV-1 positive samples. With the increase of microbicide use, pre-exposure prophylaxis and reported poor adherence, this study indicates that plasma samples are not the ideal sample type for testing adults when ARV exposure is unknown. The high percentage of adult samples that were missed would have serious implications for decreasing HIV-1 transmission rates.

WEHD0103 CD4 count at antiretroviral therapy initiation and the risk of loss to follow-up: results from a multicentre cohort study

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Background: WHO now recommends routine viral load (VL) monitoring, and the scale up of this has started in sub-Saharan Africa. Recent publications from the region suggest that often patients with detectable viral load delay switching to second line ART or are not switched.

Methods: We performed a retrospective audit of a sample of patients on first line ART with detectable viral load who were managed through a treatment failure pathway consisting of: 1) review of the results by the clinician; 2) case discussion in the weekly multidisciplinary “switch-meeting”;

Conclusions: Patients initiating ART at higher CD4 counts may be at increased risk for LTFU, particularly early after ART initiation. With programmes initiating patients at progressively higher CD4 counts models of ART delivery need to be reoriented to support long-term retention.

WEHD0104 Clinical decision and outcomes of patients suspected of treatment failure and tested for HIV-viral load at the Infectious Diseases Institute (IDI), Kampala, Uganda

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Background: WHD now recommends routine viral load (VL) monitoring, and the scale up of this has started in sub-Saharan Africa. Recent publications from the region suggest that often patients with detectable viral load delay switching to second line ART or are not switched.

Objective: To evaluate the outcome of patients with a VL>1,000 copies/ml accessing care at a large urban HIV Centre in Kampala, Uganda.

Methods: At IDI VL tests have been available since 2005. Until December 2014 these were reserved for patients with documented immunological or clinical failure. Those patients with detectable viral load are managed through a treatment failure path-way consisting of: 1) review of the results by the clinician; 2) case discussion in the weekly multidisciplinary “switch-meeting”;

Conclusions: We performed a retrospective audit of a sample of patients on first line ART with viral load >1,000 in 2014; data was extracted from 95 randomly sampled clinic files and the clinic database.
**WEPC00105**

**Classification of HIV virological failure using whole blood versus plasma viral load**

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**Background:** In resource limited settings, timely plasma separation and transportation to centralised laboratories is a major challenge to the scale-up of viral load (VL) testing. Whole blood (WB) collection and testing through either dried blood spots (DBS) or point-of-care VL assays are potential solutions. However, there is limited evidence on the performance of WB-based VL assays against plasma controls. The per treatment/processing (DBS versus fresh blood samples) and sample input volume. The performance at 1000 copies/ml of DBS protocols and point-of-care devices remains significantly varied and further development is required to ensure minimal VF misclassification.

**Methods:** We evaluated three WB VL testing platforms, Alere q HIV-1/2, DBS Abbott RealTime HIV-1 and Roche CAP/CTM HIV-1 (DBS, free virus elution protocol) using routine clinical whole blood versus plasma viral load assays are potential solutions. However, there is limited evidence on the performance of WB-based VL assays.

**Results:** Of the 299 samples selected, 153 (51%) had plasma VL>1000 copies/ml. Abbott DBS VL had the best overall VL correlation with its plasma counterpart (r=0.76), followed by the Roche DBS VL (r=0.67) and Alere q HIV-1/2 (r=0.69). Among samples with VF, Alere q HIV-1/2 and Abbott DBS assays were highly sensitive, correctly classified 100% and 98% of the samples respectively. Roche DBS assay was only able to identify 53% of the VF samples correctly. For samples with plasma VL>1000 copies/ml there were upward misclassification due to further VL>1000 copies/ml identified by WB VL on both Alere q HIV-1/2 (85%) and Abbott DBS VL (21%) when compared to the plasma reference, while Roche DBS VL showed 95% agreement in this category. Receiver operating characteristic analysis revealed that the threshold of log_{10} 4.12, 3.43 and 2.60 copies/ml provided the best overall VL classification for Alere q HIV-1/2 (85%), Abbott DBS VL (94%) and Roche DBS VL (82%) respectively.

**Conclusions:** Variable was noted between the different WB VL assays with difficulties assigning a uniform threshold across all platforms, reflecting the differences in sample treatment/processing (DBS versus fresh blood samples) and sample input volume. The performance at 1000 copies/ml of DBS protocols and point-of-care devices remains significantly varied and further development is required to ensure minimal VF misclassification.
WEPDC0102
The Canadian perinatal HIV surveillance program (CPHSP): program description and treatment and transmission

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**Background:** The Canadian Perinatal HIV Surveillance Program (CPHSP) is an active surveillance program generating national data on all HIV+ women and their infants in Canada since 1980. We describe the CPHSP’s evolving methodology and analyze mother-infant pair (MIP) demographics, antiretroviral treatment and vertical transmission (VT) rates in Canada from 1990-2013.

**Methods:** MIPs are identified at 22 centers following obstetric or pediatric referral for care. Data is entered via a secure web-based Oracle database, which is managed and analysed by the CHSRF-Canadian HIV Trials Network. A nationally representative steering committee provides direction and oversight. Data collected include maternal characteristics, antiretroviral therapy (ART) and infant outcome. VT rates are based on data of MIP delivered in Canada and identified within 3 months after birth; infants identified beyond 3 months of birth are tracked separately.

**Results:** Among 2914 MIP from the combination ART (cART) era (1997-2013), the overall VT rate was 2.1% but only 7% in MIP receiving cART and 0.1% in women receiving >4 week of cART. Of 200 identified HIV+ women giving birth in Canada in 2013, 76% acquired HIV heterosexually, 11% through injection drug use (IDU) and 2% vertically; 53% of mothers were Black and 23% Aboriginal. The proportion untreated steadily decreased from 20.3% in 1997 to 3.0% in 2013. Aboriginal women (7%) continued to represent the largest proportion of untreated women (7%) in 2013, though this decreased from a peak of over 20% during the period 2005-2006. A similar improvement was seen among women, with 3% untreated in 2013. In 2013, seven (3.5%) women had no antenatal cART or suboptimal treatment, the lowest annual number and percentage in the cART era, resulting in two children becoming infected.

**Conclusions:** The CPHSP allows for comprehensive identification of perinatal HIV exposure and outcomes trends in Canada. Ongoing challenges include ensuring all MIPs are captured given Canada’s geographically and demographically diverse population and low HIV prevalence. Despite continued improvement in treatment access for pregnant HIV+ women, VT continues to occur with Aboriginal women being at greater risk of inadequate treatment and VT.

WEPDC0103
HIV acquisition after arrival in France among sub-Saharan African migrants living with HIV in Paris area. Estimations from the ANRS PARCOURS study

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**Background:** HIV acquisition among sub-Saharan migrants living in Europe has long been considered to predominantly occur before migration because of generalized HIV epidemics in sub-Saharan African countries. Recent evidence suggests that a substantial proportion have acquired HIV while they were living in Europe. In the UK, this proportion was recently estimated at 31% using a CD4-based modelling approach. Such an estimate is not currently available for France.

**Methods:** We estimated the proportion of sub-Saharan migrants who acquired HIV infection after their arrival in France using life-event and clinical information on a random sample of HIV-infected hospital outpatients born in sub-Saharan Africa in Paris region. We assumed that HIV infection had probably been acquired in France if at least one of the following life-event criterion was fulfilled: i) HIV diagnosis >10 years after arrival in France, ii) >1 negative HIV test in France, iii) sexual debut after arrival in France. If none of these criteria was fulfilled, we estimated the duration from HIV infection based on first CD4 count measurement using statistical modelling. Infection was assigned in France if, out of 500 durations estimated for each individual, >50% (median scenario) or >95% (conservative scenario) fell within the period while individuals were living in France.

**Results:** Of the 888 HIV-infected adults born in sub-Saharan Africa included in the analysis, we estimated that 49% [95% confidence interval: 45-53] in the median scenario and 35% [31-39] in the conservative scenario acquired HIV while living in France. This proportion was lower for women than men (30% [25-35] versus 44% [37-51] in the conservative scenario) and increased with duration in France.

**Conclusions:** The proportion of sub-Saharan African migrants having acquired HIV infection while living in France is high, highlighting the need for improved focused HIV prevention. This requires a better understanding of the determinants of HIV infection in France in this population.
Evidence of local HIV transmission in the African community of King County, Washington

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Background: In many parts of the U.S., immigrants from sub-Saharan Africa comprise a large proportion of heterosexual HIV cases. However, little is known about the frequency of ongoing HIV transmission within these communities.

Methods: Public Health–Seattle and King County staff routinely interview patients newly reported with HIV infection, and attempt to contact sex partners to ensure notification and HIV testing. We describe the characteristics, testing history, and partner outcomes for African-born persons newly reported with HIV infection in King County (KC), WA from 1/1/2010-12/31/2013. Additionally, we reconstructed an HIV-1 pol phylogeny for 1430 cases diagnosed in KC 2008-2014, with 100 sequences each from Kenya and Ethiopia added for African references.

Results: During the study period, 1,148 adults were reported with HIV in KC, including 101 (8.8%) born in Africa. Of 63 cases in African-born individuals with new HIV diagnoses, 49 (77.8%) were interviewed for partner services. Seven reported being diagnosed with HIV-infection before U.S. arrival and were excluded from further analysis, leaving 42 individuals. Median time from U.S. arrival to HIV diagnosis was 7.0 years (range: 8 days-26.7 years). Most were born in East African countries (N=34, 81.0%). Twenty-seven (64.3%) were women; mean age was 42.6 years (range: 24.9-62.2).

Sixteen (38.1%) cases reported at least one negative test prior to HIV diagnosis, and 11 (31.4%) reported ≥1 negative HIV test after U.S. arrival. Pol genotypes were available for 7 of these 11 cases; for 6 of these 7, a local case was the nearest phylogenetic neighbor, and 2 were infected with subtype B virus. This suggests local transmission sources for these 6 cases. The 42 newly diagnosed individuals identified 47 partners; 6 (12.8%) partners had been diagnosed with HIV infection prior to further analysis, leaving 42 individuals.

Conclusions: We found substantial evidence of ongoing HIV transmission in the African community of KC. Additional efforts are needed to increase HIV testing and prevention among African immigrants in the U.S.

Heterogeneity of the HIV epidemic in rural Africa: findings from a geospatially informed study of HIV epidemiology in fishing, trading, and agrarian communities in Rakai, Uganda

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Background: National and district level HIV prevalence rates may obscure substantial variation of HIV disease burden at the community level. Understanding the extent to which HIV differs across communities and the drivers of disparities and similarities within individual districts may offer opportunities for a more effective, targeted HIV response.

Methods: HIV prevalence and risk behaviors were assessed among 17,109 individuals (53.8% female vs. 46.2% male) in 40 communities in Rakai District, Uganda between August 2011 and October 2013 through the population-based Rakai Community Cohort Study. Communities were classified as lakeside fish landing sites (n=44), agrarian (n=27), or trading communities (n=9) based upon occupation analysis. HIV prevalence was geospatially mapped using Bayesian methods and variability across and within community classifications was characterized. Differences in risk behaviors between communities were assessed using modified Poisson regression models.

Results: There was large variation in HIV prevalence, ranging from 9% to 43%, across communities (see Figure below). Fish landing sites had a mean HIV prevalence of 41% (range: 37-43%). Mean HIV prevalence in trading communities was 17% with substantial variability (range: 11-22%) and 14% in agrarian communities, also with substantial variability (range: 9-26%). Agrarian and trading communities in close proximity (<18 km) to fishing landing sites had HIV prevalence ranging from 11% to 26%. Overall, HIV prevalence was higher among women than men (p=0.01), and the disparity was greatest in the fish landing sites (49% vs. 34%). The proportion of males and females reporting ≥4 sex partners in the last year was 6.4 (95% CI: 4.1-11.0) and 3.2 (95% CI: 2.7-3.8) times higher in fishing communities than in the agrarian/trading population, respectively. Levels of consistent condom use with non-marital partners were significantly lower in the fish landing sites (RR=0.80, 95% CI: 0.09-0.94).

Cost-effectiveness of implementing CRAG-LFA screening for cryptococcal meningitis among people living with HIV in Uganda

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Background: Cryptococcal meningitis (CM) constitutes a significant source of morbidity and mortality in resource-limited regions. One million cases occur annually, representing 10-30% of HIV-related death in prevalent regions. Optimal interventions for CM prevention remain unclear. The recently developed serum cryptococcal antigen lateral-flow assay (CRAG-LFA) is highly sensitive and specific, and may allow early detection of subclinical cryptococcosis in those at risk of developing CM. We sought to determine the cost-effectiveness of implementing CRAG-LFA screening for people living with HIV in Uganda compared to other interventions for CM prevention.

Methods: A decision-tree model was constructed to compare three strategies for cryptococcal prevention among people living with HIV (PLWH) with CD4< 100: Standard of care (SOC, i.e. no cryptococcal screening), CRAG-LFA screening followed by evaluation and treatment of cryptococcosis, or universal primary prophylaxis (UPP) with fluconazole for all patients and no CRAG-LFA screening. Primary outcomes were expected costs, DALY’s, and incremental cost-effectiveness ratios (ICERs). In sensitivity analysis we analyzed the impact of costs, prevalence, and alternative clinical algorithms on the cost-effectiveness of CRAG-LFA screening.

Results: CRAG-LFA screening was associated with an ICER of $5.88 per DALY averted compared to SOC, and was highly cost-effective at current willingness to pay thresholds for Uganda. CRAG-LFA screening dominated the UPP intervention (i.e. both cheaper and more effective). Overall, implementation of CRAG-LFA screening was projected to cost $1.46 more per person than SOC, and could reduce the relative risk of cryptococcal-associated mortality by over 42%. When including the cost of lifetime ART, the ICER for CRAG-LFA screening was $557 compared to SOC and still considered cost-effective. In sensitivity analysis, prevalence of baseline CM and cost of the CRAG-LFA influenced cost-effectiveness. In probabilistic sensitivity analysis, the CRAG-LFA screening intervention was cost-effective in 100% of simulations, and cost-saving in 35% of simulations.

Conclusions: CRAG-LFA screening is extremely cost-effective with the potential to prevent significant morbidity and mortality from CM in vulnerable populations, and represents excellent value for money as a screening intervention for HIV programs in Uganda.
**WEPPD0102**  
Lost opportunities to identify and treat HIV-infected patients: results from a comprehensive study of provider-initiated HIV testing and counseling (PITC) in Malawi

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**Background:** Early diagnosis and treatment of HIV improves patient outcomes and minimizes risk of transmission. Provider-initiated testing and counseling (PITC) is an effective case-finding strategy, but implementation models vary. Malawi Ministry of Health (MOH) guidelines recommend routine opt-out PITC, in line with WHO recommendations for countries with generalized epidemics, but little is known about its implementation. Our objective was to assess PITC implementation in Malawi.

**Methods:** We conducted a cross-sectional study of PITC implementation at 118 clinics and wards within 12 MOH facilities in central Malawi during June-July 2014. Quantitative data describing patient visits and HIV tests recorded during 2013 was abstracted from MOH HIV testing reports. Only 7.7% (86,657/1,102,802) of patient visits in 2013 included an HIV test. Subgroup analysis of TB and antenatal clinics with available data demonstrated that HIV status was ascertained in 94.3% (5,203,615) and 86.8% (26,831,061) of patients, respectively. Providers most commonly cited test kit shortages (71/71 providers), inadequate physical space (58/71), and inadequate number of HIV counselors (32/71) as challenges in PITC implementation. Providers from inpatient units cited the inability to test on weekends (7/11 providers), inadequate physical space (58/71), and inadequate number of HIV counselors (32/71) as challenges in PITC implementation. Providers from inpatient units cited the inability to test on weekends (7/11 providers), inadequate physical space (58/71), and inadequate number of HIV counselors (32/71) as challenges in PITC implementation.

**Results:** Variable models of PITC were reported across facilities and departments (Table 1). Overall, symptom-based PITC was most commonly reported. Only antenatal and maternity (20/24) departments reported implementing routine opt-out testing. Use of a PITC register varied significantly according to department type.

**Conclusions:** Various models of PITC concurrently exist at MOH facilities in Malawi. Only antenatal and maternity clinics demonstrated high rates of routine opt-out PITC. The low ratio of facility visits that included an HIV test suggest missed opportunities for HIV testing. However, the high proportion of patients at TB and antenatal clinics with known HIV status suggests routine opt-out PITC. Various models of PITC concurrently exist at MOH facilities in Malawi. Only antenatal and maternity clinics demonstrated high rates of routine opt-out PITC. The low ratio of facility visits that included an HIV test suggest missed opportunities for HIV testing. However, the high proportion of patients at TB and antenatal clinics with known HIV status suggests routine opt-out PITC.
WEPPD0103 Evaluation of HIV PIMA™ CD4 point-of-care test operation by trained non-health workers in rural health centers in Chiradzulu District, Malawi


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Background: CD4 count is essential to identify antiretroviral treatment (ART) eligibility. For over a decade, Medecins Sans Frontieres and the Ministry of Health provide ART in 10 rural health centers (HCs) in Chiradzulu District, Malawi. From June 2013, Alem’s PIMA™ CD4 point-of-care (POC) test is being implemented in the HCs. Shortage of health-care and laboratory staff is an issue in this setting. We assessed task-shifting of PIMA CD4 test operation to non-health workers living in the community around the HCs.

Methods: Four non-health workers received a one-week structured training on PIMA CD4 POC operation. Between June 2014 and January 2015, 351 venous blood samples of pre-ART and ART patients attending routine CD4 testing in 2 rural HCs were included. Each sample was assessed on site with PIMA by a lab technician (LT) and a trained community worker (TCW), and measured with PartecCyflow® counter at district hospital. Kappa-coefficient and percent agreement for CD4-classification below and above relevant thresholds were obtained. Bias and limits of agreement (LOA) were assessed for absolute CD4 counts. PIMA error-rates and failed runs (2 consecutive errors) were recorded and TCW-operator acceptability assessed.

Results: Three-hundred-twenty-eight venous blood samples (83% ART-patients, 68.5% female) were included. Median CD4 count (LT PIMA) was 425 cells/µl (IQR: 323, 570). Error rates were low (LT: 1.2% vs TCW: 2.4%, p<0.04) and no failed runs occurred. Good agreement was achieved for PIMA results by LTs vs TCWs for CD4 threshold 350 cells/µl (91.7% (CI95%: 87.5-95.0), kappa=0.80). The mean bias (TCW-PIMA minus LT-PIMA) was low (-2.2 cells/µl (LOA: 13.7–141.9). Bias and LOA comparing PIMA results by LTs or CTW versus Partec was similar (LT-PIMA minus Partec: -26.4 cells/µl (95.9–188.8)), (TCW-PIMA minus Partec: -3.4 cells/µl (118.0–210.0)). TCWs rated PIMA operation as very easy.

Conclusions: Adequately trained community workers delivered CD4 results equivalent to lab technicians with PIMA POC in health center laboratories. Task shifting of simplified CD4 POC-technologies to trained non-health care staff can serve as a key strategy to ensure sustainable provision of CD4-testing in support of ART-introduction in rural facilities.

WEPPD0104 Improving dried blood spot (DBS) transport logistics for early infant diagnosis (EID) in Nigeria: the SPEEID model

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Background: Who recommends that all children exposed to HIV be tested within 4 to 6 weeks of birth to ensure that all infected infants are identified and initiated on treatment early. One major challenge with EID of HIV in Nigeria remains the absence of standardized logistic sample transfer systems, resulting in long turnaround times between date of sample collection and date of return of result to the mother. To address this challenge, the USAID-funded ProACT project implemented by MSH, pioneered the “Strengthening the Process and Efficiencies for dried blood sample (Dbs) transport, which remains one of the major challenges affecting EID of HIV in Nigeria.

Methods: We carried out a retrospective analysis of logistic data from 177 samples transferred from 28 PMCT sites using the SPEEID model over a 12 month period from March 2013 to February 2014 in Kwara State, North-Central Nigeria.

Results: A review of the data showed a reduction in turnaround time for return of results from 3-6 months to 3-4 weeks utilizing the SPEEID model. Results were received for 97% of samples (171/177) transported with this model, compared to 51% previously. The average cost of sample transfer was estimated at between $20-$40 per batch and remains comparatively less expensive to other models by at least 30%.

Conclusions: The MSH SPEEID model remains an indigenous, cost effective, sustainable, and time sensitive sample transfer model which ensures that exposed infants are able to receive their EID test results quickly. This approach may be easily replicated by other partners working in similar resource limited settings, as it provides a practical solution for DBS sample transfer, which remains one of the major challenges affecting EID of HIV in Nigeria.

WEPPD0105 Trends in early infant HIV diagnosis and treatment (EIDT) services in rural South-West Uganda (2011-2014)

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Background: In Uganda, 39% of HIV exposed infants (HEI) were HIV tested within 2 months and less than 30% of children accessed to ARVs (UNAIDS, 2014) which reveal challenges to reach to EIDT services. Through implementation of Strengthening TB and HIV/AIDS response in Uganda Southwestern Region (STAR-SW) project, EGPFA provides support to districts and sites to strengthen and increase access to EIDT services. This includes training and mentoring site-based health care workers (nurses, clinicians) on proper utilization of EID guidelines (counseling and testing manuals, treatment protocols), optimizing patient care flow, expanding points of care, strengthening laboratory capacity, utilization of EIDT clinical registers and reporting, and conducting regular data reviews for continuous improvement. This report describes trends of accessing EIDT services under this project.

Methods: Using HIV program data from the Uganda Health System for January 2011 to June 2014, we conducted an EIDT analysis covering all 192 supported sites. Indicators analyzed were number of HIV-positive pregnant women identified during antenatal care, HIV-positive mothers delivered at health institutions, HEI received ARV at birth, exposed infants tested for HIV within two months after birth. ARV uptake and HIV testing coverage were estimated by dividing number of HEI received ARVs at birth and who were tested within two months between HIV-positive pregnant women in ANC, respectively. Descriptive and trends analysis were conducted.

Results: By January 2011, HEI testing coverage was 17.8%, which increased to 47.5% in December 2012. With the rollout of the Option B+ in early 2013, HEI testing continued to increase and reached around 63% in mid-2014 (trend R²=0.8147). Simultaneously, HEI receiving ARVs at maternity progressively increased over time from 17% (312/1,799) in January 2011 to 32% at the end of 2012, peaking at 48% (8662/20,266) in June 2014.

Conclusions: HIV testing and ARV uptake for HEI have progressively improved in STAR-SW catchment area. The various site level of support provided by EGPAF seems to have contributed to these results. EGPAF will continue supporting the national and district health systems in further expansion of EIDT services as well as on further analysis of disaggregated data, informing quality improvement interventions, and planning additional operational research studies.
Background: HIV-IgM antibody is detectable within 2 weeks following infection and is therefore an important immunoassay target for early HIV antibody detection. The objective of this study is to determine if the proven early HIV antibody sensitivity of the 60 second INSTI HIV-1/HIV-2 Antibody test, is due to its ability to detect HIV-IgM antibodies.

Methods: The INSTI HIV-1 gp41 recombinant antigen was applied to a HIV-IgM ELISA to demonstrate its ability to capture HIV gp41 IgM antibody. This HIV-IgM ELISA assay was run on 6 commercial early seroconversion samples, known to be HIV-IgM positive, and 5 long term HIV positive serum samples. A separate experiment to demonstrate that the dye-labelled recombinant Protein-A-based colour developer (CD) used in the INSTI assay has affinity to human IgM was conducted. 0.5µg of purified human immunoglobulins (IgM, IgD, IgA, IgE, and IgG) were blotted onto nitrocellulose (NC) and probed with the CD to observe for spot development. Finally, to determine if INSTI performance is affected by IgM removal, IgM was removed by human anti-IgM MicroBeads on 21 early seroconversion samples with known or undetermined levels of HIV-IgM and with 5 samples from long term HIV-positive samples. INSTI results were observed for reduced test spot intensity following IgM removal.

Results: The gp41-based HIV-IgM ELISA was positive for the 6 early seroconversion samples that were known INSTI and HIV-IgM positive, and negative for the 5 long-term HIV positive samples indicating the assay signal was due to HIV-IgM capture by the immobilised gp41 antigen. The dye-labelled recombinant Protein-A used in the INSTI colour developer produced distinct spots for purified IgM, IgA, and IgG blotted on the NC membrane. Following IgM removal from 21 seroconversion samples with known or undetermined HIV-IgM levels, 10/21 samples became INSTI HIV negative from INSTI HIV positive. In 10/21 samples test spot intensity was reduced by >50% and 1/21 samples slightly <50%, while the 5 long term HIV positive samples showed no reduction (Table 1).

Conclusions: The INSTI HIV-1/HIV-2 Antibody Test is shown to detect HIV gp41 specific IgM antibodies in early HIV infection which enhances its utility in early HIV infection.
Wednesday 22 July
Poster Exhibition

Entry (attachment, receptors and co-receptors, penetration and tropism)

**WEPEA100**

**CXCR4 tropic HIV-1 is a cause of but not a result of CD4+ T cell count depression**

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**Methods:** We enrolled 6 patients, who are hemophiliacs, were infected with HIV-1 at early 1980s, and were antiretroviral therapy (ART) naive over 20 years. We checked viral sequences (340 bp) around V3 region of HIV-1 env using GS Junior and analyzed the data using Amplicon Variant Analyzer. Virotropisms were predicted by geno2pheno [coreceptor]. 2.5 with cutoff value at false positive ratio (FPR) <5 %. Initially we checked viral sequences of 6 patients at ART naive and latest samples. If X4 virus was found, we then checked viral sequences of previous samples to determine when X4 virus appeared. Phylogenetic analysis was conducted by Genetyx software with neighboring method.

**Results:** X4 viruses were found in 2 patients at the samples of just before starting ART (CD4 counts were 88 and 44 (µL)]. Other 4 patients did not have X4 virus (CD4 counts were 289, 234, 545, and 363 (µL)]. The earliest samples containing X4 viruses were, respectively, at 16 months ago (CD4 count was 619 (µL). Population of X4 viruses was 0.9 %. Lowest FPR was 1.7 %, and at 34 months ago (CD4 count was 221 (µL). Population of X4 viruses was 75.5 %. Lowest FPR was 0.5 %) from their ART start. After X4 virus appeared, decrease speeds of CD4 count became faster (403 and -67 CD4 count (µL/year) than before (-23.2 and -16.4 CD4 count) (µL/year). Phylogenetic analysis showed that viruses made clearly different clusters in 6 each patient. X4 viruses formed subclusters in the clusters of 2 each patient.

**Conclusions:** X4 viruses emerged while CD4 counts were still high, followed by rapid CD4 count decrease. It suggests X4 virus is a cause of but not a result of CD4 count depression. Phylogenetic analysis shows these X4 viruses emerged by evolution, not by superinfection.

**WEPEA101**

**Deciphering the interactions between the V1V2 domain of the HIV-1 envelope protein gp120 and α4β7 integrin of the host cell**

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**Background:** Data from the landmark RV144 HIV-1 vaccine trial indicated that antibodies directed to the V1V2 region of the envelope protein, gp120, provided modest protection against HIV infection. The V1V2 region has been reported to interact with integrin α4β7, which may serve as a co-receptor for HIV. Some studies have demonstrated that HIV-1 antibodies are protective against pseudoviruses and block V1V2 binding to α4β7. Yet, other studies showed that this interaction is not essential for HIV-1 infection. To date, the specificity of V1V2-α4β7 interaction, which residues are involved, and the role the interactions play in HIV-1 entry, remains unresolved.

**Methods:** We have constructed a variety of recombinant proteins containing the V1V2 domain from several HIV-1 clades. These include: V1V2 scaffolded to the bacteriophage T4 proteins, Soc (small outer capsid protein), or the 12-mer small terminase protein, gp16, and HIV-1 envelope proteins and trimers. We have also developed a sensitive cell-binding assay using α4β7-expressing RPMI 8866 B cells, which lack the CD4 receptor. A series of purified HIV-1 envelope protomers and trimers. We have also developed a sensitive cell-binding assay proteins, Soc (small outer capsid protein), or the 12-mer small terminase protein, gp16, and using α4β7-expressing RPMI 8866 B cells. However, the specificity determinant appears to be located in the V1 region. Further mutational analysis revealed specific glycosylation patterns within the V1 region that are important for binding. These results led us to propose a potential new α4β7 binding site in the V1 loop of the HIV-1 envelope protein gp120, which may have important implications in the design of V1V2-based HIV-1 vaccines.

**WEPEA102**

**Reverse transcription and integration**

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**Methods:** When treated with the new integrate inhibitor (INI) dolutegravir (DTG), patients previously treated with older INIs have lower response rates than other patient populations but are unable to develop the DTG resistance mutation R263K. We investigated whether the presence of INI resistance mutations affects the emergence of R263K.

**Results:** When treated with the new integrate inhibitor (INI) dolutegravir (DTG), patients previously treated with older INIs have lower response rates than other patient populations but are unable to develop the DTG resistance mutation R263K. We investigated whether the presence of INI resistance mutations affects the emergence of R263K.

**Conclusions:** The combination of INI resistance mutations with R263K does not usually lead to increased fitness or drug resistance. The combination of N155H and R263K, however, does represent a possible mechanism through which resistance may develop. This combination was recently identified in a patient failing an older INI, and the N155H pathway is increasingly being associated with DTG failure in the clinic. In accordance with this, we have also shown that select secondary mutations common to N155H also have a compensatory effect in the N155H/R263K background, and found that T97A, E152Q, and G163R were each able to enhance INB [coreceptor] enzyme performance biochemically.

**WEPEA103**

**Use of amplification refractory mutation system PCR assay as a simple and cost-effective tool to detect HIV-1 drug resistance mutations**

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**Methods:** The main obstacle to successful antiretroviral therapy (ART) is the emergence and transmission of HIV drug resistance mutations; resistance testing is established by sequencing but its feasibility is limited in resource-constrained settings by high cost, suggesting the need for a sensitive, cost effective, and simplified method to identify HIV-1 drug resistance (HIVDR) mutations. In this study, the Amplification Refractory Mutation System (ARMS)-PCR, a point mutation assay, was developed and used to investigate the most frequent HIVDR mutations affecting first line ART.

**Background:** The need for a sensitive, cost effective, and simplified method to identify HIV-1 drug resistance (HIVDR) mutations. In this study, the Amplification Refractory Mutation System (ARMS)-PCR, a point mutation assay, was developed and used to investigate the most frequent HIVDR mutations affecting first line ART.
WEPEA104
Identification of HIV aberrant strains in Cameroon

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Background: The identification of many HIV recombinants forms in Cameroon, coupled with the fact that HIV-1 Group O, N and P were first identified in this region, makes HIV landscape in this region complicated. Therefore this country is likely to harbor aberrant and rare HIV variants.

Methods: Blood specimens were collected from 1,881 persons in 4 regions of Cameroon during HIV voluntary counseling and testing sessions. Samples were screened with HIV rapid tests (Determine HIV1/2, Hexagon HIV1/2) onsite and HIV infected patients were referred to HIV treatment and care centers. Non-reactive samples to HIV rapid testing were then tested with 15 synthetic peptides derived from the consensus sequences of V3 loop of different HIV and SIV strains to identify aberrant HIV strains circulating in Cameroon. The 15 peptides used included HIV-1: group F2, Ncon, Ocon, Obe, Oem, PFR, PCM, CRF02_AGcm, SIV: CPZus, CPZcam3, CPZus, CPZag1, CPZcm2, G0rmf, G0pft, G0pft.

Results: Out of 1,881 persons screened on the field with rapid tests, 114 samples were reactive giving a HIV prevalence of 6.1%. Out of 950a for screen positive V3 peptide ELISA, 25 were reactive (OCD0>5.50) at least one of the 15 peptides tested. Most of the samples reacted to CRF02_AG and 2 peptides with 1.9% and 0.9%, respectively; followed by CPZant with 0.3%, 0.19% of samples reacted to CPZcm2, ConP, CPZus, CPZag1, CPZcm2, ConO and ConN. No sample reacted to ConO or G0pft. G0pft, G0rmf, Pcm, Obe and ConO. Samples that reacted to at least one of the HIV/SIV V3 peptides will further be tested by PCR using specific primers. Positive samples to PCR will be used in characterizing genetic subtype of the virus infecting the study subjects and identify aberrant HIV-1 strains.

Conclusions: Our preliminary results indicate the possible circulation of aberrant HIV strains in Cameroon and the inability of current available HIV diagnostic tests to efficiently identify all HIV infected persons. Thedentification and characterization of these aberrant HIV variants will lead to the improvement of diagnostic methods, treatment strategies and more importantly set the stage for an efficient HIV vaccines since.

WEPEA105
Withdrawal of dolutegravir in early phases of HIV-1 infection in tissue culture does not abrogate antiretroviral activity

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Background: Dolutegravir (DTG) has shown greater efficacy than Raltegravir (RAL) in suppressing HIV-1 replication in treatment-experienced individuals. Biochemical experiments studying the dissociative half-lives of these Integrate (IN) Strand-Transfer Inhibitors (INSTIs)

Methods: Samples from 75 HIV-1 infected patients (33 ART-naïve and 42 on ART) living in Cameroon were used to assess the performance of ARMS-PCR assay in its ability to detect M184V, T215Y/F, K103N, and Y181C mutations. For comparison, sequencing of HIV-1 reverse transcriptionase was mutanously performed and discordant samples were tested with Trugen HIV-1 genotyping kit, a FDA-approved genotyping assay.

Results: ARMS-PCR assay was able to detect M184V, T215Y/F, K103N, and Y181C mutations with sensitivity of 96.8%, 85.7%, 91.3%, and 70%, respectively, and specificity of 90.6%, 95%, 100%, and 96.6%, respectively, when compared with sequencing data. The results indicated the highest positive predictive value for K103N (100%) and the highest negative predictive value for M184V (97.5%). Moreover this assay was able to correctly detect the different HIV-DR mutations present in a subject molecular clone obtained from NH reagent program. ARMS-PCR efficiently identified mutations in individuals with different HIV-1 clades (CRF02_AG and non-CRF02_AG), different ART and varying HIV-1 viral loads.ARM-PCR (ARMS PCR) assay of detection in serially diluted samples for mutations M184V, T215Y/F, K103N and Y181C: < 75 copies/ml, 143 copies/ml, 143 copies/ml and 36 copies/ml respectively. More so, this assay was more cost-effective than other genotyping assays requiring only $10 to cover reagent cost of one mutation.

Conclusions: The good performance, the cost-effectiveness, and the simplicity of the ARMS-PCR suggest that this assay is a suitable tool to monitor HIVDR patterns. This assay will help improve care and management of HIV-1 infected patients in regions with limited resources and also improve ART programs; Thereby reducing the rate of acquired and transmitted drug resistance. Viral assembly and maturation

WEPEA106
Development of an in vitro assay to assess the function of naturally occurring HIV-1 Vpu sequences without codon optimization

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Background: Vpu is a highly variable HIV-1 accessory protein that facilitates virion release. Codon optimization is often required to enhance Vpu expression in vitro and as a result, little is known regarding the functional diversity of naturally occurring Vpu sequences. We developed an assay to assess Vpu’s two most well-characterized functions - cell-surface tetherin (BST2/CD317) and CD4 downregulation - in non-codon-optimized subtype B and C sequences.

Methods: Vpu sequences from the HIV-1, subtype B and HIV-1, subtype C reference strains were PCR-amplified using forward primers located 100, 50 and 0 bases upstream of the Vpu start site and a reverse primer 57 bases downstream of Vpu’s stop codon, and cloned into the pSELECT-GFP expression vector. Site-directed mutagenesis was used to construct NL4-3 Vpu sequences lacking a native cryptic start/stop motif located 5 bases upstream of Vpu’s start codon. A published codon-optimized Vpu sequence and an empty pSELECT-GFP expression vector were used as positive and negative controls. Vpu constructs were transfected into an immortalized 293T cell line, and tetherin or CD4 downregulation assessed by flow cytometry 20 hours later. The downregulation activity of each Vpu construct was compared to that of codon optimized Vpu.

Results: As expected, codon-optimized Vpu displayed robust downregulation of tetherin and CD4 (8-10 fold and ~10-fold, respectively), which was designated as 100% activity for comparative analyses. In contrast, Vpu clones encoding ~50 or more bases of sequence upstream of the Vpu start site exhibited < 20% ability to downregulate either receptor, regardless of subtype. However, subtype B and C Vpu sequences cloned directly at the Vpu start site exhibited 82% and 77% tetherin downregulation function and 49% CD4 downregulation function for both subtypes. Elimination of the cryptic start/stop motif 5 bases upstream of Vpu in subtype B did not enhance protein function.

Conclusions: Our results indicate that the function of naturally occurring HIV-1 Vpu isoforms can be assessed in vitro without codon optimization by excluding sequence information upstream of the Vpu start site. This finding opens the possibility of functionally assessing patient-derived Vpu clones.
Transcriptional and gene expression regulation (including regulatory genes)

WEPEA107
HIV-1 Rev regulates the expression of Tat and viral replication via modulation of NAD(P)H: quinone oxidoreductase 1 (NQO1)

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Background: HIV-1 encodes two regulatory proteins, Tat and Rev. Tat and Rev increase the steady state levels of all viral transcripts. Rev, on the other hand, increases the stability of singly spliced or unspliced HIV-1 genomic RNA and downregulates levels of Tat, Rev and Nef mRNAs resulting in a switch from early Rev-independent to Rev-dependent gene expression associated with late stages of viral life cycle. The regulatory feedback mechanisms governed by Tat and Rev ensure the delicate balance between early and late infection. HIV-1 proteins are also known to interact with one another to modulate various functions. HIV is reported to degrade the Vpr protein and Nef promotes the degradation of Tat. So, we studied the inter-regulation of two regulatory proteins (Tat and Rev) of HIV-1.

Methods: The expression and LTR transcriptional activity of Tat was studied in presence of HIV-1 Rev in HEK-293T and CHME3 cells. The destabilization of Tat by Rev was studied by cycloheximide chase assay. RT-PCR analysis was also done. MG132 treatment and ubiquitination assay was performed to check translational regulation of Tat by Rev. The expression of Tat was also checked in presence of NLS or NES deletion mutants of Rev to find out the domain of Rev required for regulation of Tat expression. The expression of NQO1 was studied in presence of Rev in HEK-293T cells.

Results: Rev induced specific degradation of Tat protein and downregulation of NAD(P)H: quinone oxidoreductase 1. Tat degradation was not due to transcription but was at the level of translation involving proteasomal machinery. Nuclear export signal (NES) region of Rev was found to be critical for its ability to degrade Tat protein but have no affect on its interaction with Tat suggesting that it is an interaction independent phenomenon involving host proteins. NQO1 is known to stabilize unstructured proteins and might stabilize the expression of Tat. Rev was decreasing the expression of NQO1. Rev mediated downregulation of Tat via NQO1 degradation was observed to take place predominantly in cytoplasm.

Conclusions: HIV-1 Rev decreases Tat levels by downregulating NQO1. Expression of Tat is downregulated during latency. So, these observations are important to understand HIV-1 biology and latency.

WEPEA108
Analysis of in vivo splice site usage by HIV-1 transcripts through deep sequencing: high diversity of spliced RNA expression patterns and identification of new splice sites

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Background: HIV-1 RNAs are generated through a complex splicing mechanism and are classified in 3 major categories: unspliced, singly spliced (SS) and doubly spliced (DS). The complexity of HIV-1 splicing is increased by optional incorporation of noncoding exons and by redundant 3' splice site (3'ss) usage by some RNAs. Knowledge of in vivo HIV-1 splicing patterns is scarce.

Here we analyze in vivo HIV-1 splice site usage through deep sequencing.

Methods: CD4+CD25+ lymphocytes were immunomagnetically separated from peripheral blood mononuclear cells from 19 HIV-1-infected individuals and total RNA was extracted. HIV-1 DS and SS RNAs were amplified separately by RT-PCR in 19 and 12 samples, respectively, using primers recognizing sequences in outer exons common to all RNAs of each category. Deep sequencing was done with 454 GS Junior+ System (Roche). Sequences were identified through alignment with HIV-1 reference sequences generated by all possible combinations of all reported HIV-1 exons, using BWA-MEM. Sequences with ambiguous assignments with BWA-MEM were mapped to the HXB2 genome using Sequence Locator program.

Results: In total, 9,196 and 3,250 sequences derived from HIV-1 DS and SS RNAs, respectively (mean, 484 and 271 per sample), were identified, corresponding to 87 different RNA classes. Mean relative proportions in DS RNAs were nef 70.5%, tat 17.5%, vpr 2.3%, and in SS RNAs, env 75.6%, tat 9%, vpr 15.4%, vif 0%. A great diversity of expression patterns was observed, frequently differing from those reported in vitro infection. Particularly, a substantially greater SS vpr RNA expression than reported was observed in most samples. In 4 samples, 5 unreported 3'ss were identified, 3 used by nef and 2 by rev RNAs. Rev RNAs predominantly used 3'ss A4e in a subtype B sample and A4f in a subtype C sample. RNAs incorporating noncoding exons 2 and/or 3 were predominantly in nef, rev and env RNAs in 52.6%, 35.7%, 7.7% and 42.1% samples, respectively.

Conclusions: We report the first study on in vivo HIV-1 splicing patterns analyzed through deep sequencing. A great diversity of patterns was observed, frequently discordant from those reported in vitro infection, and 5 new HIV-1 splice sites were identified.

Intrinsic cellular defences and restriction factors

WEPEA109
Decreased interferon signature in HIV-1 viremic controllers

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Background: Several host-encoded interferon-inducible antiviral factors suppress HIV-1 replication in a cell-autonomous fashion in vitro. The relevance of these defences to the control of HIV-1 in vivo in humans remains to be elucidated. Recent data from Sander et al. suggest that administration of interferon to monkeys, and hence the modulation of restriction factor expression at different stages of SIV infection dramatically determines disease outcome. We hypothesized that host restriction factors play a role in disease outcome in chronically HIV-1-infected individuals.

Methods: A total of 99 chronic HIV-1-infected individuals were selected from the cohort at the National Institute of Respiratory Diseases in Mexico City and divided into 3 groups: 1) Low viremic (VL < 2,000 copies and CD4 >250), 2) High viremic (VL >10,000 copies and CD4 >250) and 3) Advanced infection (VL >10,000 copies and CD4 < 250). Twenty HIV-1-uninfected individuals from the same ethnic background were used as a control group. CD4+ T cells were enriched from whole PBMC and the expression of 42 established anti-HIV-1 genes was determined by quantitative real-time PCR.

Results: We consistently detected an overexpression of restriction factors and ISGs in individuals with advanced disease, followed by high viremic individuals (<p 0.0001, Kruskal-Wallis Test). Low viremic individuals had the lowest expression, even compared to uninfected. The expression of IFITM1, RT1F, TRIM22, RASD2/2/3, and TNF111 significantly correlated with VL in viremic individuals with advanced infection (p<0.03, p> 0.05). Finally, we performed 4-digit HLA typing and found unconventional HLA-B haplotypes to be associated with either control (B*3902) or risk (B*3905) of HIV-1 disease and restriction factor expression profile.

Conclusions: In conclusion, we show evidence for the existence of novel mechanisms associated with protection or risk of HIV disease progression in a previously uncharacterized population with unique immunogenetic characteristics.

WEPEA110
Differential effects of cell-surface CD4 and tetherin on ADCC mediated by non-neutralizing and broadly neutralizing anti-HIV antibodies: the role of Nef and Vpu

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Background: The advent of monoclonal antibodies capable of broadly neutralizing HIV variants and recent demonstrations in humanized mice of how some of these antibodies can impact latent virus reservoirs in a Fo domain-dependent manner have rejuvenated interests in the area of humoral/immune immunity for HIV cure. HIV accessory proteins Nef and Vpu have been shown to promote escape from ADCC that is mediated by non-neutralizing antibodies by down-regulating CD4 and BST2/Tetherin. Indeed, the HIV receptor CD4 is down-modulated by both proteins, while BST2, which retains progeny virions at the cell surface, is down-regulated by Vpu. In doing so, the virus ensures that ADCC-mediated epitopes, including those transitonally exposed upon CD4-Env interactions, remain unmasked. Here, we:

1) delineated mechanistically the relative contributions of CD4 and BST2 to ADCC;
2) ascertained whether this mode of immune evasion is relevant to broadly neutralizing antibodies; and
3) assessed whether latently infected T cells, upon reactivation, are susceptible to ADCC.
WEPEA111
PKR as a restriction factor during HIV-1 infection counteracted by virus-induced cellular mechanisms

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Background: Several cellular restriction factors control the replication of HIV. Many have their activity controlled by viral proteins, but for several, no viral-encoded counteracting factor has been identified. Several restriction factors are induced by interferon (IFN), showing an interplay between innate and intrinsic immunity. The IFN-induced protein kinase RNA-activated (PKR) represses the expression of several viruses and acts as a potent HIV-1 inhibitor. PKR phosphorylates the α subunit of the translation initiation factor eIF2α and consequently inhibits protein synthesis. We showed that PKR is activated at the beginning of HIV-1 infection in peripheral blood mononuclear cells (PBMCs) followed by a deactivation due, in large part, to cellular mechanisms involving the TAR RNA binding protein (TRBP), the adenosine deaminase PACT in PBMCs of non-infected, HIV-infected naïve patients and HIV-infected treated patients by flow cytometry for Env recognition by anti-HIV Env antibodies and susceptibility to ADCC.

Methods: Primary CD4+ T cells or T cells expressing only CD4, B272, or both were infected with CCR5-tropic wild-type HIV or those deficient of Nef, Vpu or both proteins. Infected T cells were examined by flow cytometry for Env recognition by anti-HIV Env antibodies and susceptibility to ADCC. Non-neutralizing and broadly neutralizing anti-HIV antibodies can mediate efficient ADCC if relevant epitopes are exposed, although CD4 and B272 contribution to this process is markedly different between these two classes of antibodies. Approaches aimed at neutralizing ADCC evasion by HIV Nef and Vpu would be important to the development of more robust anti-HIV responses and effective shock-and-kill strategies against latently infected cells.

WEPEA112
Comparison of gene expression profile between human and macaque dendritic cells infected with virus carrying or not Vpx-loaded particles and assessment of their pathogenic impact

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Background: Dendritic cells (DC) are antigen presenting cells that play a central role in the regulation of the immune response and whose functions depend on their stage of differentiation. Besides, DCs are characterized by a highly restrictive environment to HIV-1 replication. Susceptibility of DC to infection by different lentiviruses is related with the presence of the Vpx protein that overcomes restriction due to SARAH1. Current findings suggest that productive infection of immature-DC (IDC) is detected by sensor proteins that activate interferon-mediated responses that interfere with viral propagation and decrease virulence. However, few data have been provided about mature DC (MDC) infection.

Methods: To get a better insight into the pathogenic consequences of DCs infection we assessed changes in gene expression with a whole genome microarray when IDC or MDC were productively infected using Vpx-loaded HIV-1 particles. Based on microarray data we performed additional studies using qPCR to analyze transregulatory changes provoked by infection of human and macaque IDC and MDC in restrictive (HIV-1) and productive (HIV-1+Vpx, HIV-2 and SIVmac) conditions.

Results: Strong differences in gene expression were found according to DC differentiation and type of infection. Whereas in IDC productive HIV infection strongly induced class-I-interferon-stimulated-genes such induction was not produced in MDC. In contrast a sharp decrease in CXCR3-binding chemokines was observed when MDC were infected with Vpx-loaded particles and this reduction resulted in decreased trans-infection of CD4 lymphocytes and decrease of viral reserves. Similar patterns of gene expression were found when dendritic cells were infected with HIV-2 and SIV that naturally express Vpx from their genomes. Overall these results suggest that, paradoxically, restriction of HIV-1 infection in DCs results in increased virulence through different mechanisms. In IDC, restrictive infection avoids sensing and induction of interferon-mediated responses whereas in MDC the production of CXCR3 binding chemokines is not modified in the absence of productive infection leading to lymphocyte attraction to the immune synapse, enhancement of HIV-1 trans-infection and an increase in viral reserves size.

Conclusions: Our data confirm previous observations and propose new pathogenic mechanisms to understand how restriction of HIV-1 replication in DC favors viral dissemination and increased virulence in infected host.

WEPEA113
A pseudo-glycodendrimer inhibits DC-SIGN-mediated HIV trans-infection and interferes with DC-SIGN signal

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Background: DC-SIGN is involved in the initial stages of mucosal HIV infection. DC-SIGN mediates binding of HIV to CD4+ T cells and interferes with DC-SIGN signal. Binding of HIV to CD4+ T cells on gp120, mediates trans-infection of CD4 T cells. Furthermore HIV interaction with DC-SIGN subverts its normal immune-activating functions shifting the Th1/Th2 balance towards a Th2 response that favours the persistence of the virus. HIV binding to DC-SIGN induces intracellular signalling pathways that trigger activities required to viral replication and promote immunosuppressive responses by interfering with TLR signalling. Pseudo-mannosylated compounds were synthesized in the attempt to compete with the binding of DC-SIGN to HIV gp120 and interfere with the immune-suppressive DC-SIGN signalling.
WEPEA114

Investigation of which NK cell populations expressing or not NKG2A, KIR2DL3 or KIR3DL1 are activated by autologous HIV-infected CD4 T cells

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Background: Carriage of certain NK cell receptor (NKR)/HLA ligand pairs is associated with slow time to AIDS in HIV-1 subjects and protection from infection in HIV-exposed seronegative subjects, implicating NK cells in HIV control. NK cells acquire functional potential through licensing, which requires engagement of inhibitory NKR (NKRIs). NKG2A, KIR2DL3 (2DL3) and KIR3DL1 (3DL1) by their ligands. NKG2A interacts with HLA-E presenting leader peptides from HLA-I proteins, 2DL3 and 3DL1 interact with HLA-C1 and Bw4+ HLA-A/B antigens, respectively. Functional responses of NKG2A+ and 2DL3+ NK cells and the impact of NKG2A, 2DL3 and 3DL1 expression on NK responses to iCD4 cells are currently unknown. Here, we examined the functional profiles of the eight possible NKG2A+/−2DL3+/−3DL1+/− populations responding to autologous HIV infected CD4 (iCD4) cells.

Methods: We studied 20 HIV-negative subjects. Responses to HIV were assessed by co-culture of NK cells with autologous iCD4 cells. Flow cytometry was used to gate on NKG2A+/− 2DL3+/−3DL1+/− populations and detect at possible Boolean combinations of CD107a, IFNγ, and CCL4 functional subunits.

Results: CD4 induced differential frequencies of NKG2A+/−2DL3+/−3DL1+/− populations with total responsiveness, tri-functional, CD107a+IFNγ, IFNγ+CCL4 and IFNγ response profiles (p≤0.02). The frequency of functional responses to iCD4 of NKG2A+/−2DL3+/−3DL1+ populations were higher than that of NKG2A/2DL3+2DL3− NK cells (p≤0.01). Co-expression of 3DL1 on either NKG2A+/−2DL3− or NKG2A+/−2DL3+ NK cells did not modulate their responsiveness to CD4. A lower frequency of NKG2A+/−2DL3− from HLA-C1 than C2/C2 carriers responded to CD4 while NKG2A co-expression eliminated this difference.

Conclusions: These investigations suggest that 3DL1 has a minimal impact on NK cell functionality to CD4. In contrast, 2DL3 has an impact on functionality which is enhanced by NKG2A co-expression. 2DL3+ NK cells from carriers of the ligand for 2DL3 are less responsive to CD4 than those from carriers lacking the 2DL3 ligand (HLA-C2/C2). Co-expression of NKG2A and 2DL3 abolishes the suppression of 2DL3+ NK function in NK cells from HLA-C1 carriers. These data suggest that the NKG2A receptor has an important role in modulating NK cell mediated anti-HIV responses.

WEPEA115

Enhanced capacity of NK-cells from carriers of the protective KIR3DS1 homozygous genotype to inhibit HIV replication in autologous infected CD4 T cells

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Background: In previous studies we identified 2 genotypes encoding Natural Killer (NK) cell receptors with and without their putative HLA ligands that are associated with protection from HIV infection. NK cells from carriers of the Killer Immunoglobulin-like Receptor (KIR) 3DL1 high expression allele genotype with HLA-B*51 (N=15) inhibited HIV replication in autologous HIV infected CD4+ T cells more potently than those from carriers of control genotypes such as HLA-Bw6 homozygotes (N=15). Here we investigated whether carriers of the other protective KIR3DL1/51 genotype, KIR3DS1 (N=15), also have an enhanced capacity to inhibit HIV replication in autologous cells

Methods: 22 HIV+ subjects were studied. 3DS1+ with no alleles encoding the putative HLA-B*51 ligand for this receptor (n=7), 3DS1+I heterozygotes who were ‘BoI positive (n=6) and Bw6+ (Bw6 antigens do not interact with 3DS1 or 3DL1) (n=9). Isolated CD4+ T cells were activated for 4 days and infected at a multiplicity of infection of 0.01 with HIV1. Cytokine production and IFNγ secretion were assessed. NK cells and iCD4 cells were co-cultured for up to 7 days. On days 3, 7 and 10 supernatants were tested for p24 levels. Results were reported as percent inhibition of p24 in the presence versus absence of NK cells.

Results: NK cells from carriers of the 3DS1+ genotype inhibited HIV replication more potently than those from Bw6+ and those from carriers of 3DS1+I. Furthermore, isolated CD4+ T cells were activated for 4 days and infected at a multiplicity of infection of 0.01 with HIV1. Cytokine production and IFNγ secretion were assessed. NK cells and iCD4 cells were co-cultured for up to 7 days. On days 3, 7 and 10 supernatants were tested for p24 levels. Results were reported as percent inhibition of p24 in the presence versus absence of NK cells.

Conclusions: NK cells from subjects positive for the activating 3DS1 receptor and negative for the licensing KIR/HLA 3DL1/51*+80 are able to suppress HIV replication in autologous iCD4 cells. This activity may be a mechanism underlying the association of the 3DS1 genotype with protection from HIV infection.

WEPEA116

DNA methylation analysis of natural killer cells during HIV-1 infection

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Background: In HIV infection, several dysfunctions associated with natural killer (NK) cells have been reported which increase the susceptibility of infected individuals to opportunistic infections. In this way, our aim is to characterize the phenotype and function of NK cells from untreated HIV+1 patients and correlate to epigenetic changes in these cells.

Methods: Control samples were obtained from healthy blood donors (n=20) and HIV-1+1 patients (n=21) from Hospital das Clinicas de Ribeirão Preto. Plasma levels of proinflammatory molecules were determined by Multiplex Platform and ELISA. NK cell frequency was determined by flow cytometry. NK cell was obtained by magnetic separation and its function was evaluated by cytotoxicity assay. Also, cytokines were quantified in the supernatant of the cytotoxicity assay by Multiplex Platform. DNA was purified from NK cells and global DNA methylation was measured by ELISA.

Results: Plasma levels of proinflammatory cytokines were increased in HIV-1 infected individuals with significant increasing of TNF-α (15.43 ± 6.975 pg/mL) and IP-10 (1871 ± 2074 pg/mL). Also, the molecular inflammatory markers CD14s and CD163s were significantly increased. NK cell frequency was decreased in HIV-1 patients (7.973 ± 5.294) compared to control (11.65 ± 6.247). NK cell subpopulations (CD56dimCD16+ and CD56+CD16−) were also decreased in HIV-1 patients. Otherwise, the percentage of the non-functional NK subpopulation (CD56+CD16−) was significantly increased in HIV-1 patients (8.443 ± 0.08). Furthermore, NK cells from HIV-infected patients showed lower percentage of cytotoxicity compared to control group and IFNγ production by NK cells was decreased in the HIV group (0.688 ± 0.7748 pg/mL). The percentage of global DNA methylation of NK cells was similar between the groups, however it was observed higher DNA methylation in NK cells from HIV-1 patients (47.48 ± 20.47) with advanced disease (p>0.05). Finally, the higher percentage of global DNA methylation in HIV-1+1 patients with advanced disease could be correlated to the worst prognostic, remaining to be determined which specific genes are downregulated by this alteration.
MECHANISMS UNDERLYING SYSTEMIC IMMUNE ACTIVATION AND INFLAMMATION

WEPEA1119

HIV-1-infected patients under suppressive cART present with various patterns of persistent immune activation: the ACTIVIH study

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Background: HIV-1 infection induces a global immune activation fuelled by several causes. Immune activation is reduced under combination Antiretroviral Therapy (cART), but usually not abolished. In the ACTIVIH study, we analyzed whether persistent immune activation is qualitatively the same for all successfully treated patients or whether different patterns of immune activation may be identified.

Methods: ACTIVIH is a cross-sectional and observational study. HIV-1 infected adults (>45 years) under cART were included if their CD4 count was over 200 mm3, and their viral load below 50 copies/ml for at least 2 years. We measured in 89 patients 55 cell surface and soluble markers of inflammation, and CD4+ T cell, CD8+ T cell, B cell, NK cell, monocyte, neutrophil, and endothelial activation. We clustered the dataset with two independent hierarchical clustering analyses using respectively correlation and Euclidean distance to measure proximities/distances between markers and patients.

Results: We identified 6 main groups of patients presenting with very different patterns of immune activation that may be clustered in 5 groups of markers (Figure). Using ANOVA results corrected by False Discovery Rate for multiple testing, more than 80% of markers were on compared to control group. Interestingly, we did not observe nitric oxide release in M1 or M2a supernatant after PAMPs stimulation. Further, the CCL3 and IP-10 expression in HIV-1+ plus HAART-derived macrophages was higher than observed in control group. In all the samples, Arg-1 expression was not detected, even under PAMPs stimulation.

Conclusions: HAART protocols exert a differential impact in the profile of cytokines and chemokines released by macrophages after PAMPs stimulation. The evaluation of therapy effectiveness based on macrophage functions may be helpful to understanding the immunologic state of patient and prevent the occurrence of opportunistic infections.
average significantly different for at least one group of patients with regards to the other ones (p < 0.05). Two groups of patients presented with a statistically significant increase in almost all markers of immune activation comparatively to the other groups. By contrast, one group had low levels of immune markers. The four other groups presented with intermediate, specific profiles of immune activation. For example one of these subgroups presented with CD4+ and CD8+ T cell activation, and another one with monocyte and NK cell activation.

Conclusions: Successfully treated patients are not equal in terms of persistent immune activation. These different patterns of immune activation may be the consequence of different causes, and may result in different comorbidities. A better understanding of the links between causes, patterns, and consequences of immune activation might lead to the identification of predictive markers of specific comorbidities, and facilitate an immunosuppressive therapeutic approach tailored to each patients group.

CP and MY contributed equally to the study.

WEPEA120
The different patterns of immune activation in virologic responders are linked to various causal factors

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Background: By measuring 55 cell surface and soluble markers of infiltration, and CD4+ T cell, CD8+ T cell, B cell, NK cell, monocyte, neutrophil, and endothelial activation in 89 patients, we have recently shown in the ACTIV/HIV study that HIV-1-infected adults under combination antiretroviral therapy present with 6 different patterns of immune activation. Immune activation may be fueled by residual viral production, microbial translocation, infections, CD4 lymphopenia, immunosenescence and a deficit in Treg function in this study. In question we wondered whether the diversity of the patterns of immune activation we observed might be the consequence of the diversity of these causes.

Methods: To answer this question, we analyzed in these patients putative causes of their immune activation. To this aim, we quantified markers of causal factors, i.e. their CD4 count and residual viremia, their plasma level of bacterial DNA, their level of CD4+ and CD8+ T cell (CD57+, eventually CD25- and CD7-) and NK cell (CD56+CD16+) senescence, as well as the frequency of their total (CD45RA+) and naive (CD45RA-) T cells. We also determined if they were coinfected with Epstein-Barr virus, cytomegalovirus, and hepatitis A/B/C virus. We looked for significant differences in these markers of causal factors between the different patterns of immune activation using ANOVA for quantitative causes and chi-square test for qualitative ones.

Results: We found no correlation between either residual viremia, microbial translocation, or coinfection and immune activation. By contrast, CD4 count, the frequency of Treg cells, and the senescence of NK and T cells were significantly linked to immune activation. In the joint figure, the level of the markers of each of these causes of immune activation is indicated for each group of patients (the darker the higher). Interestingly, the levels of these markers of causes were highly variable in-between the patients groups.

Conclusions: Our data suggest that the diversity of the patterns of immune activation observed in virologic responders might be the consequence of the diversity of the causes of this activation. A diagnosis of the causes of immune activation in each patient might lead to a specific elodiologic therapy.

CP, PC and MY contributed equally to the study.

WEPEA121
Elevated levels of circulating nucleosomes in HIV-infected women: cause or consequence of chronic immune activation?

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Background: Circulating DNA is present in plasma/serum, mainly complexed with histones as nucleosomes. The detection of nucleosomes is representative of cell death from apoptosis or necrosis. Inflammation induced pyroptosis and activation induced apoptosis is associated with enhanced cell death in HIV infection. We hypothesize; higher circulating nucleosomes levels will be associated with cell death in HIV infected subjects contributing to inflammation/activation.

Methods: We studied 44 individuals from the Women’s Interagency HIV Study (25 HIV+ antiretroviral (ARV) naïve with CD4 >350cell/mm3) and 19 socio-demographically matched HIV negative controls. Immune activation (HLADR+CD38+) and apoptosis (intracellular Caspase-3) markers were assessed in PBMCs using multi-parametric flow-cytometry and inflammation markers [Tumor Necrotic Factor-Receptor- I (TNFR-I), & IL-6] were measured in paired plasma using ELISA. Circulating nucleosomes (c-Nucs) were quantified in plasma using Cell Death Detection Plus-ELISA to detect histone-associated DNA fragments (mono-nucleosomes and oligonucleosomes). Differences between groups were detected using t-test and associations between markers determined by Spearman’s correlation coefficients.

Results: HIV+ve group had mean (SD) CD4 numbers 654 (289) and viral load with mean (SD) 17.036 (30.359) HIV RNA copies/mL. Significant differences were observed between HIV+ve compared to HIV-ve subjects in c-Nucs levels [Mean (SD) 48.242(7.81) vs. 28.37 (25.56) res., p=0.022], TNFR-II [Mean pg/mL (SD) 3392 (1796) vs.1630 (605) resp., p=0.001], CD8 T cell activation [% CD8 HLADR+CD38+ (SD) 9.75 (7.70) vs.2.48 (2.56) resp., p=0.030] and C-T cell Caspase-3 [% (SD) 4.38 (3.74) vs. 2.24 (1.02), p=0.03]. CD4 cells significantly correlated with c-Nucs (r=0.47, r=0.367) and CD8 T cells (p=0.036, r=0.316), programmed to undergo activation induced cell death by apoptosis.

Conclusions: Circulating nucleosomes correlated with activation induced cell death in HIV infected women. Circulating nucleosomes can stimulate the innate and adaptive immune system in HIV infection, keeping it chronically activated.

Mechanisms of T cell depletion and reconstitution

WEPEA122
HIV-infected individuals with suboptimal CD4 restoration despite suppressive antiretroviral therapy exhibit altered CD4+ T cell subsets and escalated both CD4+ and CD8+ T cell exhaustion

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Background: Poor immunological recovery despite virological successful antiretroviral therapy (ART) is partially explained by persistent immune activation, whereas the mechanism for defective immune restoration has not been fully clarified. We conducted T cell subset analysis in HIV-controlled patients with ART.

Methods: Peripheral blood mononuclear cells were isolated from 74 HIV-infected patients under suppressive ART for at least 2 years and analyzed the expression of markers related to activation (IL-7Rα, CD38), senescence (CD57), exhaustion (PD-1, CTLA-4, Tim-3, LAG-3, 2B4), apoptosis (Fas) and thymic function (CD31) on CD4+ and CD8+ T cell subsets. Tregs (CD4+CD25+FoxP3+) and effector T cells (CD4+CD25-CD127−) were also analyzed for their expression of activation, senescence and exhaustion markers. To answer this question, we analyzed the expression of markers for defective immune restoration has not been fully clarified. We conducted T cell subset analysis in HIV-controlled patients with ART.

Methods: Peripheral blood mononuclear cells were isolated from 74 HIV-infected patients under suppressive ART for at least 2 years and analyzed the expression of markers related to activation (IL-7Rα, CD38), senescence (CD57), exhaustion (PD-1, CTLA-4, Tim-3, LAG-3, 2B4), apoptosis (Fas) and thymic function (CD31) on CD4+ and CD8+ T cell subsets. Tregs (CD4+CD25+FoxP3+) and effector T cells (CD4+CD25-CD127−) were also analyzed for their expression of activation, senescence and exhaustion markers. To answer this question, we analyzed the expression of markers for defective immune restoration has not been fully clarified. We conducted T cell subset analysis in HIV-controlled patients with ART.

Results: Twenty-eight patients were classified as IR, and 46 patients as CR. CD4 count at the beginning of ART were lower in IR than CR (126 vs 221/mm3, p=0.0167). The proportion of naive CD4+ T cells was decreased (33.9 ± 41.6%, p=0.0442) and that of EM CD4+ T cells was increased (11.8 vs 8.5%, p=0.0168). Total number of CD8+ T cells was lower (692 vs 856/mm3).
**WEPEA123**

**HIV-1 group M subtypes display differential rates of CD4 T cell decline**

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**Background:** HIV-1, the etiological agent of AIDS, can be categorized into evolutionarily distinct clades. The most prevalent of these clades is Group M (Major) which can be further subdivided into 9 subtypes: A-D, F-H, J and K. The predominant viral subtypes of the epidemic in Sub-Saharan Africa are A, D and C, with subtype C making up more than 50% of global infections alone. Unfortunately, despite their importance in global health, these subtypes are studied far less frequently relative to subtype B, the predominant viral subtype in North America and Europe. This study sought to compare rates of pathogenesis between these understudied subtypes in a natural history cohort.

**Methods:** A cohort of HIV positive Zimbabwean and Ugandan women with known dates of infection with their CD4+ memory T-cell and viral loads monitored every three months post-infection. Subtype was determined via PCR of the viral envelope. All analyses were done using Generalized Estimating Equations (GEES, n=302) and Generalized Linear Models (GLMs, n=68).

**Results:** These data showed distinct patterns of T-cell decline between different HIV subtypes. Infection with a subtype C virus shows a significantly lower rate of cell decline in both total CD4+ cells as well as in CD4+ memory subsets compared to subtypes A and D (p<0.01 and p<0.003 respectively). Additionally, subtype C infections demonstrate a significantly longer time to viral load set point with no difference in total viral load at set point relative to subtypes A and D (p=0.009 and p=0.001 respectively). Finally, acute early viruses (within 3 months of infection) were isolated from this cohort and their viral envelopes were cloned into a reporter system.

**Conclusions:** Our findings suggest that, even under prolonged and fully suppressed ART, subtype C viruses enter at a reduced rate relative to subtypes A and D (p=0.009 and p<0.001 respectively). Finally, acute early viruses (within 3 months of infection) were isolated from this cohort and their viral envelopes were cloned into a reporter system. Captured virions and SF162 strains were captured with 15 nm magnetic nanoparticles (MNPs) coupled to one of several monoclonal antibodies recognizing particular conformations of Env. Captured virions were then stained with fluorescent anti-Env antibodies different from the capture antibody and separated from free antibodies on a magnetic column. A range of antibodies targeting various Env forms were used and their representation on individual viral particles was assessed.

**Results:** We demonstrated a non-uniform distribution of functional and non-functional Env spikes on individual virions, where differential patterns of antibody staining revealed virus populations that were homogeneous or mosaic with respect to functional and various non-functional forms of Env. Also, we identified extra-cellular vesicles (EVs) that carry gp120 and affect HIV infection. The presence of various functional and non-functional Env spikes corresponds to ability of HIV-1 to infect TZM-bl cells and human tissues ex vivo.

**Conclusions:** Flow virometry allowed the evaluation of the distribution of functional and non-functional spikes on individual virions to establish the relationship between the number of variously conformed Env molecules and infectivity of virions. We showed that what we call “HIV suspensions” are mixtures of true viruses carrying gp120 in different conformations, EVs carrying gp120, and intermediates between viruses and EVs, all important for HIV infection. Analysis of individual virions is important for understanding of HIV transmission, pathogenesis and for development of anti-HIV-1 vaccines, which must neutralize all functional spikes irrespective of their viral context.

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**Pathogenesis in gut, lymphoid tissues and bone marrow**

**WEPEA124**

Flow virometry: envelope heterogeneity on individual HIV-1 virions

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**Background:** The ability of HIV to infect depends on the presence of “functional” spikes of envelope spike glycoproteins (Env) of non-covalently linked gp120-gp41 heterodimers. However, other non-functional Env conformations, including uncleaved precursors (gp160), aberrant oligomers, monomers and gp41 stumps devoid of gp120 are also thought to be displayed on virions. The extent to which functional and non-functional forms of Env are co-displayed on individual virions requires development of new techniques to analyze individual virions.

**Methods:** We have developed a new nanoparticle-based technique, “flow virometry”, to probe the confinement of Env on the surface of individual particles using a panel of anti-Env antibodies that discriminate between different conformations of these molecules. HIV-1 virions of Bal and SF162 strains were captured with 15 nm magnetic nanoparticles (MNPs) coupled to one of several monoclonal antibodies recognizing particular conformations of Env. Captured virions were then stained with fluorescent anti-Env antibodies different from the capture antibody and separated from free antibodies on a magnetic column. A range of antibodies targeting various

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**Microbial translocation and microbial dysbiosis**

**WEPEA125**

Serum-derived bovine immunoglobulin (SBI) correlates with levels of microbial translocation (MT) and reduced mucosal damage


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**Background:** SBI is a medical food that improves HIV enteropathy and increases CD4+ T-cell density in diarrheal GALT. These studies sought to identify microbiome correlates of the effect of SBI on HIV enteropathy and MT.

**Methods:** 8 subjects (pts) on suppressive ART with HIV enteropathy received SBI (Entera Health, Arvink, IA) 5 gms/day for 8 weeks (wks) and 5 continued for 48 wks. 16S DNA from the stool were sequenced using Illumina MiSeq Sequencer and processed using the QIIME pipeline. Serum lipoteicoic acid (LTA), from gram-positive cell walls, anti-flagellin IgA (aFlig-A), and I-FABP, released from damaged enterocytes were measured by ELISA. Bacterial 16S rDNA from serum was quantified by qPCR. Median values and nonparametric analysis are reported.

**Results:** There were no treatment effects on LTA and 16S rDNA levels, but I-FABP fell in 4/8 subjects who finished 48 wks of SBI and aFlig-A declined in 6/8 pts (P<0.15). The Bacteroidetes/Firmicutes ratio, which is low in obesity, increased in 6/8 pts from 0.27 to 0.55 (P=0.11). Clostridiales (order) fell in 6/8 from 56.6% to 51.4% (P=0.0003). At the family level, Ruminococcaceae correlated with LTA (P=0.05, P<0.003), and Veillonellaceae with LTA (P=0.0498, IL-7Rα; 58.4 vs 69.8%, P=0.0112). The surface expression of CTLA-4 in T cells was faint but was significantly reduced in the all subsets in CD4+ T cells (11.0 vs 16.8%, P=0.0333) and also tended to be downregulated in Treg subset (14.6 vs 22.6%, P=0.0331).

**Conclusions:** Our findings suggest that, even under prolonged and fully suppressed ART, subtype C viruses enter at a reduced rate relative to subtypes A and D.
WEPEA126

Influence of HIV infection and antiretroviral therapy on the immune status and microbial translocation in HIV-infected children in Vietnam

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Background: The destruction of CD4+ T-cells particularly Th17 subset in the gut-associated lymphoid tissue, intestinal microbial translocation, and chronic systemic immune activation are reported as the main pathogenesis of HIV infection. A few studies on these in children have been reported. This study aimed to investigate the influence of HIV infection and antiretroviral therapy (ART) on the immune status and the microbial translocation in HIV-infected Vietnamese children.

Methods: This was a cross-sectional study carried out in the National Hospital of Pediatrics in Hanoi, Vietnam in May 2012. Blood samples were collected from 60 HIV-infected children [HIV(+), age 2.0-11.0 years, male/female 26/34] and 20 HIV-uninfected children [HIV(-), age 2.0-8.3 years, male/female 8/12], and analyzed immunologically and bacteriologically. ART(+) children [ART(+), ART duration 0.8-5.8 years] and 20 HIV-uninfected children [HIV(-), age 2.0-8.3 years, male/female 26/34]: 31 without ART [ART(-)] and 29 with ART [ART(+)]. The cells were defined as: Th1 (CXCR3+), Th2 (CXCR4+), Th17 (CXCR3+CCR6+), Treg (regulatory T, CD25+CD127low), CD4+ T-cells and Treg cells were counted (cells/µl), Th17 count (cells/µl), Th1 count (cells/µl) and Th2 count (cells/µl) were compared between HIV(+), ART(+) vs ART(-), ART(+), ART duration 0.8-5.8 years, and 20 HIV-uninfected children [HIV(-), age 2.0-8.3 years, male/female 8/12], and analyzed immunologically and bacteriologically. ART(+) children [ART(+), ART duration 0.8-5.8 years] and 20 HIV-uninfected children [HIV(-), age 2.0-8.3 years, male/female 8/12], and analyzed immunologically and bacteriologically. ART(+) children [ART(+), ART duration 0.8-5.8 years] and 20 HIV-uninfected children [HIV(-), age 2.0-8.3 years, male/female 8/12].

Results: Compared with HIV(-) group, ART(+) had significantly lower viral load than ART(-). The decrease of CD4+Th1/Th2/Th17/Treg counts, significantly higher proportions of activated CD8+ cells, CD69+ cells, CD8+ T-cells and the CD8+ counts correlated significantly with the children's age (HIV infection period) in ART(-). Bacterial 16S/23S rRNA was not detected in whole blood samples but the rDNA was detected in plasma of ART(+) (25.8%) and HIV(-) (15%) (p=0.49). In ART(+), the increase of CD4+Th2/Th17/Treg counts correlated significantly with ART duration, but Th17 counts were restored to the Th1 level of HIV(-) after about 1 year of ART; the proportion of activated CD8+ cells and the CD69+ cell counts declined significantly with the ART duration, but CD8+ cell levels in plasma showed no significant change. ART(+) had significantly lower viral load than ART(-).

Conclusions: In children, HIV infection reduced CD4+Th1/Th2/Th17/Treg counts, enhanced CD8+ cell activation and sCD14 level in plasma. ART restored CD4+Th1/Th2/Th17/Treg counts, suppressed CD8+ activation, but showed little influence on sCD14 levels. HIV infection tended to increase microbial translocation but not significantly.

WEPEA127

TLR2 stimulation acts synergistically with acetate stimulation to promote HIV-1 infection of CD4+ T cells

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Abstracts

Background: Following primary infection, HIV-1 breaches the integrity of gut and/or female genital tract mucosal epithelial barrier allowing bacterial translocation. Those anaerobic microorganisms may stimulate CD4+ T-cells through Toll-like receptor (TLR) and the production of short-chain fatty acids. In this study, we investigated the effect of acetate combined, or not, to TLR2 ligation on the susceptibility of T4 cells to HIV-1 infection.

Methods: Primary human resting T4 cells were stimulated for 72h with anti-CD3/CD28 antibodies +/- acetate and Pam3CSK4 (TLR2 ligand). Cells were then infected with the R5 HIV-1-based reporter virus NL4-3-Bal-IRES-HSA for 72h. The effect of acetate +/- Pam3CSK4 stimulations on T4 cells' susceptibility to HIV-1 infection was then analyzed by flow cytometry where the percentage of productively infected T4 cells expressing HSA was evaluated and confirmed by p24 ELISA. The effect of acetate +/- Pam3CSK4 stimulations on cell distribution, proliferation and activation and on the relative susceptibility of CCR5+/- T4 cells to HIV-1 infection were analysed by flow cytometry to explain the correlation between those stimulations and T4 cells' susceptibility to HIV-1 infection.

Results: Acetate and acetate/Pam3CSK4 stimulations increased respectively a 3-fold and a 6-fold increase in the percentage of infected (HSA+) T4 cells compared to controls (n=3). This was reflected on viral p24 production as assessed by ELISA (n=3). However, neither acetate nor acetate/Pam3CSK4 stimulations affected cell distribution (n=3), proliferation (n=4) and the relative susceptibility of CCR5+/- T4 cells to HIV-1 infection (n=3). Most importantly, acetate and acetate/Pam3CSK4 stimulations increase cell activation as reflected by a significant increase in CD69 and CD154 cell surface expression.

Conclusions: We suggest that acetate stimulation plays a significant role in early HIV-1 infection by increasing cell activation. We also propose that this augmentation of T4 cells' susceptibility to HIV-1 infection induced by acetate stimulation may be synergistically enhanced by TLR2 ligation. These results highlight the possible importance of early interactions between HIV-1 and female genital tract mucosal microbiota where bacteria act via the production of short-chain fatty acids and/or their pathogen-associated molecular patterns.
Mechanisms underlying immune reconstitution inflammatory syndrome (IRIS)

**WEPEA128**

Ethnicity impacts inflammatory and coagulation profile in HIV patients

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**Background:** Biomarkers of inflammation and coagulation are independent predictors of morbidity and mortality in HIV infected patients. Multiple studies have investigated biomarkers in HIV study cohorts, however whether ethnicity or country has an effect on those biomarkers is unknown. We aimed to investigate the influence of ethnicity/country on biomarker levels in similar HIV infected patients at similar stages of HIV infection.

**Methods:** Cryopreserved baseline plasma specimens were analyzed using ELISAs, electrochemiluminescence, and enzyme-linked immunofluorescence assay from two hundred sixty seven ART naive patients with CD4 < 100 cells/ul, participating in the CADIRIS trial from clinical sites in Mexico (N = 124) and South Africa (N = 128). Sparse canonical correlation was performed to demonstrate the distribution of biomarkers between the two countries (Figure 1A). Median levels of biomarkers from each site were compared with Wilcoxon rank-sum test, and then these variables were subsequently adjusted using multivariate analysis (Figure 1b).

**Results:** Baseline patient characteristics that differed significantly between Mexico and South Africa included age (35 vs. 38 years, p < 0.006), gender (12% vs. 54% female, p < 0.001), CD4 count (31 vs. 37 cells/ul, p < 0.034), hemoglobin (13 vs. 12 g/dL, p = 0.03), AIDS defining illness (79% vs. 43% of patients, p = 0.001), and prevalence of active TB (1.7% versus 28% of patients, p < 0.004). Baseline plasma HIV viremia and CD4 T cells did not differ significantly. After adjusting for baseline characteristics, patients from the Mexican cohort had higher levels of fibrinogen, LTB4, P-selectin, protein S, and sCD40 ligand. After adjusting for baseline characteristics, patients from the Mexican cohort had higher levels of fibrinogen, LTB4, P-selectin, protein S, and sCD40 ligand.

**Conclusions:** Our data suggest that inflammatory and coagulation biomarkers may vary significantly by region or ethnicity and that country-specific data may be needed in studies using biomarkers as predictors or clinical trial end points. Further studies are needed to evaluate how these differences may also contribute to HIV pathogenesis and prognosis in diverse populations.

Central nervous system

**WEPEA129**

Cell-to-cell transmission of HIV from lymphocytes to astrocytes via a unique, CXCR4-dependent mechanism

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**Background:** HIV reservoir in the brain represents a major barrier for curing HIV infection. As the most abundant, long-lived cell type, astrocytes play a critical role in maintaining the reservoir; however the mechanism of infection remains unknown. Here, we determine how viral transmission occurs from HIV-infected lymphocytes to astrocytes by cell-to-cell contact.

**Methods:** Human astrocytes were exposed to HIV-infected lymphocytes and monitored by live-imaging, confocal microscopy, transmission and 3-dimensional electron microscopes. A panel of receptor antagonists was used to determine mechanism of viral entry. An in vitro BBB model was established to test the migration of HIV-infected lymphocytes.

**Results:** We found that cell-to-cell contact resulted in efficient transmission of X4- or X4R5-using viruses from T lymphocytes to astrocytes. In co-cultures of astrocytes with HIV-infected lymphocytes, the interaction occurred through a dynamic process of attachment and detachment of the two cell types. Infected lymphocytes invaginated into astrocytes or the contacts occurred via filopodial extensions from either cell type, leading to formation of virological synapses. In the synapses, budding of immature or complete HIV particles from lymphocytes occurred directly onto the membranes of astrocytes. This cell-to-cell transmission could be almost completely blocked by anti-CXCR4 antibody and its antagonist, but only partially inhibited by CD4, Icam1 antibodies. Furthermore, SDF-1 that can be secreted from astrocytes in patients with HIV-associated neurological diseases significantly triggered the migration of HIV-infected lymphocytes across the BBB.

**Conclusions:** Cell-to-cell transmission was mediated by a unique mechanism by which immature viral particles initiated a fusion process in a CXCR4-dependent, CD4-independent manner. These observations have important implications for developing approaches to prevent formation of HIV reservoirs in the brain.

Mechanisms underlying co-morbidities in ARV treated individuals

**WEPEA130**

IL18 and ALOX5AP mRNA levels are increased in HIV-infected individuals despite the use of HAART

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**Background:** Persistent inflammation is thought to be related to a high prevalence of HIV-associated comorbidities. It has been shown that HAART introduction diminishes the levels of inflammatory proteins in HIV-infected individuals, but not to the levels observed in non-infected subjects. However, the transcriptional involvement of blood cells in HIV-related inflammation is still uncertain.

The purpose of our study was to test if the mRNA levels of 9 genes involved in inflammation (CXC1R1, IL8, CXCL2, LTA, IL6, ALOX5, ALOX5AP, IL18 and CCL5) are affected by HAART treatment in blood cells of HIV-infected subjects.

**Methods:** This cross sectional study included 142 treated HIV-infected individuals, 31 untreated HIV-infected individuals and 19 uninfected controls. RNA was extracted from blood cells using standard methods. Relative quantification of mRNA levels (RQ) was performed using quantitative PCR methodology. Results were analyzed with the ΔΔCt method using ACTB as Housekeeping gene. Mann-Whitney U and Kruskal-Wallis tests were performed to study the variations of mRNA levels. Statistical analyses were conducted using SPSS and Expression Suite Statistical Packages.

**Results:** mRNA levels of ALOX5AP and IL18 were found significantly different when comparing the three groups (HIV untreated, HIV treated and uninfected controls). Increased ALOX5AP and IL18 mRNA levels were observed when comparing HIV-uninfected and HIV-treated infected individuals.
Viral mechanisms of HIV/SIV persistence and latency

**WEPEA131**  
**Low frequency of HIV rebound after antiretroviral treatment interruption**  
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**Background:** HIV persists in latent reservoirs and produces viral rebound upon interruption of antiretroviral therapy (ART). Understanding the temporal kinetics of viral recrudescence upon interruption of ART is important for current curative strategies aimed at achieving ART-free viral remission.

**Methods:** We have analysed clinical data on time to viral rebound after ART-interruption from four independent patient cohorts totalling 101 patients. This includes patients treated with a variety of ART regimes, treated at different stages of HIV infection (including primary infection, n=59), treated with latency reversing agents (n=9) and monitored regularly for viral rebound. We fitted a model of exponential distribution of time to detection, we derived an average frequency of viral remission.

**Results:** The time between ART-interruption and viral detection varied widely among different patients. However, within all patient cohorts, time to detection followed an exponential distribution. Fitting the distribution of time-to-detection, we derived an average frequency of viral recrudescence of once every 6 days (range 5.1 - 7.6 days between the four cohorts). This rate is over 30 times lower than previous estimated and suggests that a reduction in the reservoir size of around 61-fold would be required to extend the average time-to-recrudescence to about one year. Analysis of the time-to-recrudescence in a cohort of SIV infected macaques treated early in infection reveals an average frequency of reactivation events of once every 1.7 days over three times more frequent than in HIV infection in humans.

**Conclusions:** Previous studies have suggested that HIV reactivates from latency around five times per day, based on indirect estimates of rates of acquisition of drug resistance under ART. We estimate a frequency of reactivation that is 30 times lower (once every 6 days), based on analysis of time to recrudescence. This has important implications for how much the latent reservoir will need to be reduced to produce significant remissions after ART-interruption.

**WEPEA132**  
**Dynamic imaging of intracellular glutathione redox potential of HIV-1 infected macrophages and its exploitation by Mycobacterium tuberculosis through its lipids**  
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**Background:** Oxidative stress plays an important role in HIV-1 pathogenesis. Several markers of oxidative stress including glutathione, thioredoxins, cysteine, etc. were found to be altered in HIV-1 infected patients. Conventional measurements of oxidative stress upon HIV-1 infection are either based on redox dyes or invasive technologies, thereby introducing oxidant artifacts and preclude dynamic measurements. In this study, we have utilized a novel non-invasive technology based on genetically encoded redox biosensors, to measure redox potential of HIV-1 infected macrophages in real-time.

**Methods:** Since intracellular levels of oxidized (GSSG) and reduced glutathione (GSH) are used as indicator of cellular redox potential, we non-invasively tracked glutathione redox potential (EGSH) of HIV-1 infected macrophage cell line (U1) using a highly sensitive and specific bioprobe, Grx1-roGFP2. We report precise measurements of EGSH in sub-cellular compartments during HIV-1 infection. We also measured EGSH during HIV-1 activation from latency using lipids isolated from different clinical strains of M. tuberculosis. We performed oxidative stress and antioxidant defense pathway-focused human gene expression array during latent and reactivation phase of HIV-1 infection using UT and its uninfected counterpart U937 cells. Lastly we performed ART-PCR analysis using selected set of oxidative stress genes on RNA isolated from the PBMCs of HIV-1 infected symptomatic individuals.

**Results:** We show that the steady-state EGSH of cytost and mitochondria in both HIV-1 infected (U1) and uninfected (U937) macrophages was highly reduced (~310 mV to ~320 mV). In contrast, activation of HIV-1 replication induces significant oxidative shift in the EGSH (~240 mV) of mitochondria and cytosol. We found that EGSH of UT-cells dynamically responds to pro-apoptotic signal, H2O2, to modulate resistance towards oxidative stress and apoptosis. Importantly, we show that bioactive-lipids synthesized by cellular drug-resistant isolates of Mycobacterium reactivate HIV-1 through modulation of intracellular EGSH. Finally, the expression analysis of UT and patient PBMCs demonstrated a major recalibration of cellular redox homeostatic pathways during persistence and active replication of HIV-1.

**Conclusions:** Since redox signaling is believed to play an important role in HIV-1 reactivation and progression to AIDS, we believe that this technology will open up new avenues of research pertaining to the development of novel intervention strategies against HIV-1 infection.
WEPEA134
Purging HIV-1 from latent reservoirs using human methyltransferase inhibitors

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Background: In this in vitro model of latency, PMA/PHA and the potent HDACi romidepsin had strikingly different effects on the accumulation of US-RNA, MS-RNA and viral production. While successful HDACi agents yield small increases in US-RNA, synergistic strategies that achieve a larger accumulation of MS RNA may result in enhanced release of latent HIV.

Methods: We used CD8 T-cells depleted PBMCs isolated from 15 HIV HAART-treated patients with undetectable viral load over a period 4 years. We measured HIV-1 recovery in ex vivo cell cultures first activated by PHA for one day and then treated with deoxycytidine and BIX-01294 and cultivated in RPMI medium supplemented with IL-2 and fetal bovine serum while CD8 T-cells depleted PBMCs activated with PHA and then cultivated in RPMI medium supplemented with IL-2 and fetal bovine serum were used as control samples.

Results: HMTIs induced purging in 11 out of 15 subjects. Second day after treatment with the drugs, culture supernatants were tested for viral load using qPCR and the results revealed HIV-1 emergence from day 3+day 29+ (median 9) days with viral load from 2.2 log10 to 6.0 log10 (median 5.7). To find a correlation between PBMC proviral load and culture positivity, qPCR was done. Proviral load varied from 28.51 to 515.90 (median=41, mean=144). The results showed that culture positivity is independent of proviral load, CD4+ T cell nadir, time of viral load below detection limits and antiretroviral scheme.

Conclusions: As part of an attempt to HIV eradication in human hosts, it would be important to overcome HIV latency, one of the major obstacles towards the sterilizing HIV cure. We showed here that these non-administrable HMTIs may provide a therapy to purge the dormant HIV-1 from reservoirs possibly in combination with other chronic reprogramming drug. Therefore, clinical grade HMTIs should be synthesized or screened and evaluated to exploit their HIV reactivation potential.

WEPEA135
Host cellular factors and latency

WEPEA136
Transcriptional profiling identifies RORC and PPARG as two major mechanisms regulating HIV permissiveness in primary Th17 cells

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Background: Th17 cells are major players in mucosal immunity. Th17 cells are highly permissive to HIV infection, while Th1 cells are relatively resistant. As a consequence, Th17 cells are depleted in HIV-infected subjects and their frequency is partially restored under antiretroviral therapy. Our recent studies demonstrated persistence of HIV reservoirs in CD4+ T-cells expressing the Th17 marker CCR6 in ART-treated subjects. To identify molecular mechanisms of HIV permissiveness in Th17 cells, we performed a genome-wide analysis of gene expression in Th17 vs. Th1 cells.

Methods: Th17 (CCR4+CXCR3-CCR6+) and Th1 (CCR4-CXCR3+CCR6-) subsets were sorted by flow cytometry and stimulated via CD3/CD28 Abs. The expression of 47,000 probe-sets was tested using the Illumina BeadArray technology. Transcripts were classified by biological functions using Gene Set Variation Analysis and Gene Ontology. Real-time RT-qPCR and fluorescence microscopy were used to validate differentially gene expression. RNA interference was used to evaluate the role of top-modulated genes in regulating HIV permissiveness. Cyto- kine production and proliferation was measured by flow cytometry. HIV infection-integration was quantified by HIV-p24 ELISA and normalized real-time PCR.

Results: HIV permissiveness in Th17 vs. Th1 was regulated by both entry and post-entry mechanisms. Among 2,533 “present calls”, 1,335 and 1,198 probe-sets were upregulated and downregulated, respectively, in Th17 vs. Th1 cells. Genes associated with T-cell differentiation (RORC, KLF2, ARNTL), TCR signaling (ZAP-70, Lck, MAP3K4), activation/apoptosis (PPARG, PTPN11), and HIV replication (PPARG) were upregulated in Th17 vs. Th1 cells. Genes down regulated in Th17 vs. Th1 cells and previously linked to HIV resistance included CCR5-binding chemokines and IFN-induced molecules. HIV permissiveness in Th17 vs. Th1 cells was associated with high sensitivity to TCR triggering, increased proliferation potential, and superior NF-κB DNA-binding activity. RORC RNA interference decreased HIV replication, while PPARG silencing induced opposite effects.

Conclusions: Our study reveals a unique molecular signature for HIV-permissive Th17 cells and identifies RORC and PPARG as major positive and negative regulators, respectively, of HIV replication in these cells. Novel therapeutic strategies aimed at interfering with Th17-specific transcripts may limit HIV replication and reservoir persistence, while preserving the beneficial role of Th17 cells in mucosal immunity.
WEPEA137

Modulation of HERV family expression after treatment with HDAC inhibitors

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Background: Human Endogenous Retroviruses (HERVs) comprise about 8% of the human genome. Some autoimmune diseases and cancers have been associated with the expression of HERV-K, which is the most recently integrated family of endogenous retroviruses. The production of HERV-K derived proteins in HIV infected cells provides a potential target for HIV eradication. Latently HIV infected remain as the major obstacle for HIV eradication. Use of histone deacetylase inhibitors (HDACi) to induce HIV expression in resting cells is a promising strategy for HIV latency reversal.

Methods: In this study we quantified the reactivation of five different families of HERVs by three non-selective HDACi (Vorinostat, Panobinostat and Romidepsin) in a latently HIV-1 T-cell model.

Results: After a 5-hour pulse with each HDACi, Vorinostat (1000nM), Panobinostat (50nM) and Romidepsin (50nM), we detected a 23.3%, 32.1% and 59.8% reactivation of HIV-1, respectively by measuring intracellular KC57 expression by flow cytometry. We also detected an increase in the gene expression of tested HERV families (R, K, H and P), with Panobinostat having the strongest ability to induce expression HERV-K. Further analysis within the HERV-K family, revealed that the pol gene was the most expressed gene compared to gag and env.

Conclusions: These data demonstrate the dynamic regulation of HERV expression after treatment with HDACi and future HIV-1 therapeutic strategies should consider the influence of the reactivation of endogenous retroviruses in infected cells.

Cellular and tissue reservoirs of HIV/SIV

WEPEA138

Distinct HIV genetic populations in effector T cells after prolonged therapy

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Background: The effect of prolonged antiretroviral therapy (ART) on the genetic composition of persistent HIV in cellular reservoirs is unknown. We examined the genetic makeup of HIV DNA sequences within T-cell subsets from peripheral blood and gut tissue of patients on ART for >15 years.

Methods: Using single-proviral sequencing, we isolated HIV DNA from naïve, stem cell memory (TSCM), central (TCM), transitional (T(TM)), and effecter (TEM) CD4+T-homing CD4+ T cells infected with integrated latent virus. This latent reservoir involves several memory CD4+T-cell subsets at distinct differentiation stages with different phenotypic and functional properties, forming distinct sub-reservoirs. Precise immunological characterization of the latent HIV reservoir, including the size of each sub-reservoir, is important for the complex challenge of therapeutic purging. The relative size of each sub-reservoir may depend on the drug resistance profile and therefore vary according to the time on ART. Here, we determined the decay rates of latently infected memory subsets.

Results: We conducted a cross-sectional study on 45 strictly selected homogeneous patients. Inclusion criteria were: plasma virus load undetectable for 24 to 189 months without any viral blip and a CD4+ T-cell count higher than 500 mm³ of blood.

Conclusions: These data demonstrate the dynamic regulation of HERV expression after treatment with HDACi and future HIV-1 therapeutic strategies should consider the influence of the reactivation of endogenous retroviruses in infected cells.

WEPEA139

Progressive contraction of the latent HIV reservoir around a core of less-differentiated CD4+ memory T cells

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Background: HIV can persist within a small pool of long-lived resting memory CD4+ T cells infected with integrated latent virus. This latent reservoir involves several memory CD4+ T-cell subpopulations at distinct differentiation stages with different phenotypic and functional properties, forming distinct sub-reservoirs. Precise immunological characterization of the latent HIV reservoir, including the size of each sub-reservoir, is important for the complex challenge of therapeutic purging. The relative size of each sub-reservoir may depend on its drug resistance profile and therefore vary according to the time on ART. Here, we determined the decay rates of latently infected memory subsets.

Methods: We conducted a cross-sectional study on 45 strictly selected homogeneous patients. Inclusion criteria were: plasma virus load undetectable for 24 to 189 months without any viral blip and a CD4+ T-cell count higher than 500 mm³ of blood.

Results: Our results suggest a progressive reduction of the size of the blood latent reservoir around a core of less-differentiated memory subpopulations, consisting of central memory (T_CM), and stem cell-like memory (T_SCM) CD4+ T cells. This process appears to be driven by the differences in initial sizes and decay rates between latently infected memory subsets. Our results also suggest an extreme stability of the T_CM sub-reservoir, which is directly related to cumulative plasma virus exposure before the onset of ART.

Conclusions: Latently infected T_CM and T_SCM should be a priority target for therapeutic strategies. Our results stress the importance of early initiation of effective ART to limit the size of the T_CM sub-reservoir.

WEPEA140

Quantification and replication competency of HIV-1 following latency disruption in CD4+ T cells

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Background: The size of the latent reservoir in a patient with ART induced HIV suppression can be estimated by viral outgrowth in a limiting dilution culture of activated CD4+ T cells. A culture well containing HIV is typically detected with p24 ELISA, but recently HIV RNA RT-PCR has been shown to be more sensitive. This allowed us to determine the proportion of cells producing viral RNA that resulted in replication competent virus.

Methods: Resting memory CD4+ T cells from virally suppressed patients were stimulated with beads coated with antibodies against CD2, CD3, and CD28, and plated in limiting dilution in two conditions: 1) 100,000 MOLT-4/CCR5 cells per well and IL-2 were added on 1 day to facilitate viral outgrowth, or 2) the reverse-transcriptase inhibitor efavirenz was present immediately on day 0 to suppress viral replication, with no exogenous cells or IL-2 added. Culture media was collected and replaced every 4 days, and the viral RNA isolated and then quantified by real time HIV gag RT-PCR. The frequency of HIV RNA producing cells was estimated using the R package for Extreme Limiting Dilution Analysis.
Results: The frequency of HIV RNA-producing cells following latency disruption was strongly correlated under viral outgrowth vs. viral suppression conditions. In most positive wells under viral suppression, viral RNA was detectable by day 4; some were followed by an increase while others decreased. In some outgrowth wells, the amount of HIV RNA on days 8 and 12 greatly exceeded that in comparable wells in the suppression assay. Culture supernatant from positive outgrowth wells was used to infect new cultures of activated, allogeneic CD4+ T cells. In 2 experiments, each utilizing a different donor, 35% (±7.78) and 14% (±11.78) of original positive outgrowth wells supported viral growth.

Conclusions: While HIV gag RNA RT-PCR with a concentrated viral suppression culture was as sensitive for quantifying the frequency of HIV RNA-producing cells as a viral outgrowth assay, much HIV RNA recovered in the outgrowth wells, including many wells that had increasing amounts of viral RNA over time, did not represent replication-competent virus.

WEPEA141
T cell immunity in testicular tissue of ART-treated HIV-infected subjects: results from the Orchid study

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Backgrounds: HIV persistence in anatomical reservoirs is a major hurdle in HIV eradication. Testis represents a neglected but nonetheless important viral anatomical reservoir as it constitutes an immune privileged site. We assessed T-cell distribution in testis and blood in HIV-infected individuals receiving suppressive ART.

Methods: Testicular tissue and blood samples were collected from virally suppressed individuals (n=9) on ART for at least 6 months prior to surgery and uninfected controls (n=10) who underwent elective orchectomy for gender reassignment. T-cells were purified using CD3 microbeads from freshly isolated testicular interstitial cell suspensions. T-cell subsets, CCR5 and ectonucleotidases (CD39 and CD73) expression, T-cell activation, and frequency of regulatory T-cell subsets (Tregs) were assessed using multicolor flow cytometry.

Results: Lower proportions of CD4 T-cells among total cell counts were found in testis versus blood, in both HIV+ and HIV+ subjects (37±6.5% vs. 30±2.4% and 29±2.7% vs. 73±11.5%, p<0.001). A decrease in naïve and an increase in effector-memory T-cell subsets were observed in tests compared to PBMCs in both groups (p<0.001). Importantly, up to 77 fold increases in the CCR5 expression on testicular CD4 and CD8 T-cells were observed when compared to control (CD4 HIV−: p<0.001, CD4 HIV+: p=0.003, CD8 HIV−: p<0.005, CD8 HIV+: p<0.001). Increased T-cell immune activation (CD38/HLA-DR co-expression) in tests was observed in HIV+ individuals. A higher expression of immunosuppressive CD39/Tregs was found in tests of both HIV- and HIV+ subjects compared to blood (64±22% vs. 31±22%, p<0.002 and 62±11.5% vs. 42±6%, p<0.01). A massive increase in the proportion of testicular CD3 memory CD8 T cells in HIV− and HIV+ subjects versus blood was also observed (24±13.2 vs. 77±4.4% and 13±8.4 vs. 57±14.6%, p<0.001).

Conclusions: For the first time, our results indicate an increase in the proportion of effectors memory T-cells, CCR5 expression on T-cells and high expression of eCTEs in testicular tissue when compared to blood regardless of HIV status. However, virally suppressed subjects on ART had elevated levels of testicular cell immune activation when compared to HIV controls. Collectively, these findings demonstrate the contribution of distinctive T-cell distribution in testicular tissue as anatomical reservoirs for HIV persistence.

WEPEA142
Extracellular ATP induces the rapid release of HIV-1 from virus containing compartments of human macrophages

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Backgrounds: The human immunodeficiency virus type-1 (HIV-1) infects CD4+ T lymphocytes and myeloid cells, in particular tissue macrophages. In comparison to T cells, infected macrophages differ both in terms of decreased to absent cytopathicity and for actively accumulating new progeny HIV-1 virions in Virus Containing Compartments (VCC). For these reasons, infected macrophages are believed to act as ‘Trojan horses’ carrying infectious particles to be released upon cell death or functional stimulation.

Methods: The U937-derived chronically HIV-1-infected promonocytic cell line U1 was differentiated into macrophage-like cells (D-U1 cells) by PHA in the presence of urokinase-type plasminogen activator to favor virion retention in intracellular vacuoles and then shortly exposed to extracellular (e) ATP to induce their release. Primary human monocyte-derived macrophages (MDM) of HIV-1 seronegative donors were infected either with an R5 HIV-1 strain or with a VSVG-pseudotyped vector expressing eATP. Both D-U1 cells and MDM were stimulated with eATP to induce the release of virions from VCC. Live imaging analysis was used to study the morphological effects of eATP on HIV-1 infected macrophages.

Results: Short term (3-50 min) eATP stimulation induced massive membrane blebbing and a rapid release of mature HIV-1 infectious virions from primary human MDM infected in vitro in the absence of cell death. The same phenomenon was reproduced in chronically infected D-U1 cells. Virion release was associated with a depletion of intracellular virions, as measured by intracellular p24 Gag staining and by visual imaging. Pharmacological inhibition of the microvesicle release pathway and of the ATP receptor (P2X7) prevented eATP-induced virion release from both acutely infected MDM and D-U1 cells.

Conclusions: Short (min) eATP stimulation induces the release of HIV-1 virions in both primary MDM and in D-U1 cells, via interaction with P2X7R and in the absence of significant cytopathicity. Pharmacologic interference with the microvesicle release pathway and with the P2X7R prevented this effect suggesting that they could represent novel exploitable targets for interfering with the reservoir of HIV-1 infected tissue macrophages.

WEPEA143
CTLA-4-expressing memory CD4+ T cells are critical contributors to SIV viral persistence

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Backgrounds: Understanding the immunophenotype and anatomical location of latently infected cells represents a critical challenge in designing a cure for HIV. Among memory CD4+ T-cells, those expressing co-inhibitory receptors (Co-IRs) are strong candidates for being enriched in latent HIV, given their negative regulatory function and upregulation on T-cells following HIV infection. However, little is known regarding the dynamics of T-cells expressing multiple Co-IRs following suppressive ART and their contribution to the HIV/SIV reservoir, particularly in tissues.

Methods: We investigated the relationship between the level of Co-IR expression on memory CD4+ T-cells and their level of latent viral in 10 ART-treated, SIV-infected rhesus macaques (RMs). RMs initiated a 5-drug ART regimen 6-8 weeks after SIVmac251 infection, which was maintained until plasma viremia was <50 copies/ml for at least 3 months. Blood and tissue levels of memory CD4+ T-cells expressing multiple Co-IRs (PD-1, CTLA-4, TIM-3, 2B4, TIGIT) were longitudinally analyzed by flow cytometry. Memory CD4+ Co-IR+ subsets were sorted twice during viral suppression based on their expression of PD-1, CTLA-4, and TIM-3, to quantify levels of cell-associated SIV-DNA and RNA.

Results: The majority of memory CD4+ T-cells from the blood, GI tract, lymph node, and spleen expressed multiple Co-IRs, specifically PD-1 and CTLA-4, and their frequencies remained stable or increased during SIV infection, even with suppressive ART. Following 1 month of viral suppression, both memory CTLA-4+(PD-1−) and PD-1+(CTLA-4−) CD4+ T-cells harbored significantly higher levels of SIV-DNA in the LN. Yet, after 3 months of suppression, only CTLA-4+ CD4+ T-cells, in the absence of other Co-IRs, were significantly enriched in SIV-DNA in the PBMCs compared to Co-IR(-) cells, and in the LN, demonstrating the specific persistence of this virally infected subset. Furthermore, this subset did not express high levels of SIV-RNA, which suggests that these CTLA-4+ cells likely harbor latent SIV.

Conclusions: Despite comprising a small frequency of memory CD4+ T-cells, CTLA-4+ T-cells represent a novel subset of virally enriched cells that may critically contribute to persistence in ART-suppressed individuals. These findings highlight the benefit of therapeutically blocking both CTLA-4 and PD-1 to target a large fraction of the HIV reservoir.
Measurement of HIV/SIV reservoirs

WEPEA144  Defining the unique biomarkers of latently infected T cells

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Background: A critical issue in developing therapeutic approaches to HIV eradication is the identification of latently infected cells. Unfortunately, as yet there is no biomarker that distinguishes latently infected resting T cells from uninfected resting T cells. Research in developing means to identify such latently infected cells has been complicated by the fact that the number of latently infected cells in a single patient is extremely small such that it has not been possible to isolate latently infected cells in sufficient numbers in order to characterize these cells.

Methods: To overcome this limitation, we have developed a primary CD4+ T cell based ex vivo model system of HIV latency. The unique advantage of our model is that it allows us to generate a large and pure population of latently infected primary CD4+ T cells. This approach has provided sufficient material to characterize these cells and define the unique phenotypic characteristics (biomarkers) of latently infected cells. We compared the proteome of cell membranes from both latently infected and uninfected resting T cells. Differentially expressed protein(s) on latently infected T cells can be used as biomarkers.

Results: By cell membrane proteome analysis we have identified 17 putative biomarker proteins that are either predominantly or exclusively expressed on the surface of latently infected cells. We are currently in the process of evaluating these individual proteins for their potential as a latently biomarkers. The remaining results indicate that some of the proteins FSI1 predominantly express on the surface of latently infected cells. These results as well as analysis of other biomarker proteins will be further discussed.

Conclusions: In order to cure AIDS, eradication of HIV is essential and to eradicate HIV, elimination of latent virus is necessary. However, to selectively kill latent viruses, we need to know specific characteristics of cells that harbor latent viruses, in order to avoid the killing of uninfected bystander cells. Unfortunately, the biomarkers of latently infected cells have not been defined. Thus finding the unique biomarkers of latently infected cells is an initial step in developing a strategy for HIV eradication and curing AIDS.

WEPEA145  Cell-associated HIV-1 unspliced to multiply spliced RNA ratio at 12 weeks ART correlates with markers of immune activation and apoptosis and predicts the CD4+ T cell count at 96 weeks ART

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Background: Incomplete restoration of CD4+ T-cell count during virologically successful antiretroviral therapy (ART) is a major predictor of morbidity and mortality. For better understanding of HIV-1 pathogenesis and improved design of curative strategies, it is important to determine whether the degree of HIV-1 persistence, measured at baseline or early on ART, can predict subsequent immunological response to the long-term therapy and whether viral persistence is associated with host biomarkers of immune dysfunction.

Methods: Total and Epstein-Barr virus (EBV) latently infected U937 cells were infected with HIV-1NL4-3 and U87 cells were infected with HIV-1HXB2. After infection, cells were co-cultured with CD4+ T cells of HIV-1-infected individuals under suppressive HAART we isolated proviruses from CD4+ T cells of HIV-1-infected individuals under suppressive HAART we isolated proviruses from CD4+ T cells. Provirus DNA and RNA were purified and sequenced by deep sequencing. Results:

Results: No baseline HIV-1 marker was predictive of CD4+ T-cell count at 96 weeks of ART. However, at 12 weeks of ART, cell-associated HIV-1 unspliced to multiply spliced RNA ratio was significantly associated with both absolute CD4+ T-cell count at 96 weeks of ART (rho=0.56, P=0.004) and with relative increase in CD4+ T-cell count between baseline and 96 weeks of ART (rho=0.55, P=0.004). USMS RNA ratio at 12 weeks ART was not associated with baseline CD4+ T-cell count. Moreover, USMS RNA ratio at 12 weeks ART strongly positively correlated with markers of CD4+ T-cell activation (CD4+CD38+HLA-DR: rho=0.63, P=0.001). USMS RNA ratio at 12 weeks ART was significantly associated with markers of apoptosis and predicted lower CD4+ T-cell count at 96 weeks ART. Because HIV life cycle involves a temporal shift from the production of multiply spliced to the production of unspliced RNA species, higher USMS RNA ratio in a patient might reflect the higher frequency of HIV-infected cells in the later stages of viral life cycle, which is characterized by expression of viral proteins and presentation of antigens. Such cells could exert pressure on the host immune system, causing persistent immune activation and apoptosis and contributing to poor immunological response to ART.

WEPEA146  Defective HIV-1 proviruses in the latent reservoir can be transcribed and translated following latency reversal

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Background: Despite long-term highly active anti-retroviral therapy (HAART), human immunodeficiency virus-1 (HIV-1) persists as integrated proviruses, primarily in resting memory CD4+ T cells and remains the major barrier to cure. The vast majority of these proviruses are defective, containing either large internal deletions or extensive APOBEC-mediated G-to-A hypermutations. We recently discovered that many of these defective proviruses have intact promoter regions. Whether these proviruses can become transcriptionally active during the “shock-and-kill” strategies, which attempts to reverse latency and eliminate the latent reservoir, remains unknown. Further, it remains unclear whether these defective proviruses can be recognized and eliminated by the host immune responses following activation. Therefore, defective proviruses may complicate the measurement of the latent reservoir using RNA-based quantification during latency reversal trials with a potential role in immune activation.

Methods: To understand the role of defective viral genomes in viral transactivation, proviral sequences defective in gag, tat and rev were generated by site-directed mutagenesis of the NL4-3 reference strain. To reconstruct near-full-length defective proviruses from the resting CD4+ T cells of HIV-1-infected individuals under suppressive HAART we isolated proviruses through differential PCR and synthesized them by de novo gene synthesis. Primary CD4+ T-cells were transfected with these proviruses by nucleofection and activated by CD3/CD28 co-stimulation. After DNase treatment, cell-associated HIV-1 RNA was measured by quantitative RT-PCR and HIV Gag protein expression was measured by flow cytometry.

Results: Defective proviruses including hypermutated sequences with intact tat and/or rev genes can produce HIV-1 RNA at lower levels following CD3/CD28 co-stimulation. These defective proviruses are capable of producing HIV-1 viral proteins at measurable but lower levels than the NL4-3 reference strain.

Conclusions: Defective HIV-1 proviruses in the resting CD4+ T cells can be transcribed and translated following stimulation. In future latency reversal trials, these defective proviruses should be considered in determining the efficacy of treatments. In addition, a thorough investigation of the vivo impact of defective viral transcripts and truncated proteins should be considered before defective proviruses can be determined as non-pathogenic.

WEPEA147  HIV-1 transcription is stable during frequent longitudinal sampling in aviremic patients on ART: implications for HIV cure research

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Background: Reversal of latency is currently being investigated in studies aiming to reduce the HIV-1 reservoir. To best evaluate the effect of such clinical interventions in HIV-1 eradication trials, it is essential that the longitudinal dynamics of HIV-1 transcriptional activity, as well as the HIV-1 reservoir size, be fully characterized. To address this need, we conducted a longitudinal, observational cohort study that enrolled aviremic HIV-1 patients at Aarhus University Hospital, Denmark.

Methods: Inclusion criteria were CD4+ T-cell count >200/µL, 2 most recent viral load measurements < 19 HIV-1 copies/mL and at least 2 year on ART. For all participants, monthly blood samples were collected over six consecutive months. HIV-1 transcription as measured by cell-associated unspliced HIV-1 RNA (CA-US HIV-RNA) and the size of the viral reservoir were quantified in unfractionated CD4+ T cells by digital droplet PCR.

Results: During the study period (November-2013 to August-2014) we enrolled 25 patients, including 8 females and 17 males (Table-1). Each participant completed the 6-month study. For all participants, monthly blood samples were collected over six consecutive months. HIV-1 transcription as measured by cell-associated unspliced HIV-1 RNA (CA-US HIV-RNA) and the size of the viral reservoir were quantified in unfractionated CD4+ T cells by digital droplet PCR.

To calculate the longitudinal variation in these outcome measures, we first determined the absolute mean values of CA-US HIV-RNA and HIV-DNA for each individual over the six visits. Then, we determined the fold-change of the absolute values from each of the six visits relative to that mean. Finally, we determined the maximum fold-change from the absolute mean value for each patient and calculated a maximum fold-change with 95% CI for the study population.

Results: During the study period (November-2013 to August-2014) we enrolled 25 patients, including 8 females and 17 males (Table-1). Each participant completed the 6-month study. The mean maximum fold change in CA-US HIV-RNA was 1.49 (95% CI: 1.32-1.65; max. 2.30). The mean maximum fold change in HIV-DNA was of 1.30 (95%CI: 1.16-1.44; max. 2.50).
Hepatitis (excluding hepatitis C)

WEPEB313
Serial prevalence of HBV-HIV coinfection in Madrid in the period 2004-2013

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Background: Hepatitis B virus (HBV) infection affects more than 400 million people worldwide and is a common cause of liver disease and liver cancer. In Europe about 14 million people are chronically infected with HBV and thirty-six thousand people die each year from HBV-related causes. Due to common transmission routes HBV/HIV coinfection is higher than in general population. In Spain the proportion of HIV-positive patients coinfected with HBV varies from 3 to 14% in the general population at the end of the study period. The majority of the subjects were HBV e antigen (HBeAg)-negative (n=93, 70.5%) and were distributed equally in the 3TC and the TDF+3TC groups (P=0.26). Pre-treatment, median HBV DNA was 3.54 logIU/ml (interquartile range [IQR] 1.97-3.98 logIU/ml) in 3TC group and 3.49 logIU/ml (IQR 2.46-6.69 logIU/ml) in TDF+3TC group (P=0.76). In both groups over half of the subjects had pre-treatment HBV DNA <20,000 IU/ml (54.1% in 3TC and 57.7% in TDF+3TC group, P=0.67). After 48 weeks of treatment, 68.9% of patients in 3TC group versus 88.7% of patients in TDF+3TC group achieved HIV viral suppression (P<0.005). However, in patients with baseline HBV DNA>20,000 IU/ml, HIV viral suppression rates were similar in these two therapy groups (Table). In stratified multivariate regression, TDF use (RR 2.70, 95%CI, 1.99-3.65) was associated with HIV viral suppression only when baseline HBV DNA>20,000 IU/ml (Table).

Results: The prevalence of HBV infection in the overall population decreased from 2.45% (95%CI, 2.28-2.61) in 2004-2005 to 1.09% (95%CI, 1.02-1.15) in 2012-2013, P<0.0001. HBV/HIV coinfection decreased from 4.99% (95%CI, 4.03-6.11) in 2004-2005 to 1.61% (95%CI, 1.11-2.26) in 2012-13, P<0.0001, and the prevalence of HBV infection among HIV-negative subjects decreased from 2.32% (95%CI, 2.15-2.41) in 2004-05 to 1.17% (95%CI, 1.07-1.28) in 2012-13, P<0.0001. Among HIV-infected subjects the trend from 2004 to 2013 among each risk group was: IDU, 8.57% to 0%, P=0.65; MSM, 3.63% to 7.01%, P=0.68; heterosexual, 8.92% to 0%, P=0.57. The single factor associated with HIV/HBV coinfection was a high HIV RNA: OR 1.74 (95%CI, 1.004-3.021, P=0.048).

Conclusions: The prevalence of HBV/HIV coinfection decreased in Madrid between 2004 and 2013, becoming similar to the prevalence of hepatitis B in HIV-negative subjects and general population at the end of the study period.

WEPEB314
Lamivudine (3TC) with or without tenofovir disoproxil fumarate (TDF) for treatment of hepatitis B in HIV-HBV co-infected treatment-naive patients

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Background: Chronic hepatitis B virus (HBV) coinfection occurs in 10-14% of HIV-infected Chinese patients. Although TDF+3TC is recommended for treatment of HBV/HIV coinfected patients, TDF is unavailable or expensive in some resource-limited areas; thus 3TC monotherapy for hepatitis B is given. Therefore, it is important to compare the efficacy of 3TC-based antiretroviral therapy (ART) against HIV with that of TDF-based ART regimens in HIV-HBV co-infected patients.

Methods: We compared HIV treatment response in 132 HIV co-infected treatment-naive patients (HCV uninfected) from our HIV Chinese cohorts (n=61 from cohorts using 3TC and n=71 from cohorts using TDF+3TC). Plasma HBV DNA levels were determined pre-treatment and week 48 of treatment. Poisson regression with robust error variance was used to estimate relative risks (RRs) for HBV DNA suppression (<20 IU/ml). Variables with P values lower than 0.15 in either stratum were included in multivariate analyses. Age, sex, and route of transmission were also adjusted for in multivariate analyses.

Results: The majority of the subjects were HBV e antigen (HBeAg)-negative (n=93, 70.5%) and were distributed equally in the 3TC and the TDF+3TC groups (P=0.26). Pre-treatment, median HBV DNA was 3.54 logIU/ml (interquartile range [IQR] 1.97-3.98 logIU/ml) in 3TC group and 3.49 logIU/ml (IQR 2.46-6.69 logIU/ml) in TDF+3TC group (P=0.76). In both groups over half of the subjects had pre-treatment HBV DNA <20,000 IU/ml (54.1% in 3TC and 57.7% in TDF+3TC group, P=0.67). After 48 weeks of treatment, 68.9% of patients in 3TC group versus 88.7% of patients in TDF+3TC group achieved HIV viral suppression (P<0.005). However, in patients with baseline HBV DNA>20,000 IU/ml, HIV viral suppression rates were similar in these two therapy groups (Table). In stratified multivariate regression, TDF use (RR 2.70, 95%CI, 1.99-3.65) was associated with HIV viral suppression only when baseline HBV DNA>20,000 IU/ml (Table).

Conclusions: This study suggests that 3TC monotherapy is efficacious in HIV-HBV co-infection when baseline HBV DNA<20,000 IU/ml. Studies with long-term follow-up are warranted to confirm this conclusion.
WEPEB315
Analysis of current costs and target prices for entecavir, to treat hepatitis B worldwide
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Background: In 2013, an estimated 686,000 people died from Hepatitis B infection worldwide. Mass treatment programmes for Hepatitis B will require drugs available at very low costs.

International treatment guidelines recommend first-line monotherapy with either entecavir or tenofovir. While the basic patent on tenofovir expires in 2017, entecavir is already generic in several countries, including USA. The chemical structure of entecavir is closely related to abacavir, which costs <$200 per person-year in low-income countries at the dose of 600mg OD, versus 0.5mg OD for entecavir.

Methods: The clinical efficacy, chemical structures, daily doses, routes of chemical synthesis, costs of raw materials and patent expiry dates were analysed for entecavir and tenofovir. Costs of sustainable, generic production were calculated for entecavir, and compared with published originator and generic prices worldwide. Target prices assumed at least 5 million people with chronic HBV treated worldwide (less than 3% of worldwide HBV epidemic).

Results: With a daily dose of 0.5mg, one year’s supply of entecavir treatment requires 0.11g of Active Pharmaceutical Ingredient (API) per person, estimated to cost $4.54/year, based on quotations of API production from generic suppliers. With an additional $20 per year for formulation / packaging and a 50% profit margin, entecavir was estimated to cost a minimum of $36 per person-year, substantially lower than current originator and generic prices (Figure).

Conclusions: Mass treatment for Hepatitis B with generic entecavir could be achieved with very low costs (minimum $36 per person-year) in high-, middle- and low-income countries. There would be no patent restrictions to mass generic production of entecavir in most countries. However these low prices could only be achieved if volume demand increases to at least 5 million people treated with entecavir worldwide. Use of entecavir could avoid the renal and bone toxicities from long-term use of tenofovir, which is also still patented in many countries.

WEPEB316
Five-year long-term follow-up of serological responses to vaccination with two versus three doses of hepatitis A virus vaccine in HIV-infected patients receiving combination antiretroviral therapy
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Background: Whether vaccination with three doses of hepatitis A virus (HAV) vaccine, administered at week 0, week 4, and week 24, may achieve more durable serological responses than with two doses administered at week 0 and week 24 remains unknown in HIV-infected patients receiving combination antiretroviral therapy.

Methods: Between June, 2009 and December, 2010, 365 HIV-infected MSM aged 18 to 40 years who were seronegative for HAV were enrolled to receive two doses of HAV vaccine (1440 ELISA units) (n=140) or three doses (n=225). Antibody titers were determined at weeks 24 and subsequently every 24 weeks for a total of 5 years. An-HAV antibody titers were determined with the use of a commercially available enzyme-linked immunosorbtent essay (ELISA) method. Seropositivity for HAV was defined as an anti-HAV antibody titer >20 mIU/mL. The generalized estimating equations (GEE) to account for the interdependence among observations were used to compare mean response rate to different HAV doses, with adjustments made for clinical characteristics such as ART coverage, baseline and follow-up CD4 count as well as PVL.

Results: Throughout the 5-year longitudinal follow-up, patients receiving 3 doses of HAV had statistically significantly higher geometric concentrations of anti-HAV antibody than those receiving 2 doses (1.9±1.7 log10, mIU/mL at two through five years of follow-up), so were the rates of seroconversion for HAV (84.1 vs 80.3% at year 2; 86.8 vs 76.8% at year 3; 84.7 vs 74.8% at year 4, and 85.5 vs 77.1% at year 5). In multivariate analysis regarding GEE approach to define the factors associated with persistent serological responses between the second to the fifth years of follow-up, vaccination with 3 doses of HAV (adjusted odds ratio, 1.71; 95% CI, 1.02-2.85; P=0.04) and CD4≥350 cells/mm3 at time of vaccination (aOR, 2.65, 95% CI, 1.55-4.60; P=0.003) were significantly associated with persistent serological responses.

Conclusions: HIV-infected patients received three doses of HAV vaccine at CD4≥350 cells/mm3 achieved a more durable serological response than those who received two doses following vaccination in the era of combination antiretroviral therapy.
Human papillomavirus

WEPEB318

Comparison of anal cytology and human papillomavirus infection between HIV-positive and HIV-negative men in Taiwan

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Background: Men who were infected with human immunodeficiency virus (HIV), especially men who have sex with men (MSM), are at increased risk of developing anal cancer. To our knowledge, anal cytology and human papillomavirus (HPV) detection were not widely adopted in Taiwanese HIV care providers. The aim of this study was to explore the difference of anal cytology and HPV detection among HIV-positive and HIV-negative men.

Methods: Between March 2013 and December 2014, HIV-infected men who attended the outpatient clinic of Taoyuan General Hospital, Taiwan, had been enrolled voluntarily. HIV-negative men who had experienced unsafe sex and counseled for HIV test, had been enrolled for comparison. All of the subjects completed the self-administered questionnaire. Anal swabs were collected for thin-preparation anal cytology and linear array HPV genotyping testing.

Results: Totally 496 subjects were enrolled. There were 288 subjects who were HIV-infected, and 208 subjects who tested HIV-negative. Their mean ages were 30.6 years. Among them, 75% of HIV-infected men and 30.3% of HIV-negative men were tested any HPV positive (P<.001). And, there were 59.7% of HIV-positive men and 22.1% of HIV-negative men having oncogenic HPV (P<.001). HPV type 16, 11, 16 and 51 were commonly encountered genotypes. Anal cytology yielded atypical squamous cells with undetermined significance or higher grades (ASC-US+) in 20.8% of HIV-positive men and 4.7% of HIV-negative men (P<.001). In multivariable analysis, HIV infection (odds ratio [OR], 2.34; 95% confidence interval [CI], 1.04-5.24); history of sexually transmitted infections (STIs) (OR, 2.24; 95% CI, 1.09-4.76); number of oncogenic HPV types (OR, 1.35; 95% CI, 1.09-1.67); number of nononcogenic HPV types (OR, 1.24; 95% CI, 1.03-1.49), and MSM (OR, 5.58; 95% CI, 1.02-20.49) were correlated significantly with anal cytology yielding ASC-US+.

Conclusions: Our data indicates that HIV-infected men who were MSM, having past history of STIs and being infected with various types of HPV were prone to have anal cytological abnormalities. Large scale of anal screening would be suggested for anal cancer prevention.

WEPEB319

Genital shedding of Epstein Barr virus (EBV) is associated with higher prevalence and persistence of anal human papilloma virus (HPV) in HIV-infected men on antiretroviral therapy (ART)

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Background: Several studies described the co-occurrence of EBV and HPV in pharyngeal and cervical malignancies. We investigated if genital EBV shedding is associated with prevalence and persistence of HPV in HIV-infected men who have sex with men (MSM) on suppressive ART (<50 copies/ml).

Methods: 131 HIV-infected MSM were followed for 12 months and screened for multiple co-infections at several sites, including seminal EBV DNA by RT-PCR, and mRNA from the E6/E7 oncogenes for 14 high-risk HPV types (16/18/33/35/39/45/51/52/56/58/59/66) by Aptima in semen, rectum and pharynx. Primary analysis tested if seminal EBV shedding was associated with increased HPV prevalence at baseline using univariate tests and multivariable logistic regression. In participants with detectable rectal HPV at baseline, we tested if presence of genital EBV shedding at baseline also predicted reduced HPV clearance by log-rank test. Possible confounders (number of sex partners, CD4 count and plasma HIV RNA [<50 copies/ml or 50-500 copies/ml]) were included in the final model if p<0.05 in univariate analysis.

Results: Baseline prevalence of HPV was: rectal 44% (N=54/121), pharynx 3.9% (N=5/131); semen 7.1% (N=7/98). Seminal EBV shedding was detected in 27% (N=36/131). At baseline, EBV shedding was associated with more than double the prevalence of detectable rectal HPV and/or RNA (71.4% for EBV shedders versus 33.3% for non-shedders, p=0.01). There was no significant difference in detectable HPV in pharynx (2.9% versus 4.2%, p=1.00), and semen (11.5% versus 6.6%, p=0.38) between groups. In multivariable models, the odds ratio (OR) of positive rectal HPV was significantly higher in subjects with compared to without detectable EBV shedding after accounting for CD4 count and plasma HPV of 50-500 copies/ml (adjusted OR: 3.9 [95%CI: 2.3-5.3]; CD4 and HIV RNA, both p<0.05). In those with detectable rectal HPV at baseline, we found increased persistence of HPV over 12 months of follow-up (measured as time to first negative HPV test) in the EBV shedding group (p<0.01).

Conclusions: Seminal EBV shedding was associated with an increased risk of having detectable rectal HPV in a cohort of HIV-infected MSM on suppressive ART. Future studies should examine how co-infection with EBV and HPV may act synergistically in pathogenesis of ano-rectal cancer in HIV-infected individuals.
WEPEB321
Should we consider anal cancer screening in women living with HIV? Results from the EVVA study on anal intraepithelial neoplasia prevalence and acceptability of screening

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Background: Many experts recommend screening for anal cancer in people living with HIV (PLWHIV), given disproportionately high rates of this cancer in this population. Various tools can be considered for screening, but their acceptability is necessary for screening programs to be successful. The EVVA study (Evaluation of HPV, HIV and AIN in women) was conducted in Montreal, Canada, to measure the prevalence of AIN and assess the acceptability of screening in women living with HIV (WLWHIV).

Methods: EVVA is an ongoing cohort study of 150 WLWHIV. Study visits include cervical/anal HPV testing and cervical/anal cytology every 6 months for 2 years. A systematic HRA was performed at baseline and 2 years in all women, and an acceptability questionnaire was completed at the last visit (or at study withdrawal).

Results: At time of analysis, 150 women had completed the baseline visit and 56 had completed the acceptability questionnaire. Participants’ mean age was 47 (range 34-67). Prevention high-grade AIN was identified in 20 women (13%, 95% Confidence Interval 8.3-19.8%). Regarding acceptability, 78% (46/59) considered routine anal cancer screening in WLWHIV to be an absolute necessity (65-68%). Pain during anal cytology and DRE were considered similar to cervical cytology and graded with a median of 11/10. HRA was considered more painful by 83% (43/59) and graded with a median of 6/10. Yearly cervical cytology (current practice in WLWHIV) was described as very acceptable by 85% (50/59). Anal cytology was considered very acceptable yearly by 77% (44/59), and every 2-5 years by 93% (54/59). DRE was described as very acceptable every 2 years by 75% (43/59), every 5 years by 80% (52/65) and every 10 years by 92% (54/59). Pain was the main reason for low acceptability. Only one participant (2%) was opposed to screening. Embarrassment, sexual assault connotations, inconvenience, and perceived non-necessity were mentioned in comments.

Conclusions: AIN is highly prevalent in WLWHIV, and the vast majority of participants considered screening necessary and very acceptable. Pain management can be improved and potential adverse psychological effects of screening should be explored.

WEPEB322
HIV-associated neurocognitive disorder (HAND)

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Background: Antiretroviral drug (ART) concentration in cerebral spinal fluid (CSF) is widely utilised as a surrogate for central nervous system (CNS) drug exposure. However, this is a pharmacokinetic measurement with no assessment of pharmacodynamic effects. We have developed a novel CNS pharmacodynamic endpoint measurement whereby we assess the antiretroviral efficacy of CSF collected from subjects on antiretroviral therapy.

Methods: CSF samples were obtained from patients in a ‘Rilpivirine CSF study’ (n=10) and a ‘Maraviroc CNS study’ (n=12). All patients were receiving tenofovir and emtricitabine (245/200 mg once daily) as a backbone. In addition, patients received either rilpivirine (25mg once daily) or boosted lopinavir/ritonavir (450/150mg twice daily). CSF HIV-1 RNA load was undetectable in all cases. CSF samples from HIV-1 uninfected individuals without co-morbidities were used as controls (n=3). Anti-viral activity of ARV-containing CSF was assessed in PBMCs and neurologically derived cell-lines (373 and U87). Cell cultures were exposed to CSF in serial dilutions (1:2) prior to challenge with a brain-derived HIV strain (T2U). Infectivity model half maximal inhibitory concentrations (IMIC50) were calculated from sigmoid curve fits with 95% confidence intervals, and expressed as -Log IMIC50. These results were correlated with the concentration of ARVs in the CSF.

Results: From both studies demonstrated in vitro antiviral activity in all models when compared to controls. CSF anti-viral activity from patients on the ‘Maraviroc CNS study’ was significantly greater than CSF patients on the ‘Rilpivirine CSF study’.

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No significant correlations between individual CSF anti-viral activity and maraviroc CSF concentrations were observed. However, significant positive correlations were observed for individual CSF anti-viral activity with lopinavir CSF concentrations in 373 and U87 (p=0.04 and p=0.02, respectively) and with rilpivirine CSF concentrations in 373 and PBMCs (p=0.04 and p=0.04, respectively).

Conclusions: Anti-viral activity of CSF from patients participating in two controlled clinical studies was successfully calculated. Statistically significant differences between anti-viral activities of CSF from patients taking differing regimens were observed. Positive correlations between CSF anti-viral activity and ARV concentration of the third drugs rilpivirine and lopinavir indicate that these ARVs may drive anti-viral activity of these ARV combinations in the CSF.

WEPEB323
iMap: creating maps from longitudinal MR brain images of aging HIV population to drive HAND characterization

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Background: HIV-Associated Neurocognitive Disorders (HAND) are common in chronic HIV-infected (HIV+) patients over the age of 50. HAND can present in older patients similar to age-related neurodegenerative conditions, such as Alzheimer’s Disease (AD). This results in an emerging clinical dilemma. Brain imaging is a promising approach, since HAND likely has unique regional tissue atrophy patterns enabling differential diagnosis from other neurodegenerative disorders. Most brain imaging studies are limited by the assumption that selected clinical and demographic attributes are sufficient to define patient groups with homogeneous morphometry. Instead, we propose a data-driven approach, called iMap, that searches for identifying markers specific to HAND across two independently collected datasets by first grouping subjects according to structural attributes (e.g., gray matter heterogeneity) rather than presumed clinical markers.

Methods: We propose to apply iMap to a dataset (called HIV+) consisting of 50 longitudinal brain MRI scans from the UCSF Valour Lab (called HIV+), and 206 MRIs from the Alzheimer’s Disease Neuroimaging Initiative (called HIV-), which are matched with respect to age, gender, time between scans. iMap acknowledges the anatomical heterogeneity of HIV+ by grouping MRIs according to common image patterns such as shown by the map shown below.

These maps can represent the gradual transition of morphometric patterns associated with different diagnostic groups, such as HIV+ patients with normal cognition (HNC) and HAND. We will use these maps to separate HIV+ into cohorts with distinct morphometric patterns, homog- enous within each cohort, and analyze the diagnostic power of these patterns.

Results: Applied to 119 MRIs, iMap’s accuracy is 88% in separating healthy controls from AD of the HIV dataset. Simulating a modified hypergeometric distribution based on these results, we would have 99% power to reject the null hypothesis of not distinguishing HAND from
Eliciting cognitive difficulties experienced by people living with HIV

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Backgrounds: People living with HIV often report deteriorating cognition even with excellent systemic viral control. Clinicians lack the tools to systematically elicit and document cognitive concerns. Instruments used in the research setting are often too long for clinical use, while briefer questionnaires developed in other health conditions may not probe into areas that are problematic for people living with HIV. The overall aim of this study is to create a bank of items reflecting the cognitive concerns expressed by people living with HIV.

Methods: We followed the steps outlined by the FDA for developing a patient-reported outcome. Semi-qualitative interviews on an international sample of 234 HIV+ individuals were carried out in 3 independent waves using an anonymous web-based survey (Canada) and face-to-face interviews (9 countries). The reported cognitive concerns were mapped to standard neurocognitive domains to identify content coverage, and compared with the domains in existing cognitive questionnaires. All items reflecting distinct concerns were compiled to create a bilingual questionnaire that was then posted on HIV community web sites across Canada to obtain estimates of prevalence and importance. Rasch analysis was used to calibrate the items and validate short forms to fit different purposes (screening, prevalence, and change over time).

Results: 136 distinct cognitive concerns were organized in the conceptual model of 15 neurocognitive domains plus emotional concerns and change. None of the generic or HIV specific questionnaires of cognitive difficulties came close to this extent of content coverage. Memory concerns were the most common (40 items) and covered prospective, episodic, semantic, immediate and procedural memory; 15 items related to attention; 12 items were identified for each of language and executive function; 4 and 3 items related to visuospatial domain and calculation.

Conclusions: This study has identified several areas of cognitive concerns in persons living in HIV, many of which were not captured by any of the existing questionnaires. This process of due diligence has contributed unique information that will serve as the basis of the development of an HIV-specific instrument. Once finalized, comparative values will be obtained from people without HIV in order to inform clinical interpretation.

A novel method of measuring change in cognitive ability developed from CHARTER data could support international collaborations

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Backgrounds: Measuring change in cognition, a key aspect of neuroHIV research, requires summarizing results from several neuropsychological (NP) tests into a single score and calculating the difference between two test times. Raw scores are normalized using population norms, then averaged. The first step requires suitable norms which are often not available; the second step, averaging, assumes that each test contributes equally to the measure of the global construct, which may not be true. We propose a method of measuring cognitive ability that produces a summary value with mathematical properties suitable for measuring change and that does not require norms. The specific aim of this study is to estimate the extent to which raw scores from multiple NP tests can be combined on a single calibrated measurement scale.

Methods: As part of the CHARTER study, HIV+ individuals were administered a battery of 15 NP tests every 6 months. Raw scores from all tests and all time points were combined, and Rasch analysis was applied to create calibrations for each test along a common metric.

Results: 701 patients were evaluated semi-annually for 38.5 ± 30.9 months. Data from 5244 testing sessions were available for analysis. The number of discriminatory thresholds varied across tests. All 15 tests could be combined into a single measure that fits the unidimensional and hierarchical Rasch model, creating a summary score with strong measurement properties that covered a broad range of cognitive abilities (equivalent to +3 to -6 SD units, see Figure 1). The same hierarchy was observed regardless of age, gender, education, and testing session.

Conclusions: The proposed sample size should be more than sufficient for Imap to identify markers important for meeting the emerging clinical need to distinguish cognitive impairment effects of HIV from age-related neurodegenerative conditions.

Asymptomatic neurocognitive impairment (ANI) is associated with progression to symptomatic HIV-associated neurocognitive disorders (HAND) in people with HIV: results from The Ontario HIV Treatment Network (OHTN) cohort study

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Background: HIV-associated neurocognitive disorders (HAND) remain prevalent in people living with HIV. A recent study from the US CHARTER Cohort (Grant et al, 2014) has shown that Asymptomatic Neurocognitive Impairment (ANI) is associated with a 2-to-6 fold increased risk for the development of symptomatic HAND, i.e., mild neurocognitive impairment (MNI) or HIV-associated dementia (HAD). The objective of this study is to replicate and extend these results in a Canadian sample.

Methods: Study sample included 679 adults living with HIV (81% men, 62% Caucasian, 83% on cART, 72% with undetectable HIV viral load) in Toronto, Canada and who were either normal on neuropsychological (NP) testing (NP-Normal; n=357) or had ANI (n=322) at baseline. Annual NP testing was done with brief NP battery that included measures of processing speed, attention/working memory, and learning/memory (i.e., WAIS-R Digit Symbol, Grooved Pegboard, WMST-Spatial Span, and Hopkins Verbal Learning Test-Revised). Cognitive complaints were assessed with four-item Medical Outcomes Studies Cognitive Functioning scale. HAND status was assigned according to established criteria (Antinori et al., 2007). Cox proportional hazards regression model was used to estimate risk ratios for progression to symptomatic HAND.

Results: Over the follow-up period (median: 34 months), 150 individuals (59% NP-Normal and 91% with ANI at baseline) showed progression to symptomatic HAND. Participants with ANI had shorter time of progression than those who were NP-Normal at baseline, after adjusting for baseline and time-varying covariates: adjusted hazards ratio of 1.74 (95% confidence interval: 1.23-2.45, p=0.001). Among covariates examined, depression (HR=1.84, p=0.001), current cigarette smoking (HR=1.57, p=0.008), and non-Caucasian ethnicity (HR=1.62, p=0.006) were significantly associated with elevated risk of progression; whereas undetectable plasma HIV viral load was marginally associated (HR=0.68, p=0.058) with decreased risk of progression to symptomatic HAND.

Conclusions: Asymptomatic Neurocognitive Impairment is associated with almost a two-fold increased risk of progression to symptomatic HAND in our sample. Early treatment with combined antiretroviral therapy (cART) and addressing medical and mental health comorbidities may delay or lower the risk for the development and progression of symptomatic HAND.
WEPEB327
International neuropsychological normative study; neurocognitive comparison data in diverse resource-limited settings ACTG A5271
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Background: Neuropsychological impairment with ART remains prevalent despite substantial reductions in HIV Associated Dementia. There is a lack of infrastructure for conducting neurocognitive research in resource-limited settings (RLS), including training in neurological and neuropsychological (NP) assessment, and the lack of normative data needed for clinical interpretation. A5271 provided neurological training of clinical site personnel, and collected normative comparison data.

Methods: In seven RLS countries, we provided training for site personnel on the conduct of neurological and neuropsychological assessments. We collected normative comparison data on high risk HIV negatives from 10 sites in seven countries. Participants from Brazil (n=240), India (n=480), Malawi (n=481), Peru (n=239), South Africa (450), Thailand (n=240) and Zimbabwe (n=240) were enrolled at voluntary counseling and testing (VCT) sites aligned with the ACTG PEARLS (A5175) and International Neurological Study (A5198). Standardized NP exams were administered at baseline and at a six-month follow up in a subset. Participants presenting for HIV testing within 30 days at a VCT site were required to have a negative HIV test before participation at baseline and follow up. Strata were defined for country, gender, education (<10 years and ≥10 years), and age (<35 years and ≥35 years).

Results: Of the 2576 participants screened, 2400 were enrolled, and 770 completed the six-month follow up. The overall neurocognitive test means and SD's at baseline are presented in Table 1. Considerable between-country differences in the neurocognitive test scores were found as expected. For example, delayed recall differed across the sites (mean (SD)) of J ohannesburg (8.64 (2.30)), Durban (6.82 (2.30)), Lima (7.65 (2.32)), Chiang Mai (7.85 (2.32)), Pune (7.53 (2.22)), Chennai (8.88 (2.40)), Lignonville (6.94 (2.17)), Blantyre (7.96 (1.97)), Rio de Janeiro (7.47 (2.40)), and Zimbabwe (9.94 (2.26)) compared to the total sample (7.88 (2.35)). There was also variation across the age, gender and education strata.

Conclusions: Cultural, socioeconomic and likely many other factors underlie the country variations observed. This study provides infrastructure for future neurological and neurocognitive studies in diverse RLS and the normative data provided are a much needed resource for clinicians and researchers conducting neurological and neuropsychological assessment.
WEPEB330

The utility of Beck Depression Inventory (BDI)-adapted: cut-off scores for depressive symptoms screening in a specialized clinic in Mexico City. A two years' experience

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Background: In recent decades, the Beck Depression Inventory (BDI-II) has shown adequate psychometric properties in the general and various clinical populations in Mexico. Based on a previous study with Mexican HIV patients, we obtained an abbreviated version of the questionnaire to facilitate and shorten the application (BDI-II, Cronbach alpha = 0.91). Therefore the aim of this study was to obtain discriminant validity (sensitivity and specificity) of BDI-hiv against clinical diagnoses: depressive episode (F32), adjustment disorder (F43.2) and without symptoms of mental disorder (F999).

Methods: Archival data from 1761 patients assessed for mental health first time between 2013 and 2014, was analyzed. 1113 participants were selected who had an interview with ICD-10 diagnosis and also completed the BDI-hiv. ROC curves method was used for discriminant validity & Student 't test to analyze differences between viral load (VL) ≤ 5 x 1000. The statistical analysis was performed using SPSS v20. A p ≤ 0.01 was considered to be significant.

Results: Findings show that 89% were men, age of 31 ± 9.3 years, 12.0 ± 3.6 education years, 4.5 ± 4.5 years of diagnosis, VL average 250,858 ± 896,777, CD4 of 327 ± 238 and 44% treatment ART. 33% of the sample had no symptoms (F999), 31.5% had F43.2 and 13% and F32. The ROC area showed that cutoff of 5 ICD-hiv discriminate between F999 and F32, with adequate sensitivity and specificity (85.5% and 76%, respectively) with the area under the curve (AUC) = 0.865, 95% CI [0.83, 0.90], p ≤ 0.001. A cutoff 11 BDI-hiv discriminate between F999 and F10 diagnosis and also completed the BDI-hiv. ROC curves method was used for discriminant validity & Student 't test to analyze differences between viral load (VL) ≤ 5 x 1000. The statistical analysis was performed using SPSS v20. A p ≤ 0.01 was considered to be significant.

Conclusions: Our data support the clinical usefulness of this version for screening adjustment or depressive symptoms in this clinical population. The BDI-hiv has practical advantages of faster application and reduced burden on patients. We recommend a cutoff of 5 to discriminate between depressive/non-depressive symptoms, and an 11 to discriminate between adjustment/depressive symptoms.

WEPEB331

Maternal depression and maternal infant health outcomes among HIV-infected women in Kenya

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Background: Depression in HIV infected women may influence maternal and infant health outcomes.

Methods: A cross-sectional survey of mother-infant pairs attending week-6 and month-9 immunization visits in 140 maternal child health (MCH) clinics throughout Kenya was conducted between July and December 2013. Clinics were selected using probability proportionate to size sampling. Depression was assessed using the PHQ-9 screening instrument. Depression was defined as a PHQ-9 score ≥ 5, indicating at least mild depression. Data on maternal and infant health in the preceding month were obtained. Multivariable logistic regression models were used to determine prevalence, correlates, and association of maternal depression with maternal and infant health outcomes. Regression models were adjusted for clustering effects at clinical level, maternal and infant characteristics.

Results: Among 498 HIV infected women attending MCH, 116 (23%) had at least mild depression as measured by PHQ-9 criteria. Depression prevalence was comparable among the 9-month postpartum (21%) and 6-week postpartum visit cohorts (26%). Older mothers (aOR=1.28 per year (1.06-1.59), p=0.008), and those who reported intimate partner violence (aOR=2.28 (1.47-3.54), p=0.011) were significantly more likely to meet criteria for depression. Maternal depression was associated with infant symptoms including coughing (aOR=1.73 (1.09-2.75), p=0.020), difficulty feeding (aOR=2.80 (1.15-6.80), p=0.023), and vomiting (aOR=2.11 (1.12-3.44), p=0.021).

Depression was also associated with increased infant stunting (length-for-age z-score < -2) and anemia (p=0.01), however, this was not statistically significant (aOR=1.51 (0.93-2.45), p=0.098). Mothers with depression were less likely to exclusively breastfeed for at least 6 months (aOR=2.1 (0.90-4.8), p=0.001). Among women attending 9-month postpartum visit, prevalence of depression was significantly higher among those with HIV-infected infants (67% versus 19% for those with infected vs. uninfected infants, p<0.015).

Conclusions: Prevalence of depression among HIV-infected mothers was high and was extremely high among women with HIV-infected infants. Maternal depression was associated with lower rates of exclusive breastfeeding and with higher rates of infant symptoms. Interventions to address maternal depression in HIV-infected women may be useful to improve both maternal and infant outcomes.

WEPEB332

Determinants of quality of life in a cohort of people living with HIV in Nigeria

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Background: An increasing number of persons are living with HIV in this era of effective antiretroviral treatment (ART). Quality of life (QOL) is an important measure of medical outcome and well-being in this population. Few studies have reported on the factors that determine QOL of HIV infected persons in Nigeria, a country with the second largest population of people with HIV in the world.

Methods: Eight hundred and twenty-eight HIV patients randomly selected from the ART clinic of the University College Hospital, Ibadan, Nigeria were interviewed using the WHO Quality of Life instrument (WHOQOL-HIV BREF) and the Composite International Diagnostic Interview version 10.0 (CIDI-10) to ascertain the presence of depression or anxiety disorders. The associations of demographic and health-related factors with overall and domain scores on the six domains of WHOQOL-HIV were explored using linear regression models.

Results: The mean age of the sample was 41.3 years (SD=10) and 71.1% were female; 57.4% were married, 25% single, 17.6% widowed and 41.3% had 6 years or less of education. The median CD4 count was 385 cells/mm3 and 91% were on antiretroviral medication. A total of 66 (8.0%) met DSM-IV diagnostic criteria for major depression and/or generalized anxiety disorders; 55 (6.6%) had depression only, 9 (1.1%) had anxiety alone and 2 (0.2%) had comorbid depression and anxiety. Lower overall QOL was associated with female gender (p=0.002), being a widow (p=0.003), having fewer years of education (p=0.001) and having depression and/or generalized anxiety disorder (p=0.001). The presence of depression and/or anxiety disorder (related to 5 of the 6 domains of the WHOQOL-HIV instrument (coefficients ranging from 0.72-1.35 and p<0.001), lower education and gender were the most consistent factors predicting domains of QOL. Receiving antiretroviral medication emerged as a significant predictor of better health related QOL (B=0.591, p<0.001).
WEPEB333
Depression and anxiety amongst HIV-infected individuals enrolled in a public sector antiretroviral programme in Thailand

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Backround: HIV/AIDS and anxiety/depression are interlinked. HIV-infected patients suffering from depression may be more likely to have problems with adherence which may in turn result in HIV disease progression. Additionally, HIV diagnosis and/or using certain CART may trigger symptoms of anxiety/depression. We explored the prevalence and factors related to anxiety and depression in HIV-infected patients enrolled at 3 clinical sites within the Thai National HIV Treatment Program.

Methods: From January 2012 to December 2013, a cross sectional study was performed among HIV-infected out-patients aged ≥18 years attending Bannasaranaidh Infectious Institute and Thai Red Cross AIDS Research Centre, in Bangkok and Sanpatong hospital in Chiang Mai. Symptoms of anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS). An 8+ cut-off was used to identify possible cases of anxiety and depression. Multivariate logistic regression was performed to identify associated factors.

Results: Totally 2,023 (male 57%) patients were included. The prevalence of anxiety and depression were 4.8% and 3.1%, respectively; 1.3% had both anxiety and depression. In multivariate logistic models, female gender [OR=1.6 (95%CI:1.1-2.3), P=0.01], having adherence <90% [OR=2.2, (95% CI:1.5-3.4), P<0.001], fair or poor quality of life [OR=7.2, (95% CI:3.6-14.2), P<0.001] and efavirenz exposure [OR=1.6 (95% CI:1.1-2.3), P=0.001] were associated with higher anxiety or depression.

Conclusions: In this cross sectional study, female gender, poor adherence, poor/fair quality of life and efavirenz use was associated with symptoms of anxiety and depression. A brief screening test to evaluate anxiety and depression symptoms prior and during CART can help to identify those most at risk so that interventions can be implemented early. Particular attention should be given to female patients and those using efavirenz.

Malignancies (including Kaposi sarcoma, lymphoma, and non-AIDS malignancies)

WEPEB334
Treatment tolerability for squamous cell carcinoma of the anus (SCCA) among HIV+ patients on ART

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Background: Concurrent chemoradiotherapy remains the standard treatment for invasive squamous cell carcinoma of the anus (SCCA). There are limited data regarding antiretroviral era survival and treatment tolerability among HIV+ patients with SCCA. Previous data have demonstrated increased acute toxicity and poorer clinical outcomes among HIV+ patients undergoing treatment compared to HIV- patients.

Methods: We used data from the Surveillance, Epidemiology, and End Results (SEER) registry linked to Medicare claims to assess treatment adverse reactions in a cohort of male HIV+ and HIV- patients diagnosed with SCCA from 1997 to 2009. Outcomes included all-cause and anal cancer-specific mortality and treatment-associated toxicities. We used Kaplan-Meier methods to compare overall survival and anal-cancer specific survival among treated patients by complication status as well as by HIV status.

Results: 1,000 male patients with incident SCCA were included in our cohort, of whom 368 were HIV+. When compared to HIV- patients, HIV+ subjects were younger and had lower comorbidity scores in both earlier and later staged SCCA (Table 1). For early stage SCCA, HIV+ subjects had lower rates of all cause and anal cancer-specific mortality. There was no differ-
WEPEB336
The CD206 macrophage mannose receptor acts a localization portal for targeting tumor cells and associated macrophages in HIV associated Kaposi’s sarcoma

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**Background:** Inflammation plays a role advancing HIV-associated Kaposi’s sarcoma (KS). Macrophages (MØs) within KS lesions provide tumor cell growth factors, which may result from HIV activation in the microenvironment. Emerging data show that KS tumor cells co-express various MO antigens that become resistant to anti-viral therapies. MOs driving these pathological pathways share a common element, the CD206 macrophage mannose receptor. In this study, we evaluate a KS targeting agent, Manocept, which can enter tumor cells and tumor associated macrophages (TAMs) via pinocytosis of holo-CD206.

**Methods:** A single-genome sequencing approach targeting HIV env-ref was applied to DNA and cDNA generated from multiple KS biopsies and non-tumor sites in three individuals. Phylogenetic analysis estimated the evolutionary history of HIV in their tumors. The cellular location of HIV in KS tumor microarrays was assessed using in situ amplification. Synthetic Manocept with a dextran backbone, 12-20 mannose moieties, and a fluorescent tracer (Cy3) was used to locate Manocept on and in MØs and KS tumor cells. Localization Cy3-Manocept was assessed through flow cytometric quantification of Cy3-Manocept uptake using in vitro generation of monocyte-derived CD206+ MØs. The fresh HIV+ KS tissue culture followed by immunofluorescence staining and confocal imaging was performed to confirm Cy3-Manocept uptake in KS tumor cells and TAMs.

**Results:** Phylogenetic analysis demonstrated that HIV was frequently compartmentalized within tumors (p< 0.05) and originated years before HIV at non-tumor sites. In situ amplification showed HIV expressed in KS immune cells. Increasing Cy3-Manocept concentrations confirmed continuous uptake of Manocept into CD206+ MØs. HIV+ KS tissue culture studies showed both Manocept uptake and CD206 staining of TAMs and KS tumor cells (HIV+cells). Cy3-Manocept co-localized with CD206 in nearly all KS-associated cells expressing HHV8 and/or CD68, confirming that CD206 acts both as a target and Manocept concentrating receptor for TAMs and KS tumor cells.

**Conclusions:** HIV is present in KS tumors where it can compartmentalize, activate immune cells and provide growth factors for KS. Manocept can be used for imaging KS tumor cells, TAMs, and more importantly, for delivery of therapeutic/diagnostic agents capable of targeting all KS-associated cells including a potential MØ reservoir for HIV.

WEPEB337
Safety and efficacy of antiretroviral therapy in HIV-infected adults undergoing autologous or allogeneic stem cell transplant for hematologic malignancies

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**Background:** Infection plays a role advancing HIV-associated KS (KS). Macrophages (MØs) within KS lesions provide tumor cell growth factors, which may result from HIV activation in the microenvironment. Emerging data show that KS tumor cells co-express various MO antigens that become resistant to anti-viral therapies. MOs driving these pathological pathways share a common element, the CD206 macrophage mannose receptor. In this study, we evaluate a KS targeting agent, Manocept, which can enter tumor cells and tumor associated macrophages (TAMs) via pinocytosis of holo-CD206.

**Methods:** A single-genome sequencing approach targeting HIV env-ref was applied to DNA and cDNA generated from multiple KS biopsies and non-tumor sites in three individuals. Phylogenetic analysis estimated the evolutionary history of HIV in their tumors. The cellular location of HIV in KS tumor microarrays was assessed using in situ amplification. Synthetic Manocept with a dextran backbone, 12-20 mannose moieties, and a fluorescent tracer (Cy3) was used to locate Manocept on and in MØs and KS tumor cells. Localization Cy3-Manocept was assessed through flow cytometric quantification of Cy3-Manocept uptake using in vitro generation of monocyte-derived CD206+ MØs. The fresh HIV+ KS tissue culture followed by immunofluorescence staining and confocal imaging was performed to confirm Cy3-Manocept uptake in KS tumor cells and TAMs.

**Results:** Phylogenetic analysis demonstrated that HIV was frequently compartmentalized within tumors (p< 0.05) and originated years before HIV at non-tumor sites. In situ amplification showed HIV expressed in KS immune cells. Increasing Cy3-Manocept concentrations confirmed continuous uptake of Manocept into CD206+ MØs. HIV+ KS tissue culture studies showed both Manocept uptake and CD206 staining of TAMs and KS tumor cells (HIV+cells). Cy3-Manocept co-localized with CD206 in nearly all KS-associated cells expressing HHV8 and/or CD68, confirming that CD206 acts both as a target and Manocept concentrating receptor for TAMs and KS tumor cells.

**Conclusions:** HIV is present in KS tumors where it can compartmentalize, activate immune cells and provide growth factors for KS. Manocept can be used for imaging KS tumor cells, TAMs, and more importantly, for delivery of therapeutic/diagnostic agents capable of targeting all KS-associated cells including a potential MØ reservoir for HIV.
WEPEB339
Speckle tracking echocardiography-derived myocardial strain abnormalities in PLHV

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Background: While left ventricular ejection fraction is a commonly reported measure of left ventricular (LV) function, emerging data suggests that speckle tracking echocardiography (STE)-derived myocardial strain may outperform LVEF as a measure of subclinical dysfunction and in predicting adverse cardiac events.

Methods: 2D STE analyses were performed retrospectively on all transthoracic echocardiograms (TTE) performed in PLHV at Duke University Medical Center between 2001 and 2012. Global longitudinal strain (GLS) was the average of the three apical peak longitudinal strain measurements and global circumferential strain (GCS) was the average of strain measurements for the short axis view at the level of the papillary muscle for the six wall segments. Right ventricular longitudinal strain (RVLS) was analyzed using one apical view of the chamber. Cutoffs for abnormal strain were based on reference values most cited in the literature: > -16% for LV GCS, > -21% for LV GLS, and > -21% for RVLS. Demographic and CAD risk factor data were abstracted from the EMR.

Results: Among 161 PLHV with TTEs reviewed for this analysis, patient characteristics were as follows: median age at TTE 46 yrs [IQR 38,52] ; 58% male; 79% Black, 79% with diagnosis of hypertension; 35% with diagnosis of diabetes; 23% with prior heart failure. At the time of TTE, 27% had undetectable viral load, median proximal CD4 count of 238 cells/mm³ and median CD4+ cell count nadir of 155 cells/mm³.

The prevalence of abnormalities were as follows: 56% for LV GLS, 50% for LV GCS, > -21% for LV GCS and > -21% for RVLS. Demographic and CAD risk factor data were abstracted from the EMR.

Aortic compliance and axial force were lower in EFV-treated mice compared to controls. Compliance was lower at 80-90 mmHg and axial stretches of 1.6-1.8. Aortic IMT and plaque progression were not different across groups.

WEPEB340
Efavirenz leads to arterial stiffening in clinical and experimental settings

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Background: Efavirenz (EFV) is the most prescribed NNRTI-class of HIV-antiretroviral drugs, yet data investigating the role of EFV in cardiovascular disease (CVD) is lacking, particularly in sub-Saharan Africa where much of the HIV burden resides. The objective of this study was to test the hypothesis that EFV treatment mediates arterial stiffening, a key first step in the progression of CVD.

Methods: To test this hypothesis, we performed a cross-sectional clinical study and a parallel mouse study. Adult HIV-negative (n=38), treatment-naive (n=51), nevirapine (NVP)-treated (n=95), or ritonavir-boosted lopinavir (LPV(r))-treated (n=44) subjects were recruited from Black Lion Hospital in Addis Ababa, Ethiopia. Pulse wave velocity (PWV, a marker of arterial stiffness) was measured via applanation tonometry, and carotid intima-media thickness (cIMT) and brachial artery flow-mediated dilation (FMD) were measured via ultrasound. Body mass index, waist-to-hip circumference ratio, skinfold thickness, and self-reported drinking and smoking habits were measured to quantify lipodystrophy. CD4+ cell count, viral load, fasting glucose, total-, HDL-, and LDL-cholesterol, triglycerides, hsCRP, sICAM-1, sICAM-1, leptin and CBC were also measured. This work was approved by the IRB committees at Addis Ababa University and Georgia Institute of Technology. For the mouse studies, ApoE μ/μ mice were given EFV (75 mg/kg/day) (n = 5) via oral gavage for 35 days. Atherosclerotic plaque progression was quantified for thoracic aortas. Experimental procedures were approved by the Georgia Tech IACUC.

Results: PWV, FMD, and cIMT (normalized to inner diameter) were elevated in EFV-treated subjects compared to NVP-treated subjects; normalized cIMT was elevated in the EFV-treated groups compared to treatment-naive subjects. PWV and cIMT were associated with current EFV use.

Sunday June 28
Monday July 6
Tuesday July 7
Wednesday July 8
Thursday July 9
Friday July 10
Saturday July 11
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WEPEB341
Risk of cardiovascular events in efavirenz-containing vs. efavirenz-free antiretroviral therapy

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Background: Efavirenz (EFV) can elevate lipids; however, its impact on cardiovascular (CVD) outcomes is unclear. This study compared the incidence rate and hazards of CV events between patients initiating EFV-containing vs. EFV-free antiretroviral (ARV) regimens.

Methods: This was a retrospective cohort study using commercial and multiple-state Medicare claims data spanning 2005-2013. We identified ARV-naive patients who were age ≥18 years and initiated an EFV-containing or EFV-free regimen with ≥ 6 months of continuous enrollment prior to ARV initiation. Myocardial infarction (MI), stroke, and a composite CV outcome (MI, stroke, percutaneous coronary intervention, and/or coronary artery bypass graft) were ascertained using previously-validated algorithms. Outcomes were identified during an intent-to-treat (ITT) period beginning at ARV initiation and censoring at disenrollment from in-}
Bone disease (including issues related to vitamin D)

WEPEB342
Prevalence and risk factor for low bone mineral density among HIV-infected patients in Thailand


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Background: Low bone mineral density (BMD) is an emerging threat in HIV-infected patients on combination antiretroviral therapy (cART). It has been commonly documented in HIV-infected patients from many Western countries, however, there are scant published data regarding BMD in resource-limited settings, especially in Asia.

Methods: From January 2009 to December 2013, a cross sectional study was performed among HIV-infected patients aged ≥18 years attending routine clinic visits at HIV-NAT, Bangkok, Thailand. BMD of spine and hip were measured with the use of dual-energy X-ray absorptiometry. Logistic regression analyses were performed to identify factors associated with osteopenia and osteoporosis, defined as BMD T-scores between -1.0 and -2.5, and ≤ -2.5, respectively.

Results: Totally 440 (male 68%) patients with a median age of 40 years and body mass index (BMI) of 22.0 kg/m² were included. 19% of female were menopausal. 85.9% of patients were on cART with a median duration of 7.3 years; 85% and 53.4% were taking tenofovir and protease inhibitors (PI), respectively. Osteopenia and osteoporosis were diagnosed in 41.8% and 3.2%, respectively. Although, female was older than male (median 41.1 years vs 39.3 years, p< 0.003); osteopenia was significantly more prevalent in males versus females (75% vs 25%, p=0.004). In multivariate analysis, age >48 years [OR= 2.8 (95%CI 1.5-4.9), p=0.001], male gender [OR= 1.9 (95%CI 1.1-3.1), p=0.01], BMI >18 kg/m²[OR= 3.1 (95% CI 1.7-5.6), p< 0.001] and PI exposure >5 years [OR= 2.5 (95%CI 1.5-4.1), p< 0.01] were significantly associated with reduced BMD. Fractures of the femur and ankle only occurred in two males aged 46 and 48, after a fall. Conclusions: Low BMD was prevalent among HIV-infected Thai adults on cART. Increased age, male gender, lower BMI and exposure to PI were significantly associated with osteopenia/osteoporosis. Our findings highlight the need for screening guideline to identify those most at risk so that effective interventions can be implemented early. Given high prevalence of low BMD in male population, secondary causes of osteopenia/osteoporosis should be further explored.
WEPEB344
Bone mineral density and fat distribution in adults randomized to maraviroc (MVC) once daily with darunavir/ritonavir (DRV/r) vs. tenofovir/emtricitabine (TDF/FTC) with DRV/r: week-48 results from MODERN
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Background: Reduced bone mineral density (BMD) is common in HIV-infected adults taking TDF. TDF-sparing antiretroviral therapy (ART) may decrease bone loss. Maraviroc, a CCR5 receptor antagonist, has shown durable antiviral response with a favorable safety profile.

Methods: In this multicenter, double-blind, Phase III study (MODERN, HIV-1 infected ART-naive adults underwent 1:1 randomization to receive MVC 150 mg OD or TDF/FTC 200/300 mg QD each with DRV/r 800/100 mg QD for up to 96 weeks. At selected sites, a sub-study was conducted to measure BMD at hip, femoral neck and lumbar spine by dual-energy x-ray absorptiometry (DXA), bone turnover markers (BTM; osteocalcin and C-terminal telopeptide [CTX]), and body fat distribution (limb fat, trunk to limb fat ratio by DXA). Sub-study endpoints were analyzed at Week 48. The study was terminated early, in Oct 2013, due to maraviroc arm inferior efficacy.

Results: The DXA analysis included 143 participants (MVC, n=66; TDF/FTC, n=77); median age 34.0 years, 10.6% female, 23.9% non-white, mean body mass index (BMI) 25.4 kg/m². At Week 48, changes from baseline after adjusting for baseline covariates such as age, race, gender and screening BMI are shown in table below. No significant correlations between changes in BMD and changes in osteocalcin or CTX levels were observed. Lower baseline CD4 (<200 cells/µL) was the only observed predictor for larger decrease in hip BMD after adjusting for the covariates (estimate: -2.14%, p=0.0055).

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[Figure 1. Primary and secondary fracture prevention measures]

WePeb344
Decreased bone strength on hip structural analysis in HIV+ adults with versus without fractures
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Background: Bone mineral density (BMD) as assessed by dual-energy x-ray absorptiometry (DXA) is often used to assess fracture risk, but is limited by the lack of a clear fracture threshold and of validation in younger people or patients with HIV. We conducted a pilot case-control study to determine whether bone geometric parameters and estimated strength assessed by hip structural analysis (HSA) correlate with fractures in this population.

Methods: Adults with a history of low-trauma fracture after HIV diagnosis (cases) were matched 1:1 with HIV-infected adults without prior fractures (controls) based on age, sex, race and smoking history. Participants underwent DXA at the hip and lumbar spine, and image files underwent HSA by trained study personnel. The buckling ratio (a measure of cortical stability under compressive loads, i.e. axial strength), section modulus (a measure of bending strength), cross-sectional area and average cortical thickness were compared between cases and controls using Wilcoxon signed rank sum tests, with differences expressed as percentages of control group values.

Results: 23 matched pairs were included, with median (IQR) age 50 (46,56) years, 78% male, 78% white and 57% smokers. Median (IQR) duration of HIV was 19 (11,23) years for cases and 10 (7,16) years for controls. On DXA, cases had significantly lower BMD at the total hip (median difference = -3.4%, p<0.04), but not the lumbar spine (-3.47%, p=0.33). Statistically significant differences on HSA were observed at the intertrochanteric area, where the buckling ratio was 15.1% greater (p<0.01), section modulus was 12.0% lower (p=0.03), cross-sectional area was 13.1% lower (p=0.05) and average cortical thickness was 15.3% lower (p=0.02) among cases than controls (see Table). At the femoral shaft, buckling ratio was significantly greater by 8.46% (p=0.05) and average cortical thickness was significantly lower by 11.1% (p=0.04). Differences at the narrow neck did not reach statistical significance.

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Renal disease

WEPEB347
SNPs of the genes encoding transporter proteins of renal tubular cells do not associate with tenofovir-related renal dysfunction: a pharmacogenetic study

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Background: Tenofovir disoproxil fumarate (TDF) causes mitochondria toxicity in the proximal renal tubular cells, which can lead to tubulopathy and then decrement in renal function. To date, among single nucleotide polymorphisms (SNP) in the genes encoding transporter proteins at kidney tubular cells, only SNPs in the genes have been identified to associate with TDF-related tubulopathy. However, the effect of these SNPs on actual decrement in renal function remains unknown.

Methods: The association between TDF-related renal function decrement and SNPs in the ABC2 gene (rs2248425 and rs2248426) were investigated in 661 Japanese patients who initiated TDF-containing antiretroviral therapy at our clinic. Three renal endpoints were examined by the logistic regression model; decrement in estimated glomerular filtration rate (eGFR) of >10 ml/min/1.73m2 relative to the baseline, >25% decrement in eGFR, and eGFR <60 ml/min/1.73m2 ≥3 months apart.

Results: 66% of the study patients were treatment-naïve [median CD4 246 µ/l, median baseline eGFR 94.4 ml/min/1.73m2 (IQR 88.3-100.6), median exposure to TDF 3.69 years (IQR 1.93-5.58)]. Decrements in eGFR of >10 ml/min/1.73m2 occurred to 284 (70%) of 406, 155 (68%) of 227, and 22 (70%) of 28 patients with genotype C/C, C/T, and T/T at 24, respectively, and to 9 (82%) of 11, 88 (64%) of 137, and 364 (78%) of 513 patients with genotype A/A, A/G, and G/G at 1249, respectively. Decrement in eGFR of >10 ml/min/1.73m2 was not associated with genotypes either at -24 or 1249 of ABC2 (-24, p=0.57; genotype C/C versus T/T, OR 0.8, 95%CI 0.30-1.98; genotype C/T versus T/T, OR 0.7, 95%CI 0.26-3.74) (1249, p=0.24; genotype A/A versus G/G, OR 2.9, 95%CI 0.41-3.90; genotype A/G versus G/G, OR 0.7, 95%CI 0.48-1.09) in the multivariate analysis.

More than 25% decrement in eGFR and eGFR <60 ml/min/1.73m2 were not associated with genotypes at -24 or 1249 either. The results were the same when we applied the dominant, additive, and recessive models instead for statistical analyses.

Conclusions: Although SNPs at ABC2 have been known to associate with TDF-induced tubulopathy, these SNPs did not associate with actual renal function decrement in patients who initiated TDF-containing ART.

WEPEB348
Progressive kidney function decline and increasing incidence of tubular renal alteration in HIV-infected patients receiving a tenofovir-containing regimen

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Background: There are controversial data about the incidence and importance of tubular renal damage and renal function decline in patients on tenofovir (TDF).

Methods: Prospective cohort of 283 HIV-infected patients (15 no TDF, 25 naïve), with sequential determinations of estimated glomerular filtration rate (eGFR; CKD-epi equation), serum cystatin C and phosphate, and measurement in urine of proteinuria (UPC), glycosuria, phosphaturia, tubular reabsorption of phosphate -TRP-, and tubular proteins beta-2-microglobulin -B2M- and cystatin C -CysC-. Tubular dysfunction was defined as ≥3 alterations in tubular parameters, and TDF discontinuation was recommended in case of reduced eGFR and significant tubular alterations.

Results: Mean age was 46.1 years (23-74). After 58.8 months on therapy (IQR, 33.4-81.4), 96% had HIV RNA level <50 copies/ml, and CD4+ count was 586 cells/µl. Mean eGFR was 95.7 ml/min (51.3-151.2), -2.9 ml/min with respect to baseline (-9.9 TDF+IP, +2.23 no TDF; p<0.01). Also, hypophosphatemia was observed in 15%, cystatin C >1mg/dl in 28%, UPC >100 mg/dl in 40%, glycosuria in 8%, and 52% of patients had a reduced TRP (<80%). Urinary CysC and B2M were increased in TDF, especially with PI (p<0.05), and there was a significant correlation between urinary parameters and time on TDF. Thus, tubular dysfunction was found in 36% of TDF-treated patients. In a second evaluation, after 10.2 m (IQR, 4.4-12.8), patients on the same therapy progressed in comparison with TDF-discontinued patients, both in rate of eGFR (-3.45 vs +5.04; p<0.01), and in tubular damage (TRP -0.2 vs +4.1%; B2M -512 vs +4179 mg/dl). Notably, eGFR improvement was greater in patients discontinuing TDF before an established diagnosis of tubular disease (+12.8 vs +2.3 ml/min). In a third evaluation after 6.23 months (3.6-8.6), there was an additional worsening in patients continuing TDF (eGFR -2.36 ml vs +1.22 ml/min; p<0.01; 84% with TRP >80). Overall, 33% of patients discontinued TDF.

Conclusions: There is a progressive incidence of tubular damage and decreasing eGFR in patients receiving a TDF-containing regimen. Following strict criteria, one third of patients discontinued therapy, although our data suggest a greater benefit in case of early switching.
Endocrine and metabolic issues (including diabetes, hyperlipidemia)

WEPEB349

Switching lopinavir/ritonavir to atazanavir/ritonavir versus adding atorvastatin in HIV-infected patients who received second-line antiretroviral therapy with hypercholesterolemia: a randomized controlled trial

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Background: Lopinavir/ritonavir (LPV/rtv)-based antiretroviral therapy (ART) has been the recommended second-line regimen in resource-limited settings. While lipitor-lowering agents are still not available in the National AIDS Program (NAP) of many developing countries, atazanavir (ATV) has been available in the NAP of some countries for substitution of LPV in patients with LPV/rtv-induced hypercholesterolemia. This study aimed to compare lipid profiles between switching LPV/rtv to ATV/rtv versus adding atorvastatin in patients with LPV/rtv-induced hypercholesterolemia. The better strategy could be applied for the NAP in resource-limited settings.

Methods: A randomized, controlled, clinical trial was conducted in HIV-infected patients who received LPV/rtv-based regimen with hypercholesterolemia and had undetectable HIV RNA. Patients were randomized to switch from LPV/rtv to ATV/rtv (Group A) or to add atorvastatin and continue LPV/rtv-based regimen (Group B), and were followed up for 24 weeks.

Changes in lipid profiles, HIV-RNA, and CD4 were analyzed.

Results: Forty patients were enrolled, 20 in each group. Mean age was 46.8 years and 50% were males. Mean baseline CD4 cell count was 512 cells/μL. Baseline characteristics including age, sex, CD4 cell count, and duration of ART between the two groups were similar (p>0.05). Mean baseline values for total cholesterol (TC), LDL, HDL, and triglycerides (TG) were 257, 141, 45, and 293 mg/dl, respectively. There were no significant differences in lipid values at baseline between the two groups (p>0.05). At 24 weeks, mean TC, LDL, HDL, and TG between the two groups (Group A vs B) were 246 ± 195 (p=0.045), 195 ± 93 (p<0.001), 53 ± 44 (p=0.150), and 196 ± 238 (p=0.434) mg/dl, respectively. Mean reduction of TC was significantly greater in Group B when compared to Group A (55 vs 19 mg/dl, p=0.150), and 195 vs 238 (p=0.434) mg/dl, respectively. Mean reduction of LDL was also observed for LDL (35 vs -7.2 mg/dl, p<0.001). No significant changes in HDL, TG, and CD4 cell count in both groups (p>0.05). All patients had sustained virologic suppression (HIV-RNA <50 copies/ml).

Conclusions: Adding atorvastatin to unchanged LPV/rtv-based regimen results in more significant reduction in TC and LDL than switching LPV/rtv to ATV/rtv, without increased risk of virologic failure. Atorvastatin should be accessible for NAP in resource-limited settings.

WEPEB350

HIV and cardiometabolic disease in rural and urban Malawi: a population-based study

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Background: Sub-Saharan Africa faces a substantial dual burden of HIV and non-communicable diseases. In rural and urban Malawi we are conducting a large population-based study in Africa of hypertension, diabetes, dyslipidaemia and HIV.

Methods: The study is in a well-established demographic surveillance site in rural Malawi (Karonga) and an enumerated high-density area of the capital city (Lilongwe). All adult residents are consented for a lifestyle and medical history interview, examination and body measurements, fasting venepuncture (for glucose and lipids) and HIV testing. Individuals are sought on three occasions (including weekends). Resting blood pressure measurements are repeated three times.

Results: 10,785 urban and 11,322 rural participants are enrolled. Approximately 20% refused HIV testing but reported a prior test result. Crude HIV prevalence was 11.3% urban and 10.0% rural. The urban population was younger. Overall HIV positive patients were more likely than HIV negative patients to have hypertension, diabetes and dyslipidaemia (Table).

WEPEB351

Dysfunctional HDL among HIV-infected adults in Nairobi: a pilot study

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Background: High-density lipoprotein cholesterol (HDL) function may be a more accurate predictor for risk of developing atherosclerosis than absolute levels. This is important among HIV-infected individuals as antiretroviral therapy (ART) is associated with increased HDL levels. This pilot study assessed the anti-inflammatory effect of HDL on palmitate-induced inflammation of adipocytes in HIV-infected individuals with normal levels (≥40mg/dl) of plasma HDL.

Methods: HDL was isolated from plasma samples by ultracentrifugation. 3TC-L murine pre-adipocytes were propagated and differentiated according to standard procedures. The adipocytes were pre-exposed to HDL (5μg/ml) from HIV-infected individuals or control HDL from HIV-uninfected 6 for then incubated with 250 μmol/L palmitate for 24h. The HDL isolated from each sample was tested for its ability to inhibit palmitate-induced serum amyloid A3 (SAA3) gene expression in the adipocyte cultures. Total mRNAs were isolated and analyzed by reverse transcription PCR. Each sample was analyzed in triplicate and normalized using glyceraldehyde 3-phosphate dehydrogenase (GAPDH) as a housekeeping. The higher the level of SAA3 expression in the adipocytes, the less the anti-inflammatory effect of the HDL.

Results: Of the 11 ART-naive subjects, 7 were female. Median age was 30 years [Interquartile range (IQR): 27-33 years] and median CD4 count was 516.5cell/ml (IQR: 422-794). Nine subjects had viral loads >1000 copies/ml. Median BMI was 26.9 (IQR: 23.8-31.6). The mean age, gender, CD4 count and BMI were not associated with HDL anti-inflammatory activity.

Conclusions: Dysfunctional HDL levels were very high, and higher in HIV positive individuals, especially prior to ART. This group also has the highest prevalence of smoking and alcohol consumption. Despite the high prevalence of diabetes and hypertension were also higher in HIV positive people. This has implications for both the diagnosis and management of those with multiple chronic conditions in overburdened health services, particularly as they may have worse outcomes. Higher levels of hypertension in HIV test refusers may reflect general attitudes towards healthy lifestyles.

HIV positive

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<thead>
<tr>
<th>N=600</th>
<th>HIV positive and not known to be on ART (n=289)</th>
<th>HIV positive on ART (n=321)</th>
<th>HIV Status unknown (N=569)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td><strong>11.5%</strong></td>
<td><strong>11.4%</strong></td>
<td><strong>12.1%</strong></td>
</tr>
<tr>
<td>Odds ratio</td>
<td>0.98 (0.77-1.27)</td>
<td>0.98 (0.85-1.10)</td>
<td>1.16 (0.98-1.39)</td>
</tr>
<tr>
<td>Adjusted odds ratio</td>
<td>0.99 (0.77-1.27)</td>
<td>0.98 (0.85-1.10)</td>
<td>1.16 (0.98-1.39)</td>
</tr>
</tbody>
</table>

Hypertension (diastolic >90 mmHg and/or systolic>140mmHg and/or on treatment for hypertension)

Atherosclerosis risk factors among HIV-infected individuals.

These preliminary findings suggest that the anti-inflammatory properties of HDL are impaired in HIV-infected persons despite normal HDL levels. Reasons why viral load significantly correlated with the adipocyte inflammation independent of hs-CRP require further investigation. Other lipoprotein levels may be important to consider when screening for atherosclerosis risk factors among HIV-infected individuals.

HIV-positive and not known to be on ART (n=289)

HIV-positive on ART (n=321)

HIV Status unknown (N=569)

HIV-negative

<table>
<thead>
<tr>
<th>N=1,209</th>
<th>HIV positive on ART (n=227)</th>
<th>HIV Status unknown (N=542)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td><strong>11.4%</strong></td>
<td><strong>11.4%</strong></td>
</tr>
<tr>
<td>Odds ratio</td>
<td>0.98 (0.85-1.10)</td>
<td>1.16 (0.98-1.39)</td>
</tr>
<tr>
<td>Adjusted odds ratio</td>
<td>0.98 (0.85-1.10)</td>
<td>1.15 (0.98-1.39)</td>
</tr>
</tbody>
</table>

Diabetes (previous diagnosis or fasting blood glucose >7mmol/l)

Atherosclerosis risk factors among HIV-infected individuals.

These preliminary findings suggest that the anti-inflammatory properties of HDL are impaired in HIV-infected persons despite normal HDL levels. Reasons why viral load significantly correlated with the adipocyte inflammation independent of hs-CRP require further investigation. Other lipoprotein levels may be important to consider when screening for atherosclerosis risk factors among HIV-infected individuals.

HIV-positive on ART (n=227)

HIV Status unknown (N=542)

HIV positive on ART (n=227)

HIV Status unknown (N=542)
WEPEB352
Analysis of risk factors of telomere length shortening and its association with leukoaraiosis
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Backgrounds: HIV infection is associated with short telomere length (TL), which is linked to old age and cardiovascular disease risk in the general population. In this study, we measured TL in HIV-infected and uninfected individuals, and examined which biological and environmental variables determined TL. We also investigated the influence of TL on leukoaraiosis, which is an indicator of cerebral small vessel disease, in HIV-infected individuals.

Methods: Three hundred and twenty-four HIV-infected individuals on stable combination antiretroviral therapy (cART) for > 1 year who achieved a viral load < 40 copies/ml, and 112 HIV-uninfected individuals were enrolled. Relative TL in leukocytes was estimated by quantitative real-time polymerase chain reaction. Leukoaraiosis was assessed in 184 HIV-infected individuals by fluid-attenuated inversion recovery magnetic resonance imaging. We analyzed several variables such as some markers related to HIV infection, antiretroviral therapy, and social and environmental factors. Variables found to be important in univariate analysis were multivariate model candidates.

Results: In HIV-infected individuals, TL was significantly shorter, and the rate of decline by age was greater than in uninfected individuals. Simple linear regression analysis in HIV-infected individuals showed that old age, cART without integrase-stable transfer inhibitors (INSTIs), non-achievement of HIV RNA < 40 copies/ml within 1 year of initiating cART, and present and/or previous substance use were significantly correlated with shorter TL, even after adjustment for age. Other HIV disease or environmental parameters such as smoking were unrelated. Single logistic regression analysis indicated a risk of leukoaraiosis with old age, shorter TL, hypertension, and carotid artery plaque. Multivariable regression analysis indicated that old age, shorter TL were significant risk factors for leukoaraiosis, with an odds ratio of 1.167 and 1.23 (95% confidence interval, 1.04-1.31 and 1.03-1.45).

Conclusions: TL shortening is independently associated with leukoaraiosis, and is also associated with age, virological response to cART, use of INSTI, and substance use, which mask the influence of other HIV disease or environmental parameters. Good virological control with cART can help improve outcomes among HIV-infected individuals.

WEPEB353
Aging & HIV in the ANRS CO3 Aquitaine Cohort. Cross-sectional results of the Skin, Muscle & Bone Aging Determinants (SIMBAD) study
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3Université de Bordeaux, INSERM U 897, Bordeaux, France.
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8CHU de Bordeaux, Service de Médecine Interne et Maladies Infectieuses, Bordeaux, France.
9CHU de Bordeaux, Service de Médecine Interne et Maladies Infectieuses and INSERM U 897, Bordeaux, France.
10CHU de Bordeaux, Laboratoire d’Immunologie, Bordeaux, France.
11CHU de Bordeaux, Service de Médecine Physique et Résadaptation, Bordeaux, France.
12CHU de Bordeaux, Laboratoire de Virologie, Bordeaux, France.
13CHU de Bordeaux, Service des Maladies Infectieuses et Tropicales, Bordeaux, France

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Backgrounds: With increasing life expectancy comorbidities have become a concern for ART-treated people living with HIV (PLHIV). These comorbidities are more frequent at a given age than in the general population without clear explanations, except for ART or hepatitis co-infection related complications. We prospectively investigated age-related comorbidities and functional limitations and their clinical and biological determinants in PLHIV in care.

Methods: The SIMBAD study enrolled consenting adult PLHIV from the ANRS CO3 Aquitaine Cohort with a previous bone DXA measurement. Participants underwent standardized neurocognitive and locomotor functional tests, a repeat DXA, measurement of plasma 25-Ch vitamin D, T-cell immune activation (CD4+CD25+CD122+), and bone mineral density (BMD) [Total (T) and Femoral Neck (FN)]. Relative TL was estimated by quantitative real-time polymerase chain reaction in leukocytes. The main outcomes were major age-related comorbidities, including TL shortening, and functional limitations, and the associated clinical and biological determinants.

Results: 109 patients were assessed; mean age 54 years (SD: 9), 80% male, 64% homosexuals, 61% CDC stage A, and 93% with undetectable plasma HIV-1 RNA. Mean CD4+ level was 588/mm3 (SD: 217) and nadir 278/mm3 (SD: 163). Test results differed significantly from population norms for spine and femoral neck bone mineral density (BMD), the timed-up-and-go and neurocognitive tests (p<0.05), mean differences were modest and seemed to attenuate with increasing age. Marked alterations (locomotor Z-score >2, neurocognitive Z-scores >1), osteoporosis were found in <25% per domain. Tests of different domains correlated weakly (r = 0.4).

Multivariable linear regression models of femoral neck BMD, lower limb muscle performance, verbal fluency and psychomotor speed showed that increasing age was the only consistently significant determinant of poorer test results (Table). Other determinants (lean mass index, katabolism, CD4 nadir, type of ART) varied between tests. No associations were found with vitamin D levels or T-cell immune activation/senescence markers in any of the regression models.

Conclusions: This cross-sectional analysis of the SIMBAD study, bone, muscular and neurocognitive alterations appear to be of low severity and not related to biologic markers in PLHIV care. Longitudinal analyses will allow for further assessment of the relationships with aging.

Strategies to prolong long term health: screening for non-communicable comorbidity

WEPEB354
High levels of pain and undertreated pain among HIV-positive people who use illicit drugs in Vancouver, Canada
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2University of British Columbia, Department of Medicine, Vancouver, Canada.
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Background: Although the advent of highly-active antiretroviral therapy has contributed to dramatic prognostic improvements for people living with HIV/AIDS (PLHIV), there remain several barriers to achieving optimal treatment outcomes among PLHIV. Given that chronic pain is a common comorbidity among illicit drug users and PLHIV, this study investigated perceived undertreated pain, pain intensity and functional interference among a cohort of HIV-positive people who use illicit drugs in Vancouver, Canada.

Methods: Bivariable and multivariable logistic regression was used to evaluate factors associated with perceived undertreated pain among participants reporting major persistent pain in the ACCESS study, an ongoing longitudinal cohort of HIV-positive illicit drug users. Perceived undertreated pain was defined as participants believing that they required a stronger dose or type of medication for the purpose of analgesia than what they were currently prescribed. Pain intensity and functional interference were examined using the Brief Pain Inventory.

Results: Between June 1, 2014 to November 30, 2014, 215 participants were eligible for this analysis, of which 75 (34.0%) were female, and 183 (85.1%) had major pain that had persisted longer than six months. In total, 91 (42.3%) participants reported undertreated pain, which was positively and independently associated with self-managing pain (Adjusted Odds Ratio [AOR]: 2.11, 95% Confidence Interval [CI]: 1.11-4.00) and having a physical disability (AOR: 2.10, 95%CI: 1.12-3.93). Participants reporting undertreated pain had significantly higher pain intensity (OR: 1.89, 95%CI: 1.09-3.33) and functional interference (OR: 1.92, 95%CI: 1.11-3.33) than those who did not report undertreated pain.

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WEPEB356

Rates and predictors of injury among HIV-positive individuals in British Columbia, Canada


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Abstract

Background: Injuries are responsible for significant morbidity and mortality, constituting the third leading cause of death globally and the leading cause of death for those between the ages of 1 and 44 years. The epidemiology of injury among HIV+ individuals has not been well elucidated. This study seeks to characterize rates and predictors of injury among HIV+ individuals compared to the general population in British Columbia (BC), Canada, from 1996 to 2010.

Methods: An administrative database of HIV+ individuals and a comparison group consisting of a 1% sample of the general BC population was created to assess the health service use and outcomes among HIV+ individuals compared to the general population. In this analysis, rates of intentional (self-harm and assault), unintentional (falls, motor vehicle collisions, poisoning, suffocation, fire/burns, natural/environmental, other land transportation and cut/pierce injuries) and all-cause injury, classified using International Classification of Diseases 9 and 10 codes were assessed.

Results: An administrative database of HIV+ individuals and a comparison group consisting of a 1% sample of the general BC population was created to assess the health service use and outcomes among HIV+ individuals compared to the general population. In this analysis, rates of intentional (self-harm and assault), unintentional (falls, motor vehicle collisions, poisoning, suffocation, fire/burns, natural/environmental, other land transportation and cut/pierce injuries) and all-cause injury, classified using International Classification of Diseases 9 and 10 codes were assessed.

Conclusions: We observed marked population-level increases in incidence rates for both DM and HTN, but not for CVD and COPD/Diasthma among HIV-positive individuals on HAART over a ten-year period. Understanding how these chronic conditions affect future disability and death among the aging HIV-positive population is an important area of further research.

WEPEB355

Trends of non-HIV chronic comorbidities among HIV-positive individuals on highly active antiretroviral therapy in British Columbia from 2000-2009

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Abstract

Background: Highly active antiretroviral therapy (HAART) has transformed HIV from a uniformly fatal condition into a largely treatable chronic disease. Reduced HIV-related morbidity and mortality has allowed other chronic diseases to assume greater importance among HIV-positive individuals. We designed a study to characterize how HAART expansion in British Columbia (BC), Canada has affected the incidence of chronic non-HIV related comorbidities.

Methods: Our analysis was performed using an administrative population-based dataset of HIV-positive individuals (≥19 years) in BC. Using ICD-9/ICD-10 codes for case identification, we assessed the following chronic diseases among HIV-positive individuals who had accessed HAART during the study period from 2000 to 2009: cardiovascular disease (CVD), diabetes mellitus (DM), hypertension (HTN) and asthma/chronic obstructive pulmonary disease (COPD).

Results: Prevalent cases of these diseases were identified pre-baseline (4-year washout period) and excluded from the analyses. Disease incidence was determined by the number of new cases per two-year intervals over a ten-year period. We used Poisson’s log-linear regression analysis to measure trends in incidence rates.

Conclusions: We observed marked population-level increases in incidence rates for both DM and HTN, but not for CVD and COPD/Diasthma among HIV-positive individuals on HAART over a ten-year period. Understanding how these chronic conditions affect future disability and death among the aging HIV-positive population is an important area of further research.
WEPEB357
Prevalence of risk factors for non-communicable diseases (NCDs) and co-morbid conditions among adult persons living with HIV (PLWH) initiating antiretroviral therapy (ART) in Kenya

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Background: With the decrease in AIDS-related morbidity and increased longevity with ART use, non-AIDS events have become more prevalent including NCDs such as cardiovascular disease (CVD), liver disease, renal disease, and non-AIDS cancers. We report on the prevalence of risk factors for NCDs and co-morbid conditions among a cohort of PLWH initiating ART.

Methods: Between March 2014 and October 2014, PLWH initiating ART were recruited from 7 clinics in western Kenya as part of a cohort study to examine inflammatory and coagulation biomarkers. Baseline assessments included demographic characteristics, medical and family history and focused clinical assessment including blood pressure and BMI.

Results: Of 685 participants, 64% were female, median age was 34 years (29-42 years) and median CD4+ count was 316 cells/µL (175-430 cells/µL). Of all, 79% reported a history of tuberculosis (TB) and 5.5% current TB (of latter 92% pulmonary and 8% extrapulmonary). In addition, 3% of participants reported history of high blood pressure (HBP) and non reported history of diabetes. A family history of HBP and diabetes was reported by 9% and 8% of participants, respectively. Ten percent reported smoking history of median duration of 9 years (5-16 year) with 3.1% reporting current smoking and 10% current excessive alcohol use. Median BMI was 20.1 (18.7-22.6), with 72% normal BMI (BMI<18.5-25), 17% underweight (BMI<18), 9% overweight (BMI>25-30) and 2% obese (BMI>30). The mean of two measured blood pressure readings after resting indicated that 59% of the cohort had a blood pressure within normal range, 34.2% with pre-hypertensive to hypertensive blood pressure between 120/80 mmHg and 138/89 mmHg and 2% with hypertensive readings (>140/90 mmHg).

Conclusions: In this cohort of PLWH initiating ART, a substantial proportion had modifiable risk factors for CVD which were easily detected by simple screening methods. High blood pressure was common and should be prioritized for appropriate management. Simple screening for risk factors for NCDs and at minimum for HBP should be included in HIV primary care in resource-limited settings.

WEPEB358
Impact of binge alcohol on mortality among people who inject drugs

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1British Columbia Centre for Excellence in HIV/AIDS, University of British Columbia, Vancouver, Canada, 2British Columbia Centre for Excellence in HIV/AIDS, Vancouver, Canada, 3British Columbia Centre for Excellence in HIV/AIDS, University of British Columbia, Vancouver, Canada, 4Canadian Policy Research Initiative, Department of Medicine, University of British Columbia, Vancouver, Canada, 5British Columbia Centre for Excellence, University of British Columbia, Medicine, Vancouver, Canada

Background: While the impacts of illicit drug use on mortality have been well described, the impact of poly-substance use with alcohol has received less attention. We examined the impact of binge alcohol use on mortality among a cohort of people who inject drugs (PWID) in a Canadian setting.

Methods: Prospective cohort study of PWID in Vancouver, Canada recruited between May 1996 and November 2013. We ascertained mortality rates and causes of death through a confidential linkage with the provincial vital statistics registry and examined the impact of various patterns of alcohol use. The primary outcome of interest was all-cause mortality and we used Cox proportional hazard regression to determine factors associated with mortality, including socio-demographics, drug use behaviours and other risk behaviours.

Results: During the study period, 2560 individuals were followed (844 of which were HIV-positive) for a median of 75.4 months (interquartile range 37.3 - 113.2) among whom 756 (31%) participants reported binge alcohol use at any time during the study period. In multivariate analyses, binge alcohol use remained independently associated with all-cause mortality (adjusted hazard ratio=1.41, 95% confidence interval: 1.05-1.88) whereas other patterns of alcohol use were not associated with mortality.

Conclusions: Binge alcohol use was associated with all cause mortality among PWID in this setting. Since alcohol use is often overlooked as a risk factor for mortality among this population, these findings highlight the continued need to incorporate addiction treatment and public health interventions that address binge alcohol use to reduce alcohol related harms.

WEPEB359
Prevalence of HIV infection, access to care, and response to antiretroviral therapy among partners of HIV-infected individuals in Thailand

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Background: Healthcare providers usually focus on HIV-infected index patients and they show little interest of patients’ partners. Clinical studies regarding characteristics of HIV-infected patients’ partners are limited.

Methods: During January 2011-December 2013, a cross-sectional study was conducted in 2 hospital settings; a university hospital in Bangkok and a provincial hospital in northeastern part of Thailand. Factors associated with anti-HIV positive results in partners were determined by multiple logistic regression.

Results: Of 294 partners, median [interquartile range (IQR)] duration of living with HIV-infected index patients was 9.0 (4.3-15.3) years. Median [IQR] age was 38.9 (33.8-45.7) years and 56.5% were males. Of these, 73.9% had health insurance, 66.9% had heterosexual practice, 22.8% had other underlying diseases, 5.0% had positive HbsAg, 1.4% had positive HCV, and 62.2% used condoms. A total of 176 (59.9%) partners had anti-HIV positive results, 77.3% had been receiving antiretroviral therapy, 87.3% had undetectable HIV RNA and median CD4 count was 232 (98-428) cells/µl. Partners with anti-HIV positive results were older (age 40.8 years vs. 36.8 years, p=0.010), had longer duration of living with HIV-infected index patients (10.4 years vs. 6.3 years, p < 0.001), more likely to be followed at the university hospital in Bangkok (72.1% vs. 53.3%, p=0.002), have health insurance (95.1% vs. 65.2%, p<0.001), have HbsAg positive (0.8% vs. 2.5%, p = 0.001), and have anti-HCV positive (1.7% vs. 0.8%, p < 0.001). Partners with anti-HIV positive results had a higher proportion of having HIV-infected index patients with detectable HIV RNA (7.6% vs. 2.3%, p=0.082). The proportion of condom use were comparable (65.3% vs. 64.4%, p=0.835). By multivariate logistic regression, duration of living with HIV-infected index patients [odds ratio (OR) 1.05 per year; 95% confidence interval (CI) 1.01-1.08, p=0.014], had health insurance (OR 3.40; 95% CI 1.72-6.70, p < 0.001), and followed at the university hospital in Bangkok (OR 2.37; 95% CI 1.20-4.69, p=0.014) were associated with anti-HIV positive results in partners.

Conclusions: Prevalence of HIV infection among partners of HIV-infected Thai individuals is not low. Interventions for decreasing HIV transmission from HIV-infected patients to their partners should be promoted, e.g. early antiretroviral therapy and condom usage.

WEPEB360
Linkage from HIV testing to care: predictors of enrollment failure and associated factors among VCT clients newly diagnosed with HIV infection, Ho Chi Minh City, Vietnam

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Background: Ensuring that HIV-positive individuals successfully enroll for HIV care and treatment is critical to reduce mortality and morbidity and prevent further HIV transmission. To improve linkage to care, we investigated the characteristics of individuals who tested HIV-pos- itive at voluntary counseling and testing (VCT) sites, but who did not register for care services.

Methods: Program data from VCT clients newly diagnosed with HIV infection between 7/1/2011-6/30/2012 at 20 sites in Ho Chi Minh City were examined to determine predictors of enrollment at any of the 21 public outpatient clinics (OPC) in HCMC. We abstracted VCT testing dates and OPC registration dates from logbooks and matched records using a citywide database containing both VCT and OPC identification numbers. We calculated the duration of time between HIV diagnosis and OPC registration during the study, and defined failure to enroll as not having enrolled in an OPC within 17 months after testing. We used a log-binomial model to estimate adjusted prevalence ratios (APR) and 95% confidence intervals (CI) for failure to enroll.

Results: Among 1271 HIV-positive clients, 72% registered at one of 21 OPcs. Mean and median duration from HIV diagnosis to OPC registration were 35 and 19 days, respectively. In multiple regression analysis (see table), clients were less likely to enroll in care if they were aged <25 years, were from provinces other than HCMC, had no formal education, and had recently or ever injected drugs. Clients referred testing by healthcare providers were more likely to enroll in care.

Linkage to care
WEPEB361
Facilitators and barriers to linkage to HIV care among female sex workers receiving HIV testing services at a community-based organization in peri-urban Uganda

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Background: Although nearly 40% of female sex workers (FSWs) in sub Saharan Africa are HIV positive, less than half are enrolled in HIV care. We explored the facilitators, barriers and time to linkage to HIV care among FSWs receiving HIV testing services at a community-based organization in peri-urban Uganda.

Methods: We conducted a mixed-method cross-sectional study among 301 FSWs who tested HIV positive at Reach Out Mbuya Parish HIV/AIDS Initiative in Uganda from May 2012 to December 2013 according to the HCT registers. Structured interviews were conducted with 144 HIV-positive FSWs. In-depth interviews were conducted with 28 positive FSW (15 in care and 14 not in care) and five staff and eleven peer educators as key informants. Data were collected on time taken to register in care, age, marital status, distance to facility and facilitators and barriers to linkage to HIV care. Univariate and multivariable logistic regression analysis was conducted to identify socio-demographic and behavioral factors associated with linkage to care using STATA v.13 while qualitative data were manually analyzed following a thematic framework approach.

Results: Of the 301 positives, 144 (48%) were reached and of these 125 (86.8%) had registered into HIV care with 112 (76%) registering within one month of diagnosis. Participants mean age was 31 years and 14% were married. Older FSWs (>31 years) were 2.6 times more likely to register early compared to the younger FSW (95% CI: 1.01-7.04). Unmarried FSWs were less likely than married FSW to be registered within one month (Adj. OR =0.11, 95% CI: 0.01-0.96). Linkage facilitators included caring health workers, follow up by peer educators, membership to a saving group and a perceived need to be healthy. Barriers included perceived stigma, fear to be seen at the HIV clinic, fear and myths related to ART, lack of time to attend clinic, unaware of treatment center location, and financial constraints.

Conclusions: Providing friendly health care services and strengthening peer support mechanisms may enhance timely linkage into care for FSWs.

WEPEB362
Retention of patients on antiretroviral therapy in The AIDS Support Organization among patients initiating treatment from 2004-2009

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Background: We conducted a retrospective cohort analysis of clients who initiated ART in the first five years of a large ART treatment program encompassing 11 clinical care centers across Uganda to determine the proportion of those retained in care in 2013. Methods: We used data from TASO Health Information System to identify and characterize patients who initiated ART between Jan2004 and July 2009. We then examined which of these patients had at least one visit record in the database January to June 2013. For all patients we established their current status as being a known death, transferred out, lost to follow up (LTFU) or retained in care. We conducted bivariate analyses to compare baseline characteristics associated with each clinical state. We used Cox regression analysis to determine factors associated with the combined outcome of time to death or LTFU.

Results: A total number of 17,827 participants initiated ART during the study period, of whom 12,803 (72%) were female and 5024 (28%) were male. In 2013, after a median of 6 years on ART (IQR 5 - 7 years), 15,469(87%) were retained in care (1211(1%) had transferred out, 1308(8%) were known to have died and 847(5%) were LTFU. The proportion retained in care varied across the TASO centers with a range of 66% to 87% (p<0.001). Of those initiating ART in 2004-05, 82% were retained compared with 79% in 2006-2007 and 77% in 2008-09 (p<0.001). Mortality/LTFU was associated with male, WHO stage 4 illnesses, CD4 cell counts ≤200 cells/μL at ART initiation TASO center, lower education levels and having no occupation.

Conclusions: After a median of over 6 years on ART, patient retention was close to 85% in TASO programs. However, retention was lower among individuals initiating treatment in more recent years and there were large variations across the TASO sites. These suggest that additional measures could be implemented to better retain clients within TASO.

WEPEB363
Temporal improvements in clinical outcomes among HIV-positive individuals initiating combination antiretroviral therapy in Canada

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1BC Centre for Excellence in HIV/AIDS, Vancouver, Canada, 2Northern Ontario School of Medicine, Thunder Bay, Canada, 3Simon Fraser University, Burnaby, Canada, 4University Health Network, Toronto, Canada, 5University of Toronto, Toronto, Canada, 6St. Michael’s Hospital, Toronto, Canada, 7University of Ottawa, Ottawa, Canada, 8McGill University, Montreal, Canada, 9Women’s College Hospital, Toronto, Canada, 10The AIDS Support Organization, Kampala, Uganda, 11Services Coopératifs, Montreal, Canada, 12St. Michael’s Hospital, Toronto, Canada, 13Women’s College Hospital, Toronto, Canada, 14Sunshinebox Health Sciences Centre, Toronto, Canada

Background: We aim to describe temporal changes in the demographic and clinical profile of HIV-positive individuals initiating combination antiretroviral therapy (ART) in Canada from 2000-2011.

Methods: Participants of the Canadian Observational Cohort (CANOC) collaboration, a multi-center cohort of HIV-positive individuals aged ≥18 years and initiating ART naïve at 2000 in British Columbia (BC), Ontario, and Quebec, were included. Participants with <12 months of follow-up were excluded. Participants were grouped by era of ART initiation (2000-2002, 2003-2005, 2006-2008, 2009-2011). Demographic and clinical characteristics were compared

Retention in care
WEPEB364
Optimizing retention of PLHIVs in rural HIV clinics in North Central Nigeria: experience and challenges

E. Nwabueze1, N. Mutulue1, M. Makumbi1, G. Egesimba1, A. Esietowaghan1, N. Onuaguluchi1
1MSH, ProACT, Abuja, Nigeria; 2UOA, CLSM, Aberdeen, United Kingdom

WEPEB365
Impacts of the spatial ‘risk environment’ on ART interruptions among sex workers living with HIV/AIDS: implications for ART programmes and policy reforms

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WEPEB366
Retention in care of HIV-infected pregnant and lactating women starting Option B+ ART in rural Mozambique

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by era using Pearson’s χ² and Wilcoxon rank-sum tests. Cox proportional hazards models were used to estimate the effect of calendar period of ART initiation on virologic responses to ART, including time to viral load suppression (2 measures >50 copies/mL at least 30 days apart) and rebound (2 measures >200 copies/mL at least 30 days apart, after suppression).

Results: Of 8006 participants, 1453 (18%) were female, 46% lived in BC, 33% in Ontario, and 19% in Quebec. The median baseline age at treatment initiation was 38 (IQR=33-45) in 2000-2002, compared to 40 (IQR=37-47) in 2009-2011 (p<0.001). The proportion of participants with IDU history decreased from 28% in 2000-2002 to 19% in 2009-2011 (p<0.001). After adjustments for age, sex, province, transmission risk category, Aboriginal ancestry, baseline CD4 count, viral load baseline, third binary ART class, and viral load testing rate, participants initiating ART in 2003-2005, 2006-2008, and 2009-2011 were more likely to achieve viral suppression than those in 2000-2002 (aHR=1.16 [95% CI=1.07-1.25], aHR=1.22 [95% CI=1.10-1.34], aHR=1.14 [95% CI=1.01-1.26], respectively). After adjusting for the same confounders, participants initiating ART in the later eras were significantly less likely to experience viral rebound than in 2000-2002 (aHR=0.68 [95% CI=0.59-0.78], aHR=0.54 [95% CI=0.43-0.67], aHR=0.31 [95% CI=0.23-0.42], respectively).

Conclusions: Notable temporal changes in the demographic profile and improvements in virologic response to ART are evident among CANOC participants. Characterizing the demographic and clinical profile of affected populations supports the optimal delivery of clinical care for the evolving Canadian HIV epidemic.

Background: Poor retention in care is a major driver of poor program performance, poor adherence and increases resistance to ARTs and transmission of resistant virus causing morbidity and mortality. Long waiting times, non-decentralized HIV clinic days and poor client tracking and counselling services contribute significantly to poor outcomes and quality of services provision. HIV care and services are managed vertically/standalone in most hospital settings in Nigeria (separate laboratory, pharmacy and clinic days). These provide avenue for client stigmatization and attrition. Very few hospitals have currently fully integrated all their HIV care and services.

Methods: We evaluated retention rates in care for clients on ART per state among 5 of integrated health facilities versus 5 of non-integrated ones, to determine the current status and major causes of poor retention. We designed and deployed an innovative retention calendar across them. This tool tracks individual patient receiving services rather than existing aggregated tracking and counselling services contribute significantly to poor outcomes and quality of services provision. HIV care and services are managed vertically/standalone in most hospital settings in Nigeria (separate laboratory, pharmacy and clinic days). These provide avenue for client stigmatization and attrition. Very few hospitals have currently fully integrated all their HIV care and services.

Results: The analysis showed highest retention across facilities with fully integrated HIV services. 90% of these integrated facilities had client retention above 75%. Facilities with the least integration had as low as 45% retention rates. 76% out of the 90% of tracked clients using the deployed retention calendar across these 10 facilities continued with their care. The newly introduced M&E tool showcased early ART defaults and enabled easier/better services. Complaints from Health Care Workers HCWs include too many M&E tools handled manually, poor training, short staffing, and consistent staff rotation from the health ministry. Clients’ complaints were poor health care services and staff appointment.

Conclusions: Integration of ART services and the innovative retention calendar are true positives to retention in care. They provide free access to health care for PLHIV and reduction of work for HCWs. If ART services are fully integrated across all facilities, surely there will be an increase ART retention.

Background: Despite the high HIV burden faced by women in sex work (SWs), data on SWs access and retention in antiretroviral therapy (ART) are limited, with most studies focused on clinical/behavioural determinants. Using an innovative spatial approach, we aimed to explore the independent effect of spatial ‘threats’ (e.g., client violence, policing, legal restrictions) on ≥2 ART interruptions among female SWs living with HIV in Metropolitan Vancouver, BC, over a 3.5 year period.

Methods: Baseline and semi-annual questionnaire data were drawn from a prospective cohort (AESHIA, 2010-2013), and linked administrative data on ART dispensation. Using geographic information systems mapping and logistic regression with generalized estimating equations (GEE), we examined the effects of density of spatial ‘threats’ within a buffer of SWs place of residence on ART interruption (no ART dispensed for ≥2 consecutive days in a 6-month period) among women living with HIV who had previously used ART. Spatial ‘threats’ included client-perpetrated violence, police harassment, community harassment/threats, physical dislocation due to policing, and ‘red zone’/legal restrictions on working locations, and were measured as the density of reported events within a 250-meter buffer of a participants’ residential location.

Results: Among 66 SWs included in the analysis, there were 83 ART interruption events over a 3.5-year period. In a series of multivariate GEE models adjusted for key confounders (age, homelessness, injection drug use, duration of known HIV positivity), increased density of displacement due to policing within a 250-meter buffer of one’s residential location independently correlated with ART interruptions (AOR: 1.02, 95%CI: 1.00-1.04); “red zone” restrictions (AOR: 1.03, p=0.08) and combined spatial ‘threats’ (AOR: 1.00, p=0.07) were also marginally correlated.

Conclusions: Spatial ‘threats’ related to policing, legal restrictions, and other structural risks within SWs’ neighborhood environments may undermine sustained use and retention in ART. These findings contribute to a body of global evidence highlighting the ways in which laws and policies that criminalize aspects of sex work and their enforcement undermine SWs’ access to health and human rights, including retention in ART. Programmes facilitating safer working and living spaces for women living with HIV/AIDS should be explored as potential intervention strategies, alongside critically-needed policy reforms.

Background: In 2013, Mozambique adopted WHO-option B+ as the national strategy for PMTCT of HIV. We aimed to analyze retention in care of pregnant and lactating women (PLW) starting antiretroviral treatment (ART) under option B+ in Ancuabe, a rural district in Northern Mozambique with a decentralized ART provision system.

Methods: We compared outcomes of PLW starting ART under option B+ with those of children bearing age women starting ART following clinical and/or immunological criteria between July 2013 and June 2014. We also compared outcomes of B+ PLW with those of pregnant women on ART for their own health under option A between January 2011 and June 2013. LTFU was defined as not coming back to the clinic for >60 days after last visit. Categorical variables were compared using the Chi-squared test. Kaplan-Meier analyses were used to assess retention in care and multivariable Cox regression to analyze attrition. Models were adjusted for type of facility, age, baseline CD4, WHO stage and time from HIV diagnosis to ART.

Results: 106 women started ART between July 2013 and June 2014; 301 under option B+ (236 pregnant, 65 breastfeeding) and 305 following clinical and/or immunological criteria. They were followed up for 160.6 person-years. Option B+ women were more likely to be
In adjusted analysis, option B+ (HR: 2.24; CI: 1.60-3.15; p < 0.001) and baseline CD4 < 350 (HR: 1.66; CI: 0.95% - 2.33; p = 0.003) were associated with attrition. When comparing pregnant women starting ART under option B+ (n=236) and under option A (n=728), LTFU (85.3% vs. 61.4%) and death (1.45% vs. 0.4%) rates were similar but option B+ were more likely not to return after their first visit (36.4% vs. 13.9%; p < 0.001). In adjusted analyses, factors associated with higher attrition were option B+ (HR: 3.32; CI: 1.84-5.99; p < 0.001) and WHO-stage III (HR: 2.05; CI: 1.08-3.86; p = 0.03).

**Conclusions:** Retention among PWU starting ART under option B+ in rural Mozambique was poor, and seemed to be mainly driven by early losses to follow-up.

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**WEPEB367**

**Effect of gender and age on mortality and retention among HIV-2-infected individuals starting antiretroviral therapy in West Africa: a multicentre cohort study**

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**Background:** HIV-2 infected individuals usually initiate ART at an advanced age compared to HIV-1 patients and this could impact retention in care and treatment outcomes. This study aimed at investigating the effect of gender and age on mortality and lost-to-follow-up (LTFU) among HIV-2 patients in care in Africa.

**Methods:** A cross-sectional study was conducted in seven West African countries: Côte d’Ivoire, Burkina Faso, Mali, Senegal, Togo, and Benin. A total of 2379 HIV-2 infected patients aged ≥18 years were included. Mortality and LTFU were defined as death or loss of contact at least >180 days. Cox regression model was used to identify factors associated with death and/or LTFU. The median follow-up was 22.5 months (7.1-48.2) during which 150 patients died (10.8%) and 251 (18%) had haemoglobin >10 g/dL and 312 (22%) had CD4 <100 cell/µL.

**Results:** Median [IQR] age of 37 [28-51] and median CD4 count of 221 cells/µL [94-404] and 50.2% of patients were women, 482 (35%) were aged 16-39, 522 (38%) aged 40-49 years and 388 (28%) ≥50 years. The Cox regression model was used to identify factors associated with death and/or LTFU, and LTFU was considered if >180 days since last visit. Probability of death and LTFU were increased in resource-limited settings. Few studies explore the period before the start of ART (pre-ART), and gaining understanding of pre-ART is needed to improve strategies of care and maximize long-term patient outcomes. This study describes rates of mortality and lost to follow-up (LTFU) and associated risk factors during the pre-ART period.

**Methods:** We conducted a multicentric retrospective cohort study among HIV-infected adult patients followed but not yet started on ART in 41 Médecins Sans Frontières HIV programmes. Patient follow-up started at programme enrollment and ended at the earliest of: death, transfer-out, ART initiation or last pre-ART clinic visit. Risk factors for mortality and LTFU were investigated using Cox and competing-risks regression models.

**Results:** A total of 137,545 patients (61.2% women) were included in the study with a median [IQR] age of 33 [27-40], median CD4 count of 221 cells/µL [94-404] and 50.2% of them were in WHO clinical stage 3-4. Overall mortality reached 3.9% (95%CI 3.84-4.1%) and 5.2% (95%CI 5.05-5.3%) and 6.2% (95%CI 6.06-6.4%) at 3, 6 and 12 months, respectively. Patients with low CD4 counts (< 50 vs. >500, aHR=0.82, 95%CI 0.77-0.88), aged >30 years (aHR=1.23, 95%CI 1.15-1.31), treated in urban area (aHR=1.18, 95%CI 1.11-1.25) and men (aHR=1.29, 95%CI 1.22-1.37) were at higher risk of pre-ART death. LTFU reached 19.3% (95%CI 19.1-19.4%). 24% (95%CI 24.2-24.7%) and 31.5% (95%CI 31.2-31.8%) at 3, 6, and 12 months, respectively. A higher CD4 count at enrolment (≤500 vs < 50, aHR=0.62, 95%CI 0.54-0.71), younger patients (≤30 vs >50 years, aHR=1.32, 95%CI 1.25-1.38) and men (aHR=1.29, 95%CI 1.20-1.25) were associated with pre-ART LTFU.

**Conclusions:** Our study, conducted among one of the largest pre-ART cohorts, shows higher pre-ART death among patients with advanced stage of HIV disease, and those who are younger, male and treated in urban areas. LTFU rate is high and appears increased among patients with high CD4 counts at enrolment, male gender and younger age. There is an urgent need for programmes to develop targeted strategies to address associated factors to reduce rates of death and LTFU prior to ART.

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**WEPEB368**

**Risk factors for mortality and lost to follow-up before antiretroviral therapy: a multicentric retrospective cohort study of 41 Médecins Sans Frontières HIV programmes**

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**Background:** In the past decade, access to antiretroviral treatment (ART) has greatly increased in resource-limited settings. Few studies explore the period before the start of ART (pre-ART), and gaining understanding of pre-ART is needed to improve strategies of care and maximize long-term patient outcomes. This study describes rates of mortality and lost to follow-up (LTFU) and associated risk factors during the pre-ART period.

**Methods:** We conducted a multicentric retrospective cohort study among HIV-infected adult patients followed but not yet started on ART in 41 Médecins Sans Frontières HIV programmes. Patient follow-up started at programme enrollment and ended at the earliest of: death, transfer-out, ART initiation or last pre-ART clinic visit. Risk factors for mortality and LTFU were investigated using Cox and competing-risks regression models.

**Results:** The risks of death and LTFU among HIV-2 patients on ART seem comparable to those in HIV-1 patients in West Africa, despite ART initiation at an advanced age. However, the mortality and LTFU rates remain elevated in this population where preventive and corrective interventions should be explored.

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**Indicators of quality of care**

**WEPEB369**

**Findings from a cross-sectional study of health care provider attitudes toward PLHIV at Nelson Mandela Academic Hospital in Mthatha, South Africa**

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**Background:** HIV constitutes an occupational risk to healthcare professionals worldwide. This hazard is compounded in settings where supply chain inefficiencies limit compliance to universal precaution guidelines. Healthcare providers’ perceived risks of occupational exposure with HIV is largely underestimated. This investigation measured the association between sociodemographic characteristics and knowledge of modes of HIV transmission through a lens of stigmatising attitudes and practices. Participants comprised healthcare providers at the Nelson Mandela Academic Hospital in Mthatha, South Africa.
WEPEB370
Readmissions to the HIV Ward at St. Paul’s Hospital, Vancouver, British Columbia, Canada from 2005-2014

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Background: Although hospital admissions for AIDS-defining illness have declined with the advent of effective antiretroviral therapy (ART), admissions and aging-related comorbidities may now have a greater impact on hospitalizations in HIV-infected individuals. We evaluated hospital readmissions to the HIV ward at St. Paul’s Hospital (SPH) in Vancouver, British Columbia, Canada as a potential marker for comorbid health status.

Methods: We conducted a retrospective analysis of data collected for patients discharged from the SPH HIV ward between July 1, 2005 and Dec 31, 2014. Readmission was defined as having more than one admission to the SPH HIV/Admissions ward during pre-defined time-periods (7 days, 30 days, and 1 year). Vidal load, ART usage, and CD4 cell counts at the time of admission or readmission were obtained through linkage with the provincial Drug Treatment Program database. Rates of readmissions over time were determined and factors associated with readmission within 1 year were evaluated using multivariate generalized estimating equations.

Results: Of 3915 visits, 343 (8.8%) readmissions occurred within 7 days, 722 (18.4%) within 30 days, and 1740 (44.4%) within 1 year of discharge. The incidence rate of readmissions within 1 year of discharge date declined from 131.1 per 100 person-years in 2006 to 75.4 per 100 person-years in 2014 (Adjusted Relative Risk [ARR] 0.639, 95% Confidence Interval [CI] 0.911 - 0.969) (Figure 1). Factors positively associated with readmission within 1 year included AMA discharge on previous admission (ARR 1.492, 95% CI 1.142 - 1.697), current or past IDU history (ARR 1.699, 95% CI 1.379 - 2.094), and Veterans Aging Cohort Study (VACS) index score (ARR 1.012, 95% CI 1.008 - 1.017). Use of marijuana was negatively associated with readmission within 1 year (ARR 0.841, 95% CI 0.710 - 0.966).

Conclusions: Readmission rates to the HIV ward within one year of initial admission have declined over time, but represent a significant proportion of admissions. Previous discharge AMA, underlying IDU, and a higher VACS index score as a surrogate for medical comorbidity were associated with readmission. This highlights the need to enhance community continuity of care, including addictions services, and involve primary care providers in discharge planning.

WEPEB371
What is the cost of antiretroviral drug durability?

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Background: There are an increasing number of antiretroviral drug (ARV) options that may be combined to produce highly active treatment regimens. ARV quality has improved and costs have reduced. However, the need for more expensive second-line treatment is expected to increase with greater access to viral load testing and growing resistance to non-nucleoside reverse transcriptase inhibitors drugs. This reinforces the importance of optimizing the durability of first-line regimens to keep patients on effective first-line treatment as long as possible. As new drugs become available and different drug are being discussed for first-line treatment, it is important to understand the cost implications of more effective but expensive options.

Methods: We looked at durability as the time on first-line treatment, using an Excel closed cohort model to compare costs of current first-line and second-line regimens to hypothetical more expensive and more durable regimens. The costs of ARVs, toxicities and switching were included in the 20 year forecast. We used a cohort of one million patients and the current Clinton Health Access Initiative costs of the preferred first-line and second-line regimens of TDF/3TC/EFV (TLE) and AZT/3TC/LPV/r and TDF/3TC/FLV. We first assumed a conservative 10% migration rate to second-line and 10% toxicity rate.

Results: If the new regimen cost increased to $200 per person year (pp) (compared to TLE currently at $130 pp) and the migration and toxicity rates were halved, this resulted in a $20 lower cost pp over 20 years and over $400million savings. The increased durability yields 50% of the forecasted patient years that would be spent on second-line as opposed to 75% using the TLE. If the cost of the new regimen is increased to $250 pp, and TLE migration reduced to 5%, the new regimen would need to have a migration rate <1% to neutralize costs.

Conclusions: As patients are spending more time on treatment due to earlier initiation and living longer, the longevity of the first-line treatment becomes increasingly important. Greater durability means less time on more expensive second-line treatment and this exercise demonstrates the impact on total costs regardless of higher regimen prices.
### WEPEB373

**Advanced HIV disease at first presentation to HIV care: cross-sectional analysis of baseline data from the WelTel Retain study in Nairobi, Kenya**

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**Background:** Individuals who present to care with advanced HIV disease (CD4 < 200 cells/mm³ or presentation with an AIDS-defining event) have reduced life expectancy and an increased risk of onward transmission. Many HIV-positive persons in sub-Saharan Africa first present to care with advanced disease; however, little is known about whether this is because of late diagnosis or delayed entry to care after diagnosis. We conducted a cross-sectional analysis of baseline study data in Nairobi, Kenya to determine the proportion of patients presenting with advanced HIV disease and whether this was due to delayed diagnosis or a delay in seeking care after diagnosis.

**Methods:** Between April 2013 and October 2014, participants were recruited into a randomized trial and supplementary cohort study at the Kibera and Babadogo comprehensive care clinics in Nairobi. Patients were eligible to participate if they were over 18 years old, HIV-positive, and had not previously enrolled in HIV care. Pregnant women were excluded. Baseline data were collected using paper-based questionnaires and from chart reviews. Descriptive statistics were used to quantify the proportion of individuals who presented to care with advanced HIV disease (CD4 < 200 cells/mm³ or WHO Clinical Stage 4).

**Results:** Of 667 patients screened for the study, 492 eligible patients consented to participate. CD4 and WHO clinical stage data were available for 86% (464/542) and 85% (416/492) of patients, respectively. Of 154 (54/42); 32% participants who presented to care with advanced HIV disease, 82 (53%) were women and 56 (36%) were diagnosed with HIV for the first time. Among those with advanced HIV disease who had been previously diagnosed (n=98), the median time to presentation to care after initial diagnosis was 18 days (interquartile range: 5.5-72.5); 76 participants presented to care within three months of their first diagnosis. Our findings suggest that those who present to care with advanced HIV disease, late diagnosis is a significant factor.

### WEPEB374

**Cascade of care in the country of Georgia: how long it takes to achieve each stage?**

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**Background:** Georgia is an Eastern European country that provides antiretroviral therapy (ART) to all patients in need. Treatment guidelines rapidly evolved over the last 5 years towards earlier ART initiation and the country has implemented a comprehensive package of care services. We evaluated patient engagement in the HIV care continuum and time required to achieve each stage.

**Methods:** The study included HIV-infected persons diagnosed in Georgia in 2008-2012, who were followed through 2013. Data was extracted from the national HIV/AIDS database. The following stages of HIV care were quantified: HIV diagnosis, linked to care, retained in care, on ART and virally suppressed. Time to achievement of stages of care was estimated from the date of HIV diagnosis.

**Results:** Among 1,931 patients diagnosed in 2008-2012, the median CD4 count at diagnosis was 221 cells/mm³. The proportion of patients with CD4 cell count <200 increased from 65% in 2008 to 71% in 2012 (p<0.005). 365 patients died over the follow-up: 58% (71%) before linkage to care, 92 (72%) after linkage but before ART initiation and 212 (58%) after ART initiation. Among the remaining 1,563 patients, 1407 (90%) were linked to care, 129 (77%) were retained in care, 1,010 (65%) started ART and 828 (53%) achieved viral suppression. The median time to linkage was 1 month with 1,229 (79%) linked within 3 months. The proportion of patients who linked within 3 months after diagnosis increased from 71% in 2008 to 89% in 2012 (p<0.0001). The median time to ART initiation after diagnosis was 3 months. Time to ART initiation decreased from 10 months among those diagnosed in 2008 to 2 months among those diagnosed in 2012 (p<0.0001). Time to viral suppression after HIV diagnosis also decreased over time from 23 months among those diagnosed in 2008 to 8 months among those diagnosed in 2012 (p<0.0001).

**Conclusions:** Patient engagement in the HIV care continuum in Georgia has been improving over time. However, only 53% of all diagnosed patients were virally suppressed. More efforts are needed to further increase patient retention in care as well as adherence to ART.

**WEPEB375**

**From home-based HIV testing to initiation of treatment: The AIDS Support Organization (TASO) experience with Home-Based HIV Counselling and Testing (HBHCT) among adolescents in Uganda, 2005-2011**

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**Background:** We examined the cascade of HIV testing, support and treatment services in Uganda under the TASO HBHCT program and compares the patterns among adolescents aged 16-19 years with those of adults aged 20 years and above.

**Methods:** Data included individuals who were counselled and tested for HIV at their homes through the TASO HBHCT program. Analysis entailed simple frequencies to determine the proportions of adolescents and adults that: (i) tested positive among those who received HBHCT from 2005 to 2011; (ii) were enrolled in care and support programs at TASO centres among those who tested positive during HBHCT; (iii) were determined to be eligible for ART among those who were enrolled in care and support programs at TASO centres; and (iv) were initiated on ART among those who were determined to be eligible.

**Results:** Between 2005 and 2011, TASO tested a total of 55,228 clients aged 10 years and above through the HBHCT program:40% were adolescents aged 10-19 years. The proportion of adolescents who tested positive under the program was consistently lower than that of adults across the years (between 2% to 5% compared to between 10% and 14% among adults). The proportion of HIV-positive adolescents that were enrolled in TASO centres more than tripled from 9% in 2005 to 32% in 2006 and steadily increased to 41% in 2008. By contrast, the proportion of HIV-positive adults that were enrolled in TASO centres increased from 21% in 2005 to 31% in 2006 but levelling off at 33% in 2007. The proportion of adolescents who were found to be eligible for ART more than doubled from 15% in 2006 to 40% in 2011 while the propor-
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WEPEB376
Temporary changes in CD4 counts and clinical stage at HIV diagnosis over 10 years in a large, multicentric patient cohort supported by Médecins Sans Frontières

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Background: Access to antiretroviral treatment (ART) has considerably increased in resource-limited settings. However, the success of the therapy is closely linked with the level of immunosuppression and the stage of the disease at diagnosis. This study evaluates temporal changes in CD4 counts and clinical stage at HIV diagnosis in a large cohort of 41 Médecins Sans Frontières programmes in resource-limited settings over 10 years.

Methods: We conducted a multicentric retrospective cohort study among HIV-infected adult patients. Patients with at least one clinic visit were included in the study. Baseline median (interquartile range, IQR) CD4 counts and proportions of patients in clinical stage 3 or 4 were reported per year of enrollment over the period 2002-2012. Random intercept linear and logistic mixed models were fitted to assess temporal changes in CD4 counts and clinical stage at enrollment.

Results: From 2002 to 2012, 192,117 HIV-positive patients (61% females) were included in our programmes. Baseline median CD4 count at HIV diagnosis increased from 136 cells/µL (IQR 53-272) in 2002 to 203 cells/µL (IQR 75-362) in 2011 despite a slight decrease in 2012. The proportion of patients in clinical stage 3 or 4 at enrollment was stable at approximately 60% between 2002 and 2006, and then decreased to 47.8% in 2011, despite a slight increase in 2012. Results of the mixed model showed a significant increase of +7.4 cells/µL (95%CI 6.7-8.1) in baseline CD4 counts each year. In addition, females were enrolled at significantly higher CD4 counts than men (difference in 2008: +66.5 cells/µL (95%CI 63.8-69.2) in favour of females).

Conclusions: Our study, conducted among one of the largest HIV cohorts, shows that HIV-infected patients are diagnosed and enrolled at an earlier stage of disease each year. However, there is still an important proportion of patients diagnosed at advanced stage of HIV disease and more efforts are needed to diagnose patients earlier, especially targeted at males.

WEPEB377
High prevalence of late presentation among HIV-infected patients in Guinea-Bissau: a cohort study from West Africa

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Background: In sub-Saharan Africa a large proportion of HIV infected persons are late presenters (LPs) and late presenters with advanced disease (AD). Late presentation has been associated with higher mortality, higher cost of medical management, impaired CD4 cell count increment and potentially ongoing risk of HIV transmission. We describe the proportion of LP and AD at an HIV clinic in Guinea-Bissau, West Africa, to identify risk factors and to evaluate the outcome.

Methods: During June 2005 - December 2013 we included all patients ≥15 years diagnosed with HIV. Patients were followed until December 2014. AD, LP and non-LP was defined as patients with CD4 cell count at HIV diagnosis of <200 cells/µL, 200-349 cells/µL and >349 cells/µL, respectively.

Results: During the study period 5,566 patients were diagnosed with HIV (68.3% HIV-1, 17.3% HIV-2, 10.3% HIV-1/2 and 4.1% HIV type unknown) and 3,704 (67%) had a CD4 cell count measured within the first 90 days of HIV diagnosis. The median time between HIV diagnosis and CD4 cell count among these patients was 1 day (interquartile range 1-5 days). Forty-nine percent of the patients were AD and additionally 23% were LP. CD4 cell count varied in the study period, with the lowest values measured in 2007 (median 144 cells/µL) and the highest values in 2011 (median 229 cells/µL, p< 0.01). In a multivariable analysis risk factors significantly associated with AD were HIV diagnosis in 2007 versus 2013 (adjusted odds ratio [aOR] 1.9), male gender [aOR 1.5, age ≥30 years (aOR 1.6), HIV-1 infection (aOR 2.2), HIV-12 dual infection (aOR 1.7), civil status (single versus married) (aOR 1.4). Fula (aOR 1.5) and Mandinga (aOR 2.3) ethnicity. A total of 528 (14.3%) patients were registered as dead and the AD/non-LP mortality rate ratio (MRR) was 3.79 (p< 0.01). The mortality rate was not significantly higher among LP than non-LP (MRR 1.31, p=0.13).

Conclusions: A high proportion of HIV infected patients were AD and these patients exhibited a much higher mortality. Initiatives to enroll patients in care at an earlier point are needed and should focus on males, unmarried and other risk groups.

WEPEB378
Gaps in care among HIV-infected adults receiving care in western Kenya

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Background: While some individuals may permanently disengage from care, others may experience transient interruptions. We sought to characterize gaps in care among HIV-infected adults enrolled in the Academic Model Providing Access to Healthcare (AMPATH) program in western Kenya.

Methods: HIV-infected adults (≥18 years) enrolled in an AMPATH supported site between 01/2008 and 09/2012 with ≥1 follow-up visit were eligible for inclusion. This analysis was limited to visits scheduled ≥12 months prior to the database closure (09/2013). Based on the next expected visit date, five possible outcomes were determined: the patient was on time (returned ≥ 6 days from an expected visit date), had a short (<6-9 days late), medium (9-36 days late), or long gap (>365 days late), or died. Covariates included gender, age at enrollment, WHO stage,}

<table>
<thead>
<tr>
<th>Characteristics of late presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Late presenters with advanced disease (AD)</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Age &gt;30 years</td>
</tr>
<tr>
<td>Age ≤30 years</td>
</tr>
</tbody>
</table>

[Figure 1]

Time from HIV diagnosis (years)

0.00 0.25 0.75 1.00

Patient mortality (%)

0.00 0.25 0.75 1.00

CD4+ ≥ 200 CD4+ 200-349 CD4+ 350-499 CD4+ ≥ 499

During the study period 5,566 patients were diagnosed with HIV (68.3% HIV-1, 17.3% HIV-2, 10.3% HIV-1/2 and 4.1% HIV type unknown) and 3,704 (67%) had a CD4 cell count measured within the first 90 days of HIV diagnosis. The median time between HIV diagnosis and CD4 cell count among these patients was 1 day (interquartile range 1-5 days). Forty-nine percent of the patients were AD and additionally 23% were LP. CD4 cell count varied in the study period, with the lowest values measured in 2007 (median 144 cells/µL) and the highest values in 2011 (median 229 cells/µL, p< 0.01). In a multivariable analysis risk factors significantly associated with AD were HIV diagnosis in 2007 versus 2013 (adjusted odds ratio [aOR] 1.9), male gender [aOR 1.5, age ≥30 years (aOR 1.6), HIV-1 infection (aOR 2.2), HIV-12 dual infection (aOR 1.7), civil status (single versus married) (aOR 1.4). Fula (aOR 1.5) and Mandinga (aOR 2.3) ethnicity. A total of 528 (14.3%) patients were registered as dead and the AD/non-LP mortality rate ratio (MRR) was 3.79 (p< 0.01). The mortality rate was not significantly higher among LP than non-LP (MRR 1.31, p=0.13).
WEPEB379

Monitoring achievement of the latest UNAIDS HIV 90-90-90 Target: a need for harmonization of the HIV cascade of care

L. Lourenço1, M. Hull, B. Nosyk2, J. M. Montaner3, V. Lima3
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Presenting author email: lourenco@cfenet.ubc.ca

Background: UNAIDS recently released the ‘90-90-90 Target’ calling for 90% of HIV-infected individuals to be diagnosed by 2020, 90% of them to be started on ART, and 90% of them to achieve sustained virologic suppression. Achieving these goals will require uniform monitoring of HIV care outputs. The HIV cascade of care (cascade) provides a framework to identify step-wise attrition and has become a key programmatic monitoring tool. However, without standard cascade development guidelines, cascades cannot be compared across jurisdictions. Here, we use the example of four cascades to propose harmonization in stage definitions.

Methods: We compared definitions and outputs of four cascades from the USA, British Columbia (Canada), France, and Denmark.

Results: The USA, BC, and France cascades all begin with the estimated HIV-positive population. However, the Danish cascade begins with the number of diagnosed HIV cases; this immediately increases the proportion retained along their cascade. ‘Linkage’ and ‘retention’ in care definitions also varied: France was the only cascade not to distinguish between linkage and retention, instead using a composite referred to as ‘in care’. All cascades defined a stage ‘on ART’. USA and Danish cascades defined ‘on ART’ as any ART record within the year of interest. BC and France, however, required evidence of sustained use of ART within the calendar year. When defining virologic suppression, Denmark used the most recent viral load (VL) ≤ 50 copies/mL, the USA used VL<200 copies/mL at the latest available test, France used a VL < 50 copies/mL per calendar year, and BC used 2x VL<50 copies/mL over a period ≥3 months per calendar year. Consequently, the proportion suppressed amongst the estimated HIV-infected population varied substantially, at 25%, 35%, and 52% for the USA, BC, and France, respectively, and of, those HIV-diagnosed was 70% for Denmark.

Conclusions: While most visits occurred on time, gaps were common with patients experiencing multiple gaps suggesting current definitions of loss to follow up may need further consideration.

[WEPEB379 Table: Comparison of four HIV cascades of care]

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**Adjusted Relative Risk Ratio (PR Confidence Intervals)**

<table>
<thead>
<tr>
<th>Short Gap vs. On Time</th>
<th>Medium Gap vs. On Time</th>
<th>Long Gap vs. On Time</th>
<th>Died vs. On Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male- yes vs. no</strong></td>
<td>0.96 (0.94-0.98)**</td>
<td>1.09 (1.04-1.14)**</td>
<td>1.24 (1.20-1.27)**</td>
</tr>
<tr>
<td><strong>Age-52-44 vs. 18-24</strong></td>
<td>0.86 (0.83-0.89)**</td>
<td>0.62 (0.56-0.68)**</td>
<td>0.57 (0.50-0.63)**</td>
</tr>
<tr>
<td><strong>Age-45+ vs. 18-24</strong></td>
<td>0.79 (0.77-0.82)**</td>
<td>0.48 (0.44-0.51)**</td>
<td>0.43 (0.41-0.45)**</td>
</tr>
</tbody>
</table>

*Note: **p<0.05, **p=0.01, A Adjusted for calendar year at enrolment, expected frequency of visits

Author Index

Hull et al. JAMA Intern Med. 2013

Noskы et al., British Columbia, Denmark, Canada, Lancet Infectious Diseases, 2014

Hollberg et al. Sweden and Denmark PlosOne, 2013

Supaphile et al., France, CROI, 2013

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### WEPEB379

**Monitoring achievement of the latest UNAIDS HIV 90-90-90 Target: a need for harmonization of the HIV cascade of care**

L. Lourenço1, M. Hull, B. Nosyk2, J. M. Montaner3, V. Lima3

1British Columbia Centre for Excellence in HIV/AIDS, Vancouver, Canada; 2Simon Fraser University, Burnaby, Canada; 3University of British Columbia, Faculty of Medicine, Vancouver, Canada

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**Methods:** We compared definitions and outputs of four cascades from the USA, British Columbia (Canada), France, and Denmark.

**Results:** The USA, BC, and France cascades all begin with the estimated HIV-positive population. However, the Danish cascade begins with the number of diagnosed HIV cases; this immediately increases the proportion retained along their cascade. ‘Linkage’ and ‘retention’ in care definitions also varied: France was the only cascade not to distinguish between linkage and retention, instead using a composite referred to as ‘in care’. All cascades defined a stage ‘on ART’. USA and Danish cascades defined ‘on ART’ as any ART record within the year of interest. BC and France, however, required evidence of sustained use of ART within the calendar year. When defining virologic suppression, Denmark used the most recent viral load (VL) ≤ 500 copies/mL, the USA used VL<200 copies/mL at the latest available test, France used a VL < 50 copies/mL per calendar year, and BC used 2x VL<50 copies/mL over a period ≥3 months per calendar year. Consequently, the proportion suppressed amongst the estimated HIV-infected population varied substantially, at 25%, 35%, and 52% for the USA, BC, and France, respectively, and of, those HIV-diagnosed was 70% for Denmark.

**Conclusions:** While most visits occurred on time, gaps were common with patients experiencing multiple gaps suggesting current definitions of loss to follow up may need further consideration.

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**WEPEB380**

Monitoring of key performance indicators to improve management of antiretroviral treatment, upper-north region, Thailand

S. Bhakeecheep1, A. Teeraratkul2, K. Phokasawad2, P. Kantipong3, P. Pathipvanich4, T. Roels2,5

**Abstract**

The HIV/AIDS care and treatment program performance of 115 hospitals in Thailand’s Region 1 from 2010-2014 was analyzed for key performance indicators (KPIs). Patient records from the National HIV Patient Monitoring, an electronic web-based information system with real-time linkage to the National Death Registry, were used for this purpose. Selected KPIs were then graphed to represent the early ART recruitment and retention cascade.

**Background:** Monitoring data regularly in order to determine the success of the early antiretroviral treatment (ART) strategy is essential, especially in areas with high burden of HIV such as Upper-North of Thailand (Region 1).

**Methods:** The HIV/AIDS care and treatment program performance of 115 hospitals in Thailand’s Region 1 from 2010-2014 was analyzed for key performance indicators (KPIs). Patient records from the National HIV Patient Monitoring, an electronic web-based information system with real-time linkage to the National Death Registry, were used for this purpose. Selected KPIs were then graphed to represent the early ART recruitment and retention cascade.

**Key Performance Indicators**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>PWHA currently receiving services</td>
<td>27,413</td>
<td>29,764</td>
<td>31,675</td>
<td>38,087</td>
<td>39,401</td>
</tr>
<tr>
<td>% registration by 3 months after diagnosis</td>
<td>66.5 (30.0-88.6)</td>
<td>66.6 (61.3-78.6)</td>
<td>69.3 (60.0-76.0)</td>
<td>72.1 (62.5-82.1)</td>
<td>69.2 (90.7-86.7)</td>
</tr>
<tr>
<td>&lt;200 cells/mm³</td>
<td>28.1 (23.3-33.0)</td>
<td>26.8 (20.7-33.0)</td>
<td>27.0 (17.3-32.0)</td>
<td>24.1 (21.2-28.3)</td>
<td>30.7 (19.5-50.0)</td>
</tr>
<tr>
<td>&lt;500 cells/mm³</td>
<td>67.6 (22.8-83.0)</td>
<td>72.8 (61.0-84.9)</td>
<td>73.7 (65.7-79.9)</td>
<td>60.7 (45.7-72.9)</td>
<td>61.7 (45.7-78.5)</td>
</tr>
<tr>
<td>% CD4 at ART initiation &lt;=200 cells/mm³</td>
<td>5.5 (2.4-11.4)</td>
<td>5.0 (3.9-7.1)</td>
<td>6.8 (3.3-10.8)</td>
<td>6.2 (2.8-9.4)</td>
<td>6.9 (4.4-8.5)</td>
</tr>
<tr>
<td>% VL test at least once &lt;=200 cells/mm³</td>
<td>88.5 (53.9-83.3)</td>
<td>78.4 (63.3-87.5)</td>
<td>80.7 (62.4-88.1)</td>
<td>83.4 (65.5-89.4)</td>
<td>84.7 (73.2-95.6)</td>
</tr>
<tr>
<td>% VL suppressed &lt;1,000 copies/ml at 12 months after ART initiation</td>
<td>96.1 (92.0-97.1)</td>
<td>95.8 (90.8-97.5)</td>
<td>93.5 (88.9-96.3)</td>
<td>94.4 (93.9-97.4)</td>
<td>95.2 (93.9-97.1)</td>
</tr>
<tr>
<td>% death during 12 months after ART initiation</td>
<td>0.7 (1.1-2.7)</td>
<td>1.0 (1.0-1.5)</td>
<td>1.1 (0.8-1.3)</td>
<td>1.1 (1.0-1.6)</td>
<td>1.1 (1.0-1.6)</td>
</tr>
<tr>
<td>% death during 24 weeks postnatal</td>
<td>8.7 (7.4-10.3)</td>
<td>7.8 (5.5-11.1)</td>
<td>7.4 (4.0-10.7)</td>
<td>6.8 (6.9-14.8)</td>
<td>8.7 (5.7-13.5)</td>
</tr>
</tbody>
</table>

**Results:**

**Conclusions:** Differences in cascade outcomes are partially explained by varying health-care systems but also by varying cascade designs. To monitor the success of the 90-90-90 target it is, thus, reasonable to postulate that cascade definition harmonization is urgently warranted. This would ensure the promotion of best individual and societal outcomes and the ability to directly compare cascades between jurisdictions.

**WEPEB381**

**ART initiation among infants enrolled in the HITSystem in Kenya from 2011-2014**

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**Abstract**

The rate of ART initiation among HIV-infected infants enrolled in the HITSystem was higher than rates reported in other studies, while mean time to ART initiation was shorter. Mean time to ART initiation was shorter in infants tested before 24-weeks postnatal. Speed of ART initiation improved from 2011-2014.
WEPEB382
An analysis of linkage policies within the HIV continuum of care in national HIV guidelines of President’s emergency program for AIDS relief (PEPFAR)-supported countries

S. Hunter1,2, S. Nicholas1, B. Schramm2, E. Poulet2, L. Wolters3, A. Rakesh3, I. Amoros4, J.-F. Etard2,5, C. Johnson3, V. Wong1, R. Baggaley5
1Centers for Disease Control and Prevention, Atlanta, United States, 2Epicentre, Durban, South Africa, 3University of KwaZulu-Natal, Health Economics and HIV/AIDS Research Division, Durban, South Africa, 4University of Malawi, Malawi, 5World Health Organization, Geneva, Switzerland

Background: Linkage to care (LTC) is the process of supporting HIV-diagnosed persons to access medical care and HIV-negative persons to access prevention services. Forty-one per-cent of those diagnosed in Africa are not linked-to-care. Both PEPFAR’s goal of an AIDS-free generation and UNAIDS’ Three 90s targets necessitate high linkage rates. We reviewed and analyzed national HIV treatment and linkage policies to assess linkage integration.

Methods: We electronically searched for national HIV treatment policies and linkage strategies published from 2006-2014 using Google, government and NGO websites, WHO databases, and by contacting key experts. Policies were reviewed and data on linkage and referral systems for HIV prevention, care, and treatment were extracted. No geographic or language restrictions were placed on the search, however analysis was limited to PEPFAR-supported countries.

Results: In total, 25 policies were identified in 18 PEPFAR-supported countries, across 4 WHO regions (15/19 African Region, 1/19 Eastern Mediterranean Region, 2/19 Western Pacific Region, 1/19 Southeast Asia Region). 12 of which are from voluntary medical male circumcision (VMMC) countries. About half (10/19) include policies on linkages to HIV prevention, care, and treatment services. Of the 12 VMMC priority countries, only 2 include linkage and 5 mention VMMC but do not specify referral or linkage. Nearly all (19/19) countries mention a referral system to care and treatment, while only 14/19 outline referral to prevention services, most commonly prevention of mother-to-child transmission (PMTCT) services. Mention of linkage to care could be found in less than half (12/25) of total policies from 10 PEPFAR countries. The majority of VMMC policies (10/12) containing guidelines on LTC were from 2010 onward. The level of detail explaining LTC was strongest in policies dated 2013-2014.

Conclusions: Strengthening the quantity and content of policies on linkage to HIV pre- vention, care, and treatment services is needed. It appears more countries are including LTC policies in national treatment guidelines, however few include linkage to prevention, especially for HIV negative persons and few have linkage strategies. Country activities towards new global targets will require clear linkage strategies and clarification within prevention, care and treatment policies.

WEPEB383
Effect of point-of-care CD4 testing on time to ART-initiation and Pre-ART attrition in rural decentralized health centers in Chiradzulu District, Malawi

S. Nicholas1, B. Schramm2, E. Poulet2, L. Wolters3, A. Rakesh3, I. Amoros4, J.-F. Etard2,5, C. Johnson3, V. Wong1, R. Baggaley5
1Centers for Disease Control and Prevention, Atlanta, United States, 2Epicentre, Durban, South Africa, 3University of KwaZulu-Natal, Health Economics and HIV/AIDS Research Division, Durban, South Africa, 4University of Malawi, Malawi, 5World Health Organization, Geneva, Switzerland

Background: A randomized controlled trial of point-of-care (POC) CD4 testing with MSF-UNITAID funding in a decentralized health center in Chiradzulu District, Malawi identified reduced attrition in those with POC CD4. The study specifically aimed to assess if POC CD4 testing could achieve faster linkage to ART initiation in Malawi.

Methods: A non-randomized observational study was conducted in one Health Center (HC) with POC testing and two HCs with centralized CD4 laboratory testing. Data was collected from March 25 to April 23, 2014. Eligibility for CD4 was defined as a blood draw between 92 and 94 for women and 94 for men. Among patients eligible by CD4, 108 (90%) initiated ART in the POC vs 47 (47% (N=182), p<0.01). Patients were followed for 4 weeks post initiation. Pre-ART attrition was defined as died or exited within 4 weeks post initiation. At 4 weeks, pre-ART attrition was 4% in the POC and 47% in the non-POC arms (p<0.001). Median time to ART initiation was 7 days (IQR 6-24) in the POC arm vs 30 days (IQR 22-57) in the non-POC arm (p<0.001).

Conclusions: In this trial, POC CD4 provided fast linkage to ART initiation within 1 week of enrolment in rural Malawi with a non-inferior CD4 median time to ART initiation. POC testing is therefore a feasible model for fast-track linkage to ART.

WEPEB384
HIV testing and treatment cascade in rural South Africa: initial results from a representative household surveillance sample

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Background: South Africa has successfully scaled up a broad range of HIV-related pro- grammes including the provision of antiretroviral therapy (ART), HIV testing and linkage to treatment substantially improves outcomes at the individual level; at the population level, effective ART plays an important role in reducing HIV transmission. We evaluated the uptake of HIV testing and linkage to treatment in a representative household sample of rural South Africans.

Methods: The HIV Incidence Provincesal Surveillance System (HIPSS) is a longitudinal study following HIV-seroconversion in sub-districts of Vhululand and the GreaterEkurhuleni in the Umgungundlovu municipality, KwaZulu-Natal, South Africa. Population based household surveys of 10 000 individuals selected randomly in the age group 15-49 years are being undertaken. Study staff administered an in-depth questionnaire including information on the uptake of HIV testing and ART. Participant responses were linked to laboratory testing for HIV-1 RNA viral load in those who reported to be HIV positive.

Results: A total of 4778/6401 (74.6%) of randomly selected households consented to study participation. From these households 4231/4778 (88.5%), randomly selected individuals were enrolled of whom 2745/4231 (64.9%) were females and 1486/4231 (35.1%) were males. Among those who tested 2825/4231 (66.8%) of the participants had an HIV test, females (1967/2745, 71.7%) were much more likely to be tested than males (858/1486, 57.7%, p<0.001). Of those reporting to be tested, 770/1867, (39.1%) were females and 206/858 (24.0%) were males (p-value = 0.001). HIV positive 480/770 (62.3%) females and 124/206 (60.1%) were on ART (p-value=0.573) and of these 363/480 (75.6%) females and 79/124 (63.7%) males had viral suppression at < 20 copies/ml (p-value = 0.009).

Conclusions: These results suggest that there is a need for public health interventions to enhance HIV testing and ongoing support to increase access and retention on ART. Males were less likely to have received an HIV test and despite knowledge of HIV positive status were less likely to initiate ART and achieve viral suppression. Novel interventions and strategies are needed to enhance the uptake of HIV testing and effectiveness of ART in men to optimize its therapeutic and preventative benefits.

Complications of HIV, its therapy and comorbidities in children and adolescents

WEPEB385
Prevalence of and risk factors for chronic lung disease among HIV-infected children

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1Centers for Disease Control and Prevention, Atlanta, United States, 2Centers for Disease Control and Prevention-Malawi, Center for Global Health/Division of Global HIV/AIDS, Atlanta, United States

Background: HIV-infected children in resource-limited settings face serious medical com- plications especially as they survive into adolescence. We investigated the prevalence of and risk factors for chronic lung disease (CLD) among HIV-infected children in Malawi.

Methods: Between March 25 and April 23, 2014, we enrolled 615 HIV-infected children ages 5-14 years from seven outpatient HIV clinics in a cross-sectional investigation including in- depth caregiver interviews, physical exam, spirometry, laboratory testing for CD4, and medical
WEPEB387 Decreased vigorous physical activity in South African HIV-infected school-aged children on antiretrovirals

M. Wong1, S. Siau2, M.T. Yn3, R. Sheth4, P. Pathai5, F. Pinillos6, A. Coovadia7, L. Micklesfield7, L. Kuhn1, S. Arpadi7, CHANGES Study Group
1Columbia University, New York, United States, 2University of the Witwatersrand, Empilweni Services and Research Unit, Johannesburg, South Africa, 3University of the Witwatersrand, MRC/Wits Developmental Pathways for Health Research Unit, Faculty of Health Sciences, Johannesburg, South Africa
Presenting author email: mw2185@cumn.columbia.edu

Background: Despite potential importance to long-term health outcomes adversely affected by HIV, including bone and cardiometabolic health, physical activity (PA) among people living with HIV has not been well studied. We describe PA in South African HIV-infected and uninfected children.

Methods: Data were obtained from CHANGES (Childhood HAART Alterations in Normal Growth, Genes, and aDing Evaluation Study), a study of perinatally HIV-infected children and uninfected controls in Johannesburg, South Africa from 2012-2014. Age of antiretroviral initiation, HIV/RNA, CD4%, weight-for-age (WAZ) and height-for-age (HAZ) Z-scores, and frequency and duration of physical activities and sedentary behaviors by validated questionnaire were obtained. Metabolic equivalents (METS) of each PA were determined. Moderate-vigorous PA (MVPA) was defined as PA ≥3 METS, while vigorous PA (VPA) was defined as >6 METS.

Results: 213 HIV-infected and 152 uninfected children aged 6-9 years (83% of target sample) were included. Age, WAZ and HAZ were significantly lower for HIV-infected children. 93.1% of HIV-infected children were virally suppressed (HIV-RNA < 400 copies/mL), had a mean CD4% of 37.4, and were initiated on antiretrovirals at a mean age of 8.9 months (SD 5.8 months).

Asymptomatic children were significantly more physically active than symptomatic children (p = 0.004, r = 0.2). HIV-infected children had lower MVPA (p = 0.007, r = 0.17) and VPA (p = 0.003, r = 0.2) compared to uninfected children. HIV-infected children who were on antiretrovirals had lower MVPA (p = 0.003, r = 0.16) and VPA (p = 0.002, r = 0.15) compared to antiretroviral-naive children.

Conclusion: HIV-infected children have lower physical activity levels compared to uninfected children. HIV-infected children on antiretrovirals have lower physical activity levels compared to antiretroviral-naive children. Future studies are needed to determine the effects of antiretrovirals on physical activity levels.

WEPEB386 Chronic respiratory ill-health in children with vertically acquired HIV: clinical features and lung function

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Background: Limited studies suggest high rates of chronic respiratory symptoms in children with vertically acquired HIV, yet few have systematically examined symptom burden, lung function and radiological pattern.

Methods: HIV-infected older children and adolescents (age 6-16) on antiretroviral therapy for at least 6 months were recruited from Harare Hospital, Zimbabwe. Assessment included clinical questionnaire, laboratory examinations, spirometry (GL2012 reference ranges), chest X-ray and high resolution CT for children considered to have chronic respiratory disease.

Results: 96 participants were recruited (41 female, 42.7%, median age 11.1 (range 6.1 - 16.1) years, with median age at HIV diagnosis 5.2 (IQR 2.9 - 8.2). Median CD4 was 710 (IQR 458-904). All sputum TB smears were negative.

Children were frequently stunted (n=35, 36.5%). Chronic cough was reported by 20 (20.8%), of which 14 (14.5%) produced sputum spontaneously. Wheeze and dyspnoea were less common (6, 6.3% for each). 40 (41.6%) were previously treated for tuberculosis, and 5 (5.2%) for asthma. Exertional hypoaemia occurred in 21 (17.7%), and 1 child was hypoxaemic at rest. Of 82 high quality spirometry traces, obstructive and restrictive abnormalities were demonstrated in 7 (7.9%) and 19 (21.4%) respectively, with poor reversibility. Mean z-scores (SD) for spirometry were: FEV1 -0.84 (1.17), FVC -0.83 (1.24), FEF25%-75% -0.22 (1.23).

Conclusions: The burden of CLD among HIV-infected children in Malawi is substantial. Recurrent LRTIs in HIV-infected children with delayed ART initiation (i.e., shorter proportion of life on ART) appear to be an important risk factor for CLD. These findings suggest earlier initiation of ART and preventive/treatment strategies aimed at reducing LRTI burden among HIV-infected children, regardless of age, may reduce CLD risk.

Figure 1. Effect of each additional LRTI on CLD risk stratified by proportion of life on ART*. Dashed lines represent 95% CIs

WEPEB387 Decreased vigorous physical activity in South African HIV-infected school-aged children on antiretrovirals

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1Columbia University, New York, United States, 2University of the Witwatersrand, Empilweni Services and Research Unit, Johannesburg, South Africa, 3University of the Witwatersrand, MRC/Wits Developmental Pathways for Health Research Unit, Faculty of Health Sciences, Johannesburg, South Africa
Presenting author email: mw2185@cumn.columbia.edu

Background: Despite potential importance to long-term health outcomes adversely affected by HIV, including bone and cardiometabolic health, physical activity (PA) among people living with HIV has not been well studied. We describe PA in South African HIV-infected and uninfected children.

Methods: Data were obtained from CHANGES (Childhood HAART Alterations in Normal Growth, Genes, and aDing Evaluation Study), a study of perinatally HIV-infected children and uninfected controls in Johannesburg, South Africa from 2012-2014. Age of antiretroviral initiation, HIV/RNA, CD4%, weight-for-age (WAZ) and height-for-age (HAZ) Z-scores, and frequency and duration of physical activities and sedentary behaviors by validated questionnaire were obtained. Metabolic equivalents (METS) of each PA were determined. Moderate-vigorous PA (MVPA) was defined as PA ≥3 METS, while vigorous PA (VPA) was defined as >6 METS. Measures were compared between HIV-infected and uninfected children using chi-squared, t-tests, and linear regression.

Results: 213 HIV-infected and 152 uninfected children aged 6-9 years (83% of target sample) were included. Age, WAZ and HAZ were significantly lower for HIV-infected children. 93.1% of HIV-infected children were virally suppressed (HIV-RNA < 400 copies/mL), had a mean CD4% of 37.4, and were initiated on antiretrovirals at a mean age of 8.9 months (SD 5.8 months).

Asymptomatic children were significantly more physically active than symptomatic children (p = 0.004, r = 0.2). HIV-infected children had lower MVPA (p = 0.007, r = 0.17) and VPA (p = 0.003, r = 0.15) compared to uninfected children. HIV-infected children who were on antiretrovirals had lower MVPA (p = 0.003, r = 0.16) and VPA (p = 0.002, r = 0.15) compared to antiretroviral-naive children.

Conclusion: HIV-infected children have lower physical activity levels compared to uninfected children. HIV-infected children on antiretrovirals have lower physical activity levels compared to antiretroviral-naive children. Future studies are needed to determine the effects of antiretrovirals on physical activity levels.
6.7). The most commonly reported activities are listed in Table 1. HIV-infected children spent significantly less time in MVPA and VPA than controls (mean difference of 5.1 and 3.3 hours/week, p<0.005 and 0.001, respectively), including less running and skipping. The proportion of children in both groups meeting WHO recommendations for PA was similar. While HIV-infected children reported significantly less total sedentary time than uninfected children overall, the time spent in the various sedentary behaviors did not differ. Differences in VPA, running, and skipping remained significant after adjusting for age; MVPA differences however were no longer significant (adjusted 3.6 hours/week, p=0.052). When adjusted for age, WAZ, and HAZ, only VPA and running remained significant.

Conclusions: Although HIV-infected children initiated early on antiretrovirals with good virologic suppression have high levels of PA, VPA was significantly lower than healthy controls. Further investigation of reasons for these differences in PA and implications on short and long-term health outcomes throughout life are warranted.

WEPEB388
Changes in mitochondrial enzyme function as a predictor of lipodystrophy
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1Columbia University Medical Center, College of Physicians and Surgeons, Department of Pediatrics, Division of Infectious Diseases, New York, United States, 2Columbia University, Gertrude H. Sergievsky Center, New York, United States, 3University of the Witwatersrand, Faculty of Health Sciences, Johannesburg, South Africa, 4Columbia University, Gertrude H. Sergievsky Center, College of Physicians and Surgeons, Department of Epidemiology, Mailman School of Public Health, New York, United States, 5Columbia University Medical Center, College of Physicians and Surgeons, Division of Infectious Diseases, New York, United States, 6Columbia University, Department of Epidemiology, Mailman School of Public Health, ICAP, New York, United States
Presenting author email: mdf10@columbia.edu

Background: Extended longitudinal data of mitochondrial function in HIV-infected children treated with potent combination antiretroviral therapy (cART) is sparse. We used peripheral blood mononuclear cells to analyze changes in mitochondrial function over a 5-year period. Potential predictors of lipodystrophy were studied.

Methods: We analyzed data on 38 children enrolled in a clinical trial in Johannesburg, South Africa. All children initiated and were maintained on lopinavir/ritonavir-based cART with viral suppression documented through 5 years of treatment. Buffy coat samples were used for isolation of DNA and analysis of mitochondrial enzyme activity. The following markers of mitochondrial function were used: complex IV (CIV) activity (respiratory chain), citrate synthase (CS) activity (mitochondrial mass), the ratios of CIV/CS (respiratory chain function per mass) and mitochondrial to nuclear DNA. DNA measurements were performed by real time PCR. Protein was isolated and activity of CIV and CS were assayed by spectrophotometric methods. CD4%, plasma RNA and standardized clinical assessment of lipodystrophy (LD) were documented throughout follow-up.

Results: Fifty-three percent of study participants were female. Age at initiation of cART ranged from 2-23 months (mean12 months). Of the 31 children with pretreatment values, median CD4% was 15.3 and 54.8% of participants had a plasma RNA ≥750,000 copies/ml. Eighteen percent developed lipodystrophy, and 71% (5/7) were female. Mitochondrial DNA (mDNA) increased when pre-treatment values were compared to the 5-year time point. CIV and CS activity increased steadily and had not plateaued after 5 years of treatment. Despite these increases, absolute enzyme function did not reach values seen in uninfected children [CIV (2-3 Δ OD/min) and CS (10-12 Δ OD/min)] (Figure). Girls (n=20) and those who developed lipodystrophy (n=7) had early, rapid increases in CIV activity. Pre-treatment CD4% and plasma RNA did not correlate with enzyme function.

Conclusions: Although continuous recovery in mDNA and absolute enzyme activity were observed in these children, they remained below expected levels over 5 years on cART. The more rapid increases in CIV activity observed in those who developed LD suggests mitochondrial recovery may be involved in evolution of LD.

WEPEB389
Early cardio-pulmonary disease in children despite early ART: evidence from CHER cohort
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Background: Untreated HIV infection in children is associated with chronic progressive pulmonary and vascular disease. The degree to which early antiretroviral therapy (ART) prevents this is unclear. Maximal oxygen consumption (VO_max) is the gold standard measure of cardiovascular and respiratory fitness and a sensitive marker of early cardiovascular or respiratory disease.

Methods: In 125 children (77 HIV-infected; 48 uninfected), we performed a standardized 3-minute step test to estimate VO_max using a previously validated formula for healthy children aged 8-12 years. The HIV-infected children had initiated ART (lopinavir, lamivudine, zidovudine) in infancy at median 9.1 (interquartile range, IQR: 7.4 - 11.8) weeks of age. We measured fasting lipids, along with fat-free body weight and vertebral bone mineral density (BMD) using dual energy X-ray absorptiometry (DXA). Verterbral BMD z-score for age and gender was used as a surrogate marker of chronic malnutrition, and fasting total cholesterol as a surrogate for high trans-fat / high refined carbohydrate diet, which are common in our local population. Estimated VO_max was corrected for fat-free body weight before being entered into a multivariate linear regression as the dependent variable.

Results: Table 1:

<table>
<thead>
<tr>
<th>Age (median, range) (years)</th>
<th>7.7 (4.7 - 8.7)</th>
<th>5.4 (4.7 - 8.8)</th>
<th>0.0001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (male/female)</td>
<td>44% (56%)</td>
<td>63% (38%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Body mass index</td>
<td>16.2 (12.2 - 20.2)</td>
<td>17.0 (15.5 - 22.4)</td>
<td>0.08</td>
</tr>
<tr>
<td>Fat-free body mass (kg)</td>
<td>17.6 (13.0 - 22.3)</td>
<td>18.9 (17.3 - 24.2)</td>
<td>0.007</td>
</tr>
<tr>
<td>Unadjusted VO2max (ml/min/kg)</td>
<td>33.6 (23.4 - 43.9)</td>
<td>35.6 (21.0 - 51.1)</td>
<td>0.11</td>
</tr>
<tr>
<td>Verterbral BMD z-score</td>
<td>-0.5 (-2.5 - 1.8)</td>
<td>-0.2 (-2.1 - 1.7)</td>
<td>0.14</td>
</tr>
<tr>
<td>Total cholesterol (mmol/L)</td>
<td>4.2 (2.7 - 5.7)</td>
<td>3.5 (2.1 - 5.0)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Triglyceride-HDL ratio (median, IQR)</td>
<td>0.7 (0.5 - 1.0)</td>
<td>0.4 (0.3 - 0.7)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Variables are presented as mean (95% confidence interval), unless otherwise stated. IQR = Interquartile range; BMD = bone mineral density

Table 1: Description of participants

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Clinical issues in sex workers

WEPEB392
Facilitators and barriers to retention in HIV care among female sex workers enrolled in an HIV care program at a community-based organization in Uganda

S. Nakawangi1, R. Wanyenze1, F. Kahanza1, J. Matovu2, D. Nabukalu2, B. Nsangi2
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Background: Few studies have explored the factors influencing retention in HIV care among female sex workers (FSWs). We established facilitators and barriers to retention in HIV care among FSWs enrolled in a community based HIV program.

Methods: A mixed methods cross-sectional study was conducted among HIV infected FSWs enrolled at Reach Out Mbuya Parish HIV/AIDS Initiative (ROM) from May 2012 to February 2014. We conducted chart reviews and collected data on age, marital status, treatment type and site, residence, duration in care and ART, CD4 at (enrollment, ART initiation and each clinic visit) and status in care (active, lost to follow and missed appointments) for 111 FSWs. In-depth and key informant interviews were conducted with 29 FSWs and five project staff and 11 peer educators respectively. A parametric model (the Weibull distribution) was adopted to explore factors associated with retention in HIV care. Qualitative data were manually analyzed following a thematic framework approach.

Results: Of the 111 FSWs ever registered in care at ROM, 105(95%) were retained. FSWs with higher CD4 > 351 at enrollment were more likely to be retained compared to those enrolled with CD4 < 200 (adj HR: 1.66, 95% CI: 1.18-2.33, P=0.004). However, FSWs with CD4 >200 at each visit had decreased hazards of being retained compared to those with CD4 < 200 (unadj HR: 0.56, 95% CI: 0.48-0.64), P< 0.001. FSWs enrolled in a static clinic were more likely to be retained compared to the mobile outreach clinics. Facilitators for retention were the good friendly services, follow up by peer educators, encouragement from peers, different models used, being a member of a saving group and need to be healthy. Barriers to retention included stigma, drug side effects, alcohol and drugs, pill burden, multiple service providers, Gender based violence and financial constraints.

Conclusions: Retention in care for FSWs is possible with good friendly care services and intensive follow up. However there is need for continuous counseling to avoid the possible losses along the care continuum.

Clinical issues in transgender populations

WEPEB393
HIV-related health access, health seeking behaviors and health literacy in the Malaysian transgender community

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Background: Globally, transgender (TG) women are nearly 50 times more likely to be HIV-infected than their non-TG counterparts. In Malaysia, a country with one of Southeast Asia’s largest TG populations, HIV prevention efforts have long been undermined by pervasive prejudice and discrimination.

Methods: Using a chain-referral method, transgender women (n=119) and transgender men (n=36) 18 years or older in Kuala Lumpur were recruited and completed a computer-based questionnaire assessing HIV-related knowledge, HIV literacy, and general healthcare utilization.

Results: HIV testing was uncommon, with only 85 (36.2%) having ever been tested, and mean time since last test was 26.2 months. Among those tested, 13 (15.2%) reported being HIV-infected, of which 9 were currently receiving antiretroviral treatment. (ART) sex work was the most common type of employment (68.5%), with most (59.3%) stating it was their primary income source. Among those active in sex work, only 60.5% had ever been HIV tested. While nearly all (99.1%) correctly identified condoms as effective HIV prevention, mosquito bites (51.1%) and meal sharing (40.0%) were incorrectly identified as modes of HIV transmission, with no significant differences in HIV literacy responses based on gender or education level.
Nearly all participants (94.0%) did not have a primary care provider and the majority (36.8%) had not received a general physical exam in the past 12 months. However, 82.1% had seen a medical provider for any health-related need in the past 12 months. Perceptions of providers’ knowledge of TG health needs were poor, with 85.1% stating their provider had no knowledge at all of appropriate TG care.

**Conclusions:** Although TG women and men reported moderate levels of healthcare engagement, overall engagement was low within routine, general care, and HIV/STI testing including among high-risk sex workers. Health literacy regarding modes of HIV transmission was poor. Together, these data support provision of specialty clinical and educational services for the LGBT community, including routine and regular HIV and STI testing. These findings indicate a substantial need for further research to improve HIV knowledge, increase HIV testing through novel strategies to reduce barriers to testing and integrate routine testing into all outpatient environments, including venues for TG-related care.

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**Clinical issues in indigenous populations**

**WEPEB394**

Disparities in retention in care and virologic suppression rates for Aboriginal persons and persons who inject drugs in Southern Saskatchewan

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1Regina Qu’Appelle Health Region, Infectious Diseases Clinic, Regina, Canada, 2University of Saskatchewan, Division of Infectious Diseases, Regina, Canada, 3Regina Qu’Appelle Health Region, Population & Public Health Services, Regina, Canada

**Background:** Saskatchewan, a Canadian Prairie province, is currently experiencing a unique HIV epidemic characterized by high rates of transmission through injection drug use and disproportionate representation of Aboriginal persons. The Regina Qu’Appelle Health Region Infectious Diseases Clinic (RQHR IDC) provides care for over 430 HIV-positive individuals in southern Saskatchewan. We sought to determine whether disparities exist in HIV care cascade outcomes in the RQHR IDC for Aboriginal persons vs. non-Aboriginal persons, and those with a history of injection drug use vs. those without.

**Methods:** All non-transferred active HIV-positive individuals in the RQHR IDC were included in the analysis (n=398). Cascade definitions were as follows: linkage to care (seen within 3 months of first reactive HIV serology), retention in care (2 visits in previous 12 months at least 90 days apart), antiretroviral therapy (patient given a prescription for antiretroviral therapy in the previous 12 months), and virologic suppression (HIV viral load <200 c/mL in the previous 12 months). Cross-tabulations, chi-squared, and logistic regression analyses were performed. Patients with missing data were removed from individual cascade measurements.

**Results:** Aboriginal persons were less likely to be retained in care vs. non-Aboriginal persons (102/188 [54.3%] vs. 89/125 [71.2%], OR=0.48 [95% CI 0.30-0.78]) and trended towards being less likely to have a suppressed viral load (122/234 [52.1%] vs. 99/163 [60.7%], OR=0.71 [95% CI 0.47-1.07]). Patients with injection drug use as their primary HIV risk factor were significantly less likely to be retained in care (110/214 [55.6%] vs. 67/117 [57.3%], OR=0.40 [95% CI 0.23-0.69]) or have a suppressed viral load (131/252 [52.0%] vs. 74/116 [63.8%], OR=0.61 [95% CI 0.40-0.94]) vs. those without. No differences between groups were observed for either linkage to care or antiretroviral therapy.

**Conclusions:** Aboriginal persons and persons with a history of injection drug use have suboptimal retention in care and virologic suppression compared to their respective counterparts in southern Saskatchewan. Our clinic population serves as a representative microcosm of the current provincial HIV epidemic, and resources are urgently required to address these disparities and improve cascade outcomes in all patients living with HIV in the province.

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**Clinical issues in incarcerated populations**

**WEPEB395**

HIV risk and clinical characteristics among HIV-positive individuals involved in the criminal justice system: the CARE+ Corrections trial in Washington, DC


1George Washington University Milken Institute School of Public Health, Washington, United States, 2New York University School of Nursing, New York, United States, 3The Miriam Hospital, Providence, United States, 4Brown University, Providence, United States, 5Unity Health Care, Washington, United States, 6Apert Medical School of Brown University/The Miriam Hospital, Providence, United States

**Background:** Previously incarcerated individuals, particularly those recently released, have suboptimal linkage and engagement in community HIV care. We are conducting a randomized trial of an mHealth intervention (CARE+ Corrections) to increase linkage to community care among HIV-positive persons involved in the criminal justice (CJ) system. We report on the baseline characteristics of the sample.

**Methods:** We recruited HIV-positive incarcerated individuals in the District of Columbia jail (7/2014-present) and HIV-positive individuals released from a correctional facility in the previous 6 months through community and street outreach (8/2013-present). Enrollment and follow-up are ongoing. Participants completed a baseline computer-assisted personal interview regarding HIV care and medication adherence, substance use, and sexual behaviors. CD4 and HIV plasma viral load (PVL) testing were performed at baseline or obtained through medical records. Preliminary summary statistics of baseline demographic, behavioral, and HIV-related clinical characteristics are reported.

**Results:** Of 87 individuals, 68% were enrolled in the community. Mean age was 42 (Range 19-63), 65% were male, 10% were transgender (TG), and 85% were black. Participants had a mean of 8.5 (Range 1-61) previous incarcerations, for a cumulative mean length of 10.5 years (0.1-38). Among men and TG, 63% reported ever having had sex with another man. The majority (77%) met criteria for drug dependence and 36% exhibited high-risk hazardous alcohol use; 15% had ever injected drugs. High proportions of participants reported previous diagnoses of depression (78%), bi-polar disorder (54%), and/or schizophrenia (21%). Prior to the most recent incarceration, 73% reported having an HIV provider and 71% were prescribed HIV medications; among those, only half reported ≥90% adherence. Mean baseline CD4 count was 498 cells/µL (range 17-1186) and 38% were not virally suppressed (HIV PVL<100 copies/mL). Of note, 21% (24%) self-reported being diagnosed with HIV, yet only four had been treated.

**Conclusions:** Participants in the CARE+ Corrections trial represent a vulnerable population highly involved in the CJ system with significant substance abuse and mental health co-morbidities. While most have previously been in care, HIV medication adherence and viral suppression remain inadequate. Innovative interventions to link and engage this population in HIV care and improve medication adherence are urgently needed.

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**Clinical issues in other key populations**

**WEPEB396**

Socio-demographic and clinical characteristics of HIV-infected older children and adolescents diagnosed through optimised provider-initiated HIV testing and counselling in primary healthcare services in Harare, Zimbabwe

R. Ferrand1,2, G. Mchugh2, T. Bandason2, I. Kuo1, A. Kurth2, A. Cates3, C. Benz-Tramer4, K. Kranzer5

1Presenting author email: rashida.ferrand@lshtm.ac.uk

**Background:** Older children and adolescents are an underserved group in HIV programs and HIV-related mortality in this age-group continues to increase. We investigated the socio-demographic and clinical characteristics among 6-15 year olds who were diagnosed following optimum provider-initiated HIV testing and counselling (PTC) in seven primary care clinics in Harare, Zimbabwe.

**Methods:** HIV testing and counselling was offered to all children aged 6-15 years attending primary care regardless of reason for attendance, with guardian consent. All those who tested HIV-positive underwent a detailed socio-demographic and clinical assessment, including family and clinical history, HIV staging, and evaluation of growth and lung function.
Results: 379 children underwent a clinical assessment. The median age was 11.2 (IQR: 8.7-13.3) years and 48% were male. Nearly all (96%) were infected by mother-to-child transmission and 95% had a missed opportunity for previous HIV testing (see table).

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit to Primary Care Clinic in the past 6 months</td>
<td>270 (73%)</td>
</tr>
<tr>
<td>Previous TB</td>
<td>21 (6%)</td>
</tr>
<tr>
<td>Previous hospitalisation</td>
<td>100 (27%)</td>
</tr>
<tr>
<td>Parent or natural sibling on ART</td>
<td>244 (64%)</td>
</tr>
<tr>
<td>HIV suspected by guardian</td>
<td>253 (67%)</td>
</tr>
<tr>
<td>Had any of the above</td>
<td>361 (95%)</td>
</tr>
</tbody>
</table>

Conclusions: Contrary to existing data, pregnant IW in our cohort demonstrated reduced odds of psychological co-morbidities or use of DOT during pregnancy and demonstrated significantly better third trimester virologic outcomes than US NW.

Trends in morbidity and mortality

WEPEC596 Trends in AIDS incidence and AIDS-related mortality in British Columbia between 1981 and 2013

V.D. Lima, L. Lourenco, B. Yip, R. Hogg, P. Phillips, J.S.G. Montaner
British Columbia Centre for Excellence in HIV/AIDS, Vancouver, Canada
Presenting author email: vlima@cefern.ubc.ca

Background: Appropriate use of highly active antiretroviral therapy (HAART) can markedly decrease the risk of progression to acquired immunodeficiency syndrome (AIDS) and of premature mortality. We aimed to characterize the trends between 1981 and 2013 in AIDS-defining illnesses (ADI) and in the number AIDS-related deaths in British Columbia (BC), Canada.

Methods: We included data of 3550 HIV-positive individuals, aged 19 years or older, from different administrative databases in BC. We estimated the relative risk of developing an ADI over time using a Negative Binomial model, and we investigated trends in the percentage of all deaths associated with AIDS using generalized additive models.

Results: The number of ADIs has decreased dramatically to its lowest level in 2013. The peak of the AIDS epidemic in BC happened in 1994 with 596 ADIs being reported (rate 42 ADIs per 100 person-years). Since 1997, the number of ADIs decreased from 253 (rate 7 per 100 person-years) to 84 cases in 2013 (rate 1 per 100 person-years) (p-value equals to zero for the trend in the number of ADIs). We have also shown that out of 22 ADIs considered, only PCP maintained its prominent ranking (albeit with much reduced overall prevalence). Finally, we observed that over time very few deaths were related to AIDS-related causes, especially in the most recent years.

WEPEB397 Outcomes of foreign-born females in an antenatal program of a US HIV clinic

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Background: The proportion of foreign-born women in HIV and reproductive health programs in industrialized countries is steadily increasing. Female immigrants may be at particular risk for poor HIV outcomes due to social marginalization, psychological sequelae of trauma and loss, and gender-based violence. Our study aimed to determine if outcomes in pregnant HIV-infected (HIV+) immigrant women (IW) differed significantly from outcomes of United States (US) native-born women (NW) and if IW suffered from disproportionate levels of psychological co-morbidities.

Methods: We retrospectively analyzed medical record data of consecutive HIV+ women receiving outpatient antenatal care in the Northwestern Memorial Hospital Perinatal HIV Program in Chicago, USA in 2007-2012. All patients in the program had comparable insurance coverage and access to medical, social, and mental health services. Univariate analyses were used to compare sociodemographic characteristics, psychological co-morbidities, and clinical parameters of IW versus NW. For the end points that demonstrated a significant association with immigrant status, logistic regression was used to characterize adjusted effect.

Results: 221 (59%) were single-or double orphaned and only 53% had a biological parent as their current guardian. More than 50% of children had at least one change in guardianship. While the majority of children (90%) were going to school, 50% had missed a week or more of school in the past three months. Less than 50% of children affirmed knowledge of their HIV status. The median CD4 count was 380 cells/µl, with 34% having a CD4 count <500 cells/µl. There was a high prevalence of chronic respiratory disease (16% had breathlessness [MRC Dyspnoea scale >1]), 53% had cough, 31% were hypoxic (oxygen saturation < 88% at rest or following exercise).

Conclusions: There is significant delay in diagnosis of HIV in older children. HIV-infected children have complex social circumstances with orphanhood, changing guardianship and interrupted schooling and non-disclosure being common. In addition, there is additional morbidity such as chronic lung disease which is currently not addressed systematically by HIV care programs. HIV testing strategies for older children need to be developed and HIV care programs need to address complex social issues and clinical management should focus on co-morbidities as well as on delivery of antiretroviral therapy.

WEPEC597 Diabetes mellitus increases death rates among HIV-infected patients in Rio de Janeiro, Brazil

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Background: Diabetes mellitus (DM) is a major morbidity worldwide and increases the risk of cardiovascular diseases (CVD) and death. Chronic comorbidities such as DM are becoming increasingly prevalent in the HIV population. We evaluated the prevalence of DM among HIV-infected patients and its association with mortality rates (MR).

Results: Of 621 (95%) were single-or double orphaned and only 53% had a biological parent as their current guardian. More than 50% of children had at least one change in guardianship. While the majority of children (90%) were going to school, 50% had missed a week or more of school in the past three months. Less than 50% of children affirmed knowledge of their HIV status. The median CD4 count was 380 cells/µl, with 34% having a CD4 count <500 cells/µl. There was a high prevalence of chronic respiratory disease (16% had breathlessness [MRC Dyspnoea scale >1]), 53% had cough, 31% were hypoxic (oxygen saturation < 88% at rest or following exercise).

Conclusions: There is significant delay in diagnosis of HIV in older children. HIV-infected children have complex social circumstances with orphanhood, changing guardianship and interrupted schooling and non-disclosure being common. In addition, there is additional morbidity such as chronic lung disease which is currently not addressed systematically by HIV care programs. HIV testing strategies for older children need to be developed and HIV care programs need to address complex social issues and clinical management should focus on co-morbidities as well as on delivery of antiretroviral therapy.

Conclusion: We showed that the number of new ADIs and AIDS-related mortality have been decreasing rapidly over time in BC. These results provide further evidence that integrated comprehensive free programs that facilitate testing, and deliver treatment and care to this population can be effective in markedly decreasing AIDS-related morbidity and mortality, thus suggesting that controlling and eventually ending AIDS is possible.
Methods: All patients 18 year or older followed in the Instituto Nacional de Infectologia cohort from June 1986 to December 2011 were included. DM was determined through information abstracted from medical charts following Brazilian guidelines. Vital status was determined through information in the charts and recovery using a linkage algorithm. A standardized algorithm (CoDe) was used to classify causes of death (COD). Time-updated covariates included DM status, calendar year, cART use and CD4 cell counts. Demographic covariables were gender and age at entry. Poison models were used to calculate rate ratios (RR) with robust variances for mortality.

Results: Among the 4871 patients included, 1192 (24.4%) have died (MR = 4.72/100PY; 95%CI=4.46-5.03). Overall, DM prevalence was 10.2%, median age was 34.4 years and 67.5% were male (Table 1).

| Model 1 — numbers of unprotected sex and syringe sharing acts were constant within injecting network representing an urban, mixed epidemic in North America (New York, 1992-2002). We considered a model for HIV transmission among PWID in which the per-partnership transmission probability followed a binomial distribution, and then constructed more sophisticated HIV transmission models as follows: Model 1 — numbers of unprotected sex and the syringe sharing acts were constant within partnerships, and the per-act transmission probability varied by stages of HIV disease and by antiretroviral therapy adherence; Model 2 — the numbers of unprotected sex and syringe sharing acts were random and assigned from Poisson distributions, and the per-act transmission probability was as in Model 1; Model 3 — the per-act transmission probability was defined based on individual plasma HIV viral load, which has been randomly assigned: Model 4 — same as Model 3, but with two groups of partnerships: those with either higher (primary partner) or lower (casual partners) risk behavior profiles. HIV incidence trajectories outputted by each model were compared to that empirically observed. Results: Models 1 and 2 were unable to reproduce HIV incidence and prevalence estimates observed among PWID in New York between 1992 and 2002. Overall, models with less heterogeneity were more sensitive to changes in numbers of sexual and parenteral acts, producing HIV incidence up to 4 times higher than that empirically observed. Conversely, Models 3 and 4 produced satisfactory estimates of HIV incidence, and showed less sensitivity to changes in key parameter. Compared to the empirical estimate, we observed a 545% relative bias in HIV incidence among PWID in 2002 from Model 2, compared to 15% for Model 4. Conclusions: Although all models over-estimated HIV incidence, micro-simulations with greater heterogeneity in the HIV transmission modeling process, specifically transmission determined by individual viral loads, produced more robust results and better reproduced empirical epidemic dynamics.

WEPEC599 The contribution of transmission from acute HIV infection may vary by epidemic stage among people who inject drugs

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Background: HIV transmission risk is elevated during acute HIV infection (AHI), but the contribution of AHI to total transmission among people who inject drugs (PWID) remains unknown. Furthermore, the role that epidemic stage plays in determining this contribution has not been investigated. We constructed an agent-based model (ABM) to compare estimates of AHI-attributable infections to overall transmission among PWID in early versus mature epidemic stages.

Methods: The ABM was calibrated to approximate the risk behavior profiles and epidemic dynamics of early (i.e., low prevalence [3%], frequent risk behavior) and mature (i.e., high prevalence [41%], infrequent risk behavior) HIV epidemics within a large urban setting, over a ten-year period. The ABM consists of agents that interact in a dynamic sexual and injecting network representing a population of 100,000. Each agent has a time-dependent probability of transmitting or acquiring HIV, based on risk behavior, partnership characteristics, and engagement in simulated prevention interventions (i.e., HART, needle/syringe programs), as well as disease stage. Using Monte Carlo stochastic microsimulations, we classified transmission events by disease stage (where AHI was assumed to last three months and have a ten-fold probability of transmission compared to chronic infection), and then compared the AHI transmission events (as a proportion of total transmissions) between the two stages.

Results: The models approximated the conditions of typical early and mature HIV epidemics among PWID over 10 year periods. For the mature epidemic, HIV prevalence decreased from 41% to 18% with an average annual HIV incidence of 2.3% per 100 person-years. In the early epidemic, HIV prevalence increased from 3% to 8% and incidence increased from 0.2% to 2.8% per 100 person-years. On average, AHI accounted for 22% and 8% of total transmissions in early and mature epidemic stages, respectively.

WEPEC598 Understanding the effects of different HIV transmission models in individual-based microsimulation of HIV epidemic dynamics among people who inject drugs


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Background: The individual-based model simulated HIV transmission in a dynamic sexual and injecting network representing a population of 100,000. Each agent has a time-dependent probability of transmitting or acquiring HIV, based on risk behavior, partnership characteristics, and engagement in simulated prevention interventions (i.e., HART, needle/syringe programs), as well as disease stage. Using Monte Carlo stochastic microsimulations, we classified transmission events by disease stage (where AHI was assumed to last three months and have a ten-fold probability of transmission compared to chronic infection), and then compared the AHI transmission events (as a proportion of total transmissions) between the two stages.

Results: The models approximated the conditions of typical early and mature HIV epidemics among PWID over 10 year periods. For the mature epidemic, HIV prevalence decreased from 41% to 18% with an average annual HIV incidence of 2.3% per 100 person-years. In the early epidemic, HIV prevalence increased from 3% to 8% and incidence increased from 0.2% to 2.8% per 100 person-years. On average, AHI accounted for 22% and 8% of total transmissions in early and mature epidemic stages, respectively.
WEPEC600

Widespread implementation of a curative regimen would have more significant effects on HIV-1 prevalence than incidence

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Background: There is increased optimism that a cure for HIV-1 may be possible. Current strategies aim to achieve complete eradication of latent provirus, or at least provide a functional cure, in which latent HIV-1 is lowered below a threshold necessary for viral replication, progression to AIDS, and transmission. The potential impact of implementing cure programs on HIV-1 prevalence and incidence has not formally been considered.

Methods: We developed a compartmental mathematical model of HIV transmission in a sexually active population to evaluate the independent and synergistic impact of ART, pre-exposure prophylaxis (PrEP) and cure on HIV epidemics in high-prevalence settings. We explored scenarios with and without the assumption that ART treatment and viral suppression is required for cure. We calculated the basic reproduction number ($R_0$) to evaluate the potential for the HIV epidemic to be eliminated in each scenario. We analyzed the impact of curative treatment on the HIV prevalence and incidence over extended timeframes.

Results: Implementation of curative regimes had limited impact on HIV-1 incidence if ART was a pre-requisite for cure. Treatment alone resulted in $R_0 < 1$ only if more than 16% of untreated individuals initiated ART annually. Even if 50% of treated patients were cured annually, the ART initiation rate required for elimination of HIV remained above 10% under these conditions. HIV incidence was virtually unchanged during the first 20 years of cure implementation. Cure implementation had a significant impact on HIV-1 incidence only if pre-treatment with ART was not required (Fig. 1). Annual ART and cure rates of 6% were sufficient to reduce $R_0 < 1$ in the absence of PrEP. Those rates were reduced to 4% if 60% effective PrEP was used by 20% of the sexually active population to evaluate the independent and synergistic impact of ART, pre-exposure prophylaxis (PrEP) and cure on HIV epidemics in high-prevalence settings. We explored scenarios with and without the assumption that ART treatment and viral suppression is required for cure. We calculated the basic reproduction number ($R_0$) to evaluate the potential for the HIV epidemic to be eliminated in each scenario. We analyzed the impact of curative treatment on the HIV prevalence and incidence over extended timeframes.

Conclusions: Projected that gradual implementation of curative HIV-1 therapies would have a beneficial impact on HIV prevalence but not incidence. Therefore, development of HIV-1 cure technologies should evolve in parallel with ongoing research to expand HIV prevention and ART availability.

Cure is NOT contingent upon ART

Cure is contingent upon ART

Risk factors for acquisition of HIV

WEPEC601

HIV prevalence and risk behaviors among university students in Dire Dawa, Ethiopia, 2013

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Background: HIV infection among young people aged 15-24 years is often attributed to sexual exposure and assumed to be recent infection. Behavioral changes, such as condom use and limiting sex partners, and improving access to HIV prevention services have been shown to reduce new infections.

But in Ethiopia, young people, including university students, are having sex with multiple partners and using condoms inconsistently; these behaviors increase their likelihood of acquiring HIV. This assessment is, therefore, aimed to explore the risk behaviors and HIV prevalence among the students.

Methods: During April 2013, a cross-sectional study was conducted among students of Dire Dawa University, one of 13 Ethiopian universities with 7,938 students enrolled. Using a previously estimated HIV prevalence of 2.5%, 95% confidence level, 80% power, 1% margin of error, and 5% anticipated non-response rate, a representative sample of 983 students was systematically chosen by selecting every eighth student in the sample frame. Data collection and analysis were conducted using SPSS 21.0. Ethical approval is obtained from Centers for Disease Prevention and Control Atlanta and from National PRB in Ethiopia.

Results: Of 983 sampled, 967 students participated, a response rate of 98.3%. Of 967 students participating, 91 (93.9%) were tested for HIV. 4 (0.4%) were HIV positive. Half of participants (49.9%) reported ever having sex and 53.0% reported having sex in the past 12 months. Females were more likely to report first having sex after coming to the university and not having used a condom during their first sexual intercourse, and males were more likely to report sex with multiple partners in the past 12 months and having ever used alcohol or drugs.

Conclusions: Despite the low prevalence, this study may inform university policies that address educational needs and environmental factors that can contribute to university students’ increased risk of HIV infection. Engaging high school students, prior to their entry to the university setting, to introduce HIV prevention messages earlier may increase students’ competency in prevention. Tailoring interventions to both female and male students’ educational needs may increase the impact of services.

WEPEC602

Compulsive sexual behavior, substance use, depression and sexual risk-taking among young urban men who have sex with men: the P18 cohort study

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Background: Previous behavioral research has shown that young gay, bisexual and other men who have sex with men (YMSM) are at increased risk for substance abuse, mental health burden, and the Human Immunodeficiency Virus (HIV). As informed by syndemic theory, this analysis sought to further define the impact of compulsivity in sexual risk-taking behavior among a new generation of YMSM ages 18-19.

Methods: The current analysis administered the Compulsive Sexual Behavior Inventory (CSBI) as well as additional psychological, psychosocial, alcohol/drug use, and sexual behavior measures to 509 racially and economically diverse, confirmed HIV-negative, YMSM sampled from the New York City metropolitan area. A multivariable model was determined to test whether the use of alcohol and drugs mediated the relation between compulsive sexual behavior and sexual risk-taking.

Results: Alcohol and drug use were shown to significantly and completely mediate the relation between compulsive sexual behavior and condomless anal sex ($p<0.003$, $95%$ CI $0.74$, $0.99$). A Sobel test was conducted and found full mediation in the model ($p=0.01$). In addition, depression was shown to moderate the relation between compulsive sexual behavior and sexual risk-taking ($p<0.008$, $95%$ CI $0.35$, $0.86$).
depression were associated with significantly more condomless anal sex among those YMSM who scored high in sexual compulsivity.

Conclusions: Findings suggest that compulsive sexual behavior in concert with depressive symptoms and substance use exacerbate risk for sexual risk-taking among YMSM. Clinicians must take a holistic approach when providing care and need to address the underlying psychological symptoms that exacerbate risk behaviors in order to reduce HIV-risk among this new generation of YMSM.

WEPEC603
Temporary migration, multiple sexual partnerships, and sexual concurrency in the Garífuna population of Honduras

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Background: Within Latin America, Honduras has historically been one of the countries most severely affected by HIV. The Garífuna, an Afro-indigenous minority group, have been identified as a priority population for HIV prevention and control efforts in Honduras. In 2012, the HIV prevalence among Garífuna adults in Honduras was estimated at 4.1%, while the national prevalence had declined to 0.3%. HIV transmission among the Honduran Garífuna is attributed to high rates of mobility, though empirical evidence is limited. The objective of this study was to assess the relationship between temporary migration and having multiple sexual partners or concurrent partnerships among Garífuna men and women.

Methods: Data were collected through a population-based surveillance study of sexual behavior and HIV/STI prevalence in vulnerable populations in Honduras from September-December 2012. Garífuna men and women were recruited from households in randomly-selected urban districts and rural communities, and responded to a comprehensive standardized survey. The primary exposure - recent temporary migration - was defined as spending more than one month away from home in the last 12 months. Primary outcomes were multiple sexual partnerships and concurrent sexual partnerships in the last 12 months.

Results: We analyzed data from 230 men and 399 women. Fifteen percent of men and 8.5% of women were recent migrants. Men were more likely to report multiple sexual partnerships in the last 12 months compared to women (31.7% vs. 6.2%). Both migrant men and women had an increased likelihood of multiple sexual partnerships in the last 12 months compared to non-migrant men and women (31.7% vs. 6.2%). Among migrant women, 18.0% of men and 2.9% of women reported concurrent sexual partnerships. Migration was associated with concurrency among both men and women, though precision was poor for the corresponding effect estimates.

Conclusions: Multiple and concurrent sexual partnerships were more prevalent among male and female Garífuna migrants compared to non-migrants. Future research focused on HIV/STI vulnerability in Latin America should continue to incorporate measures of short- and long-term mobility.

WEPEC604
Women in peril: high levels of HIV infection risk among the male sex partners of low-income, Black women in the United States

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Background: In the United States (U.S.), black women are disproportionately affected by HIV transmitted through heterosexual contact. To assess the risk of heterosexual transmission to low-income, black women, we sought to determine whether their male sex partners were at high risk for HIV infection.

Methods: We analyzed data from women and their male sex partners who participated in the U.S. National HIV Behavioral Surveillance System (NHBS) in either 2010 or 2013. Participants were 18-60 years old, of low socioeconomic status, and recruited using respondent driven sampling. We restricted our analysis to women who were black, tested HIV-negative, did not have a history of injecting drugs, and had a male sex partner who also participated in NHBS. Men at high risk for HIV infection were defined as men who ever had sex with another man (MSM) and persons who ever injected drugs (PWID). Factors associated with having a high-risk male sex partner were analyzed using generalized estimating equations with a Poisson distribution.

Results: Of the 901 women who met our inclusion criteria, 153 (17%) had a high-risk male sex partner (7% of the male sex partners were MSM, 7% PWID, and 4% both MSM and PWID). In multivariable analysis, factors associated with having a high-risk male sex partner were age 40-60 years (Adjusted Prevalence Ratio [APR]=2.9, 95% Confidence Interval [CI]=1.6-4.1), exchanging sex for money or drugs in the year before interview (APR=1.9, 95% CI=1.3-2.6), and having a household income less than U.S.$10,000 (APR=1.4, 95% CI=1.1-1.8). In a subset of 330 women with additional sex partner data, just 2 (10%) of 20 women with an MSM partner were aware of his history of same-sex behavior and 11 (42%) of 26 with a PWID partner were aware of his history of injecting drugs.

Conclusions: Nearly 1 in 5 black women included in our analysis had a male sex partner at high risk for HIV infection, yet the women’s awareness of their partner’s risk was low. Older and socially and economically vulnerable women were especially likely to have a high-risk male sex partner. These women would greatly benefit from increased interventions, like couples HIV testing and prevention counseling.

WEPEC605
HIV incidence is low and stable in young adults who inject drugs in San Francisco: UFO study 2000-2014

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Background: The CDC’s National HIV Surveillance System shows that HIV infection among people who inject drugs (PWID) has been declining. We assessed HIV incidence, trends and primary risk factors from data collected in an ongoing prospective observational study (The UFO Study) of young adult PWID in San Francisco.

Methods: Young (< 30 years) PWID who were HCV negative were enrolled the study with survey and blood specimens collected quarterly. For this analysis we included all those who were HIV negative at baseline, enrolled and followed between 2000 and 2014, who had ≥2 visits. Date of incident HIV infection was estimated as the midpoint between last documented seronegative and first seropositive blood sample. Negative participants were censored at the last study visit date. Risk exposures were based on self-reported data. HIV infection was determined using GS HIV Combo Ag/Ab EIA (4th gen assay) with GS HIV-1 Western Blot confirmation.

Results: Overall, 10 seroconverters were identified over the 1074.8 py follow up time in 561 individuals, for an estimated HIV infection rate of 0.91/100 py (95% CI, 0.5-1.7). HIV incidence was highest among Latino or Hispanic 7.9/100py (95% CI 3.3-19.0), African-American 4.7/100py (95% CI 1.2-18.7), followed by men who reported any sex with men (MSM) 3.0/100py (95% CI 1.5-6.0). HIV incidence was stable between 2000-2 (0.6%, 95% CI 0.2-2.5) and 2012-14 (1.1%, 95% CI 0.3-4.2), with a pick in 2003-5 (2.3%, 95% CI 0.9-5.4). The IRR of MSM vs. non-MSM was 11.4 (95% CI, 2.4-53.8; P<0.001).

Conclusions: HIV infection rates were low (under 1%) in young PWID in San Francisco over the observation period. However rates were high in young male PWID who also report sex with men, Latino and African-Americans. These results show the ongoing risk of HIV in association with overlapping drug and sexual exposures. The trends overall are comparable to those seen nationally, reflecting declines. HIV prevention efforts in San Francisco and elsewhere should be scaled up to reach this younger high risk population, who are also experiencing high rate of other blood borne infections, including viral hepatitis.
WEPEC606
Household socioeconomic status, sexual behavior, and prevalence of HIV and HSV-2 among sexually experienced South African school girls: HPTN 068

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Background: Poverty is hypothesized to increase young women’s risk of HIV infection; however, little is known about the association between socioeconomic status (SES) measures and HIV risk among adolescent girls in sub-Saharan Africa.

Methods: Within a randomized controlled trial of conditional cash transfers to reduce HIV risk among adolescents (HPTN 068), we used baseline data to determine the association between three indicators of SES and self-reported sexual behavior as well as prevalent HIV and HSV-2 infection. The study took place in the Agincourt Health and Socio-Demographic Surveillance Site in South Africa, a rural area characterized by high poverty: 80% of households receive income support from the national Child Support Grant (CSG) - a non-contributory social support grant. We measured household SES using three indicators: monthly per-capita consumption expenditures, asset ownership, and parent/guardian education. We used logistic regression to estimate prevalence odds ratios (OR), controlling for orphan status, age, CSG receipt, and the other SES indicators.

Results: Among 693 sexually experienced high school girls, those from households with more assets had significantly lower odds of HIV-2 infection (OR=0.68, 95%CI: 0.48, 0.98), pregnancy (OR=0.76, 95%CI: 0.58, 0.99) and lower odds of HIV infection (OR=0.61, 95%CI: 0.36, 1.01). Girls whose parent/guardian obtained any education had significantly lower odds of sexual debut before age 15 (grade 1-11: OR=0.57, 95%CI: 0.36, 0.90; grade 12 and above: OR=0.50, 95%CI: 0.27, 0.94; among girls 15+), and had lower odds of HIV and HSV-2 infection and pregnancy (results not statistically significant). The associations with consumption expenditures were generally not significant, but higher expenditures were associated with lower odds of HIV and HSV-2 infection and pregnancy.

Conclusions: In this study, greater household wealth, measured by asset holdings, and parent/guardian education were associated with decreased odds of HIV infection and sexual risk factors. However, the specific SES measure used and the widespread coverage of social protection programs such as the CSG may be critically important in determining the association with HIV risk outcomes. SES measures that are typically used to measure poverty, such as consumption expenditures, may have a weaker association with HIV risk due to the effect of social protection programs.

WEPEC607
How common and frequent is heterosexual anal sex among South Africans? A systematic review and meta-analysis

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Background: HIV is transmitted more effectively during anal intercourse (AI) than vaginal intercourse. However, the role that AI plays in heterosexual HIV epidemics remains incompletely understood. We aimed to determine the proportion of adults in South Africa (SA) reporting heterosexual AI and how frequently it is practised.

Methods: We searched PubMed for studies published from 1990 to December 2014 reporting data on the proportion of SA adults (aged 16+) practicing heterosexual AI (i.e. Al prevalence) and on the number of AI acts (i.e. Al frequency). Where two or more estimates were available, we pooled estimates of AI prevalence using random-effects models.

Results: Of the 1367 records identified, 27 articles were included. Twelve reported on high-risk populations, mainly FSW (N=5) and STI patients (N=4). Nineteen reported on females, 10 on males, and 26 on adolescents combined. The 27 articles included 47,104 study participants aged 18-59. Fourteen articles reported on Al frequency and 15 on AI prevalence.

Pooled AI prevalence tended to be higher over shorter recall periods (lifetime[N=2]=2.3% [95% CI:1.1-3.5]; past month[N=2]=10.4% [95% CI:2.5-18.3]; with current partner[N=2]=17.8% [95% CI:7.5-28.2]) among the general population (Figure). This appeared to be confounded by confidentiality of interview method.

Among higher-risk respondents, AI prevalence was reported across too many different recall periods to pool (female range[N=4]=5.4-62.6%, male range[N=2]=21-58.2%). Among the general population, the proportion of total AI and unprotected AI (UA) acts ranged between 0.3-1.3 and 0.1-0.7 per month, respectively (N=4). The fraction of all sex acts that were AI among whole samples (i.e. including those reporting no AI) was 4.4-16.7% across studies (N=6). The fraction of all unprotected acts that were UA ranged from 4.5% to 21.0% (N=8). Among higher-risk respondents, number of AI acts/month was 0.1-1.68, with 1.6-29.2% of all acts being UA (N=1).

Conclusions: AI is common and frequent among South Africans and could therefore be a determinant in the country's HIV epidemic. Given its higher transmission risk and common practice, it is imperative that messaging on safe AI be included in HIV interventions and that products which enable safer AI be developed.

WEPEC608
Association of condom use with changing sexual roles among MSM, transgenders and hijras in India: findings from the midline study of the Global Fund-supported Pehchan programme

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Background: HIV prevalence among MSM and transgenders is disproportionately high at 4.43% and 8.82% respectively in comparison to the national prevalence of 0.3% in India. India HIV/AIDS Alliance in consortium with five partner organizations implements the five-year Global Fund-supported Pehchan programme in 18 Indian states to build the capacity of 200 CBOs to serve as effective HIV prevention partners with the National AIDS Control Programme and reach more than 450,000 MSM, transgenders and hijras (MTH) using a community-driven and rights-based approach. Pehchan conducted a midline study (2012) to determine the effectiveness of the programme’s strategy for priority interventions including condom use, sexual behaviour change, and HIV risk reduction strategies.

Methods: A mixed method of evaluation was adopted using a cross-sectional study that sampled 601 MSM, transgender and hijra respondents covering 23 districts across six states in community-based organisations that had provided services through Pehchan for at least six months. Probability Proportion to Size (PPS) method and systematic random sampling were used. Qualitative techniques of data collection namely 72 focus group discussions, 84 key informant interviews, 24 in-depth interviews, and five case studies were used. Descriptive and correlation analysis was done using SPSS.

Results: Anal sex with regular partners and non-regular partners was reported to be 86% and 55% respectively. Consistent condom use during anal sex in the previous month in which respondents were engaged in a receptive role with regular partners and non-regular partners was reported to be 58% and 64% respectively. Consistent condom use during anal sex in the previous month in which respondents engaged in an insertive role with regular partners and non-regular partners stood significantly lower at 30% and 34% respectively. Average sexual acts with MSM, TG/H played receptive role with regular and non-regular partners ranged from 5 to 9 and 8 to 16 respectively. When MTH played an insertive role, average sexual acts ranged from 1 to 3 with varied partners

Conclusions: Data suggest that MTH vary condom practices with changing sexual roles, especially reduced condom use by those in insertive roles increasing vulnerability to HIV. Appropriate interventions including targeted prevention messaging must be undertaken to address high-risk practices among MTH.
WEPEC609
Mental health and sexual risk behaviors among networks of young men in Dar es Salaam, Tanzania

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Backgrounds: 7% of the population of Dar es Salaam is living with HIV, and youth account for 60% of new HIV infections in Tanzania. Young men in Tanzania report infrequent condom use and high levels of sexual partner concurrency, both important risk factors for HIV-infection. Though partners in the past six months (47.5 vs 7.0, p<0.01), and at higher risk for HIV (SD 0.3), this has rarely been seen in the sub-Saharan context. We examined the associations between mental health (anxiety and depression) and sexual risk behaviors (condom use and concurrency) in a population of young men in Dar es Salaam.

Methods: Participants in this study are male members of 60 “camps,” or social groups occupying designated physical spaces where they socialize regularly, in Dar es Salaam, Tanzania. After random selection of camps, eligible members completed a computer assisted personal interview in the fall of 2013. Measures of condom use and concurrency were self-reported. Anxiety and depression were measured using subscales of the Hopkins Symptom Checklist-25. Hypotheses were tested using hierarchical linear modeling to account for the nested structure of the data.

Results: A total of 1280 men were interviewed at baseline. Using common clinical cutoffs, 21% of men displayed symptoms of anxiety, and 22% showed symptoms of depression. On average, men reported condom use for 42% of sex acts (SD=16) and 20% of men reported ever engaging in sex with a man. Both anxiety and depression predicted significantly greater chance of sex act without a condom (B= -0.12 and 0.11, respectively; p<.001 in both cases), and concurrency (B= 0.83 and 0.69, respectively; p< .001 in both cases). Specifically, as levels of anxiety or depression increased, frequency of condom use decreased and the likelihood of reporting concurrency increased.

Conclusions: These findings further our understanding of the mental health determinants of HIV risk in a population of high risk young men. Our results indicate intervention targeting mental health as a potential strategy to reduce key HIV risk behaviors among the growing population of male youth in sub-Saharan urban areas.

WEPEC610
Newly HIV-infected gay, bisexual, and other men who have sex with men (MSM) in Vancouver, British Columbia: preliminary findings of the Momentum Health study

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Background: We measured HIV incidence among participants in a prospective cohort of MSM in Vancouver, British Columbia and explored characteristics associated with HIV seroconversion.

Methods: The Momentum Health Study employs respondent-driven sampling to recruit participants into a longitudinal bi-behavioural cohort study with 6-monthly visits. At baseline, participants completed a computer-assisted questionnaire and nurse-administered sexual health check-up including a point-of-care HIV test. Seroconverters were participants who tested HIV-negative at baseline and HIV-positive at a subsequent visit or another testing source between visits. Behavioural data are drawn from their most recently completed questionnaire prior to HIV diagnosis. Comparisons between HIV seroconverters and non-converters who remained HIV-negative were made using non-parametric statistical tests (p<0.05).

Results: As of December 7, 2014, 378 MSM who tested HIV-negative at baseline contrib- uted a mean follow-up time of 1.27 years. The HIV incidence rate was 1.25 per 100 person-years (6 MSM seroconverted, 95% CI 0.56-2.77). Although not significantly different when compared with MSM who remained HIV-negative, all seroconverters identified as gay, 56% as Caucasian, and 5/6 were aged 30 years or less. The HIV incidence rate for MSM aged 30 years was 2.40 per 100 person-years (95% CI 0.90-5.17). Compared with MSM who remained HIV-negative, MSM who seroconverted reported a greater median number of sexual partners in the past six months (15.5 vs 4.0, p<0.01), reported greater median number of anal sex events with sexual partners in the past six months (47.5 vs 7.0, p<0.02), and felt at higher risk for HIV (SD 0.3 vs 0.0, p< 0.01). Five seroconverters had heard about Treatment as Prevention, four of post-exposure prophylaxis, and two of pre-exposure prophylaxis. There were no significant differences in the proportion of participants reporting any condomless anal intercourse, other socio-demographics, substance use patterns, mental health diagnoses, or reported prevention measures.

Conclusions: Recent HIV seroconverters were younger MSM with frequent partner change and greater rates of anal intercourse who appeared to understand that they were at higher risk for HIV acquisition. The level of awareness regarding effective biomedical preven- tion strategies among HIV seroconvertors was incomplete. These findings can help target fur- ther HIV prevention programs towards such individuals.

WEPEC611
Experiences with food insecurity and risky sex among low-income people living with HIV/AIDS in the San Francisco Bay Area: a qualitative study

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Background: Forty-nine million individuals are classified as food insecure in the United States, where both food insecurity and HIV/AIDS are prevalent among the urban poor. Previous studies have demonstrated that food insecurity is associated with risky sexual practices among people living with HIV/AIDS (PLHIV). However, no qualitative studies to date have explored the mechanisms underlying this relationship either in a resource-rich setting or among populations that include men who have sex with men (MSM).

Methods: Semi-structured in-depth interviews were conducted with 28 male and 6 female low-income PLHIV receiving food assistance from a non-profit organization in the San Fran- cisco Bay Area. The interviews explored experiences with food insecurity and perceived as- sociations with sexual risk behaviors. Interviews were conducted in English, audio-recorded and transcribed verbatim. Transcripts were coded and analyzed according to content analysis methods using an inductive-deductive approach.

Results: Food insecurity was reported to be a strong contributor to risky sexual practices among both MSM and female participants. Individuals described engaging in transactional sex (both sex work and more opportunistic encounters with casual partners) in order to alleviate food insecurity, exchanging sex for food or money to buy food and sometimes also obtaining shelter during the encounter. Transactional sex often co-occurred with destitution and home- lessness. Participants also described how the experience of food insecurity could lead to un- protected sexual activity despite knowledge of and desire to engage in safe sexual practices. Specifically, hunger could compromise an individual’s ability to insist on condom use with a casual partner, largely because the need to obtain food in the short-term was prioritized over the need to use protection.

Conclusions: Our data extend previous research by demonstrating that food insecurity may contribute to risky sexual practices among urban poor individuals in the resource-rich con- text, including among MSM. The mechanisms describing how food insecurity may contribute to transactional and unsafe sex underscore the importance of public health intervention efforts focused on structural inequalities.

WEPEC612
Low frequency of consistent condom use during heterosexual intercourse in prison among male inmates in a State Prison System in Mexico

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Background: Inmates are at high-risk for HIV and STIs. To prevent the sexual transmission of HIV and STIs inside prisons, conjugal visits have been recommended in prisons where sex is forbidden. However, little is known about condom use in prisons where conjugal visits are in place.

Methods: Cross-sectional study to estimate the proportion of male inmates who always use condom use for heterosexual intercourse during imprisonment, and identify factors associ- ated to unsafe sex. We collected data on sex behavior with structured interviews from inmates
WEPEC614
Decrease in the proportion of HIV-positive MSM followed up in hospital likely to transmit HIV between 2003 and 2011 in France: results from national representative surveys (ANRS VESPA-1 and VESPA-2)
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Background: In France, men who have sex with men (MSM) still remain the population most at risk of HIV infection, with no decrease in HIV incidence being observed. We aimed to assess changes in sexual behavior among HIV-positive MSM attending outpatient clinics using data from two national representative surveys, conducted in 2003 and 2011, respectively, by considering indicators reflecting the diverse factors that might impact HIV sexual transmission in this population.

Methods: ANRS VESPA-1 and -2 were cross-sectional surveys conducted among adult PLWH attending French hospitals. Socio-behavioural and medical data were collected. The present analysis included men who self-reported they were gay, bisexual or had had at least one male partner in the previous year (n=1117 VESPA-1, n=1337 VESPA-2). HIV-negative or unknown status partners were considered serodiscordant. The outcome was inconsistent condom use for oral or anal sex with a serodiscordant steady partner in the previous 12 months, or with a serodiscordant casual partner during their last sexual encounter. Chi2 tests were performed on weighted and calibrated data.

Results: Compared with MSM included in 2003, those in 2011 were significantly (p<10-12) older, were diagnosed with HIV longer, and reported less sexual activity. However, they had better immunovirological status (CD4>500 cells/mm3 and undetectable viral load (VL)). Globally, between 2003 and 2011, the proportion of MSM reporting inconsistent condom use with a serodiscordant steady (79% vs 86% for oral sex; 23% vs 25% for anal sex, respectively) or casual partner (76% vs 80% for oral sex; 23% vs 18% for anal sex, respectively) did not differ significantly. However, the proportion of MSM with a detectable VL engaging in unprotected intercourse with serodiscordant main (22% vs 9% for oral sex; 7% vs 1% for anal sex, respectively) and casual partners (26% vs 4% for oral sex; 8% vs 4% for anal sex, respectively) decreased noticeably.

Conclusions: The proportion of HIV-positive MSM likely to transmit HIV decreased between 2003 and 2011 despite no increase in condom use. To have an impact on HIV epidemic, additional behavioral changes will not be enough without achieving an undetectable viral load in all treated seropositive people.

WEPEC613
Risk factors for infectivity, progression and transmission of HIV
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Background: Health insurance is crucial for optimizing health outcomes for those with HIV. While research has shown that health insurance and the AIDS Drug Assistance Program (ADAP) provide needed access to antiretroviral therapy (ART), the effect of insurance on viral load among women prior to ACA implementation.

Methods:load among women prior to ACA implementation. (ADAP) provide needed access to antiretroviral therapy (ART), the effect of insurance on viral load among women prior to ACA implementation. (ADAP) provide needed access to antiretroviral therapy (ART), the effect of insurance on viral load among women prior to ACA implementation. 

Results: Among 2,107 participants, 1,670 (63.8%, 95% CI=58.8-68.9) have had sex in prison, most of them (1,628, 97.8%, 95% CI=96.8-99.8) with women. Only 149 inmates (8.9%, 95% CI=5.2-12.6) consistently used condom for heterosexual intercourse and 984 (56.5%, 95% CI=48.1-64.9) never did so. In the multivariate analysis, those who reported using drugs during incarceration, had decreased odds of having always used condom with sex for women (OR=0.8, 95% CI=0.5-0.9) and a slightly decreased odds of having any condom use (OR=0.8, 95% CI=0.7-0.9), independently of age, education, self-perceived risk of HIV, previous incarcerations, time of incarceration and consistency of condom use before incarceration. Increasing age and longer time of incarceration were also associated to lower consistent condom use. Inmates who claimed having always used condom before incarceration used it more likely (OR=7, 95% CI=4.4-11.3) for sex with women during incarceration than those who reported not having always used condom before incarceration.

Conclusions: Most inmates in these prisons with conjugal visits are sexually active during their imprisonment and the vast majority had consensual heterosexual sex, but less than 10% consistently used condoms with their female partners. Drug use was associated with inconsistent condom use. Preventive programs should include improved education, and clear policy for open, free and discreet condom distribution as well as drug use therapy.

WEPEC615
HIV risk perception and sexual risk behavior among HIV-infected married couples in rural Uganda
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Background: Studies show that married couples are at an elevated risk of HIV infection. However, few studies have explored HIV risk perception and sexual behaviors of HIV-infected married couples.

Methods: This cross-sectional study was conducted among 832 married couples aged 15-49 years, resident in three geographical strata in Rakai district, southwestern Uganda. Data collection took place between November 2013 and February 2014. HIV risk perception was defined as a respondent’s perception of the likelihood that their sexual partner might be at risk of HIV infection. Data were collected on self-reported alcohol use before sex, engagement in non-marital sex and condom use at last non-marital sex. HIV testing was done using rapid HIV antibody tests. We conducted descriptive statistics to assess HIV risk perception and sexual risk behaviors among 697 couples for whom complete HIV status data were available. Data were analyzed using STATA version 11.0.

Results: Of 697 couples, 43 (6.2%) were HIV-discordant while 41 (5.9%) were HIV positive. Men in HIV-discordant (53.5% vs. 20.9%, P=0.002) and those in HIV-positive (46.4% vs. 21.9%, P=0.02) relationships were more likely than women to believe that their partners were not at risk of HIV infection. However, a higher proportion of women in HIV-discordant (79.1% vs. 46.5%) and those in HIV-positive (78% vs. 53.7%) relationships were more likely to believe that their male partners were very or somewhat likely to be at risk of HIV infection. Men in HIV-discordant
over twenty years, with the latter accounting for long chains of secondary HIV transmissions originally related to sex work. The PAF was larger when measured earlier in the HIV epidemic (median SW-PAF from 1988-2008: 58%[20-100%]).

Conclusions: These results challenge our previous understanding of HIV epidemics. Even high HIV-prevalence epidemics can be solely driven by unprotected SW. Overall HIV prevalence and the short-term PAF are poor markers of underlying transmission dynamics and underestimate the role of SW in HIV epidemics, and thus should not be used alone to inform HIV policies and programmes. Although this model was calibrated with data from WCA, the findings have similar implications for understanding the transmission dynamics of HIV in higher East and South African prevalence settings.

Epidemiology of HIV in the general population

WEPEC616
How high can a population’s overall HIV prevalence driven by female sex work reach? Insights from mathematical modelling

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Background: HIV epidemics have been classified as “concentrated” among key populations if overall HIV prevalence was below 1%, and as “generalised” otherwise. These surveillance criteria have often been used to inform HIV prevention policies and resource allocation. We aimed to objectively demonstrate the limitation of this definition and improve our understanding of HIV transmission dynamics by determining how high a population’s overall HIV prevalence can reach in epidemics driven by unprotected female sex work (SW) (an epidemic that would have been prevented if the needs of FSWs had been addressed and transmission during sex work had been completely prevented at the onset).

Methods: We developed a deterministic model of HIV transmission specific to West and Central Africa (WCA) to simulate 1,000 plausible HIV epidemics where SW is the sole behavioral driver. The model was parameterized based on a comprehensive extraction of biological, epidemiological and sexual behavior parameters for WCA. We determined the range of plausible overall population HIV prevalence over time and the population attributable fraction (SW-PAF) of HIV due to unprotected SW over different time periods.

Results: In 1988 and 2008, overall HIV prevalence across the 1,000 plausible concentrated epidemics ranged (5th-95th percentile) between 0.1%-4.2% and 0.1%-2.8%, respectively. The maximum HIV prevalence peaked at 10-12% in mid 80’s to mid 90’s(Figure). The SW-PAF measured from 2008 was < 5%-18% over one year compared to 16-59% (median=32%)

WEPEC617
Is HIV prevalence declining in Uganda? Results from a home-based testing project

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Background: The Masaka region has been in the epicenter of the HIV epidemic in Uganda for more than 2 decades. Three surveys carried out in the decades of 1990 and 2000 reported prevalence between 8.2% and 11.2%. In the last two national surveys, prevalence in the Masaka area was 8.5% (2004) and 10.6% (2011). AIDS Healthcare Foundation (AHF) implements since 2011 a Test and Treat project aimed to cover 80% of the population of Masaka. Here we present data on HIV prevalence from that project.

Methods: Since April 2013, AHF has tested over 140,000 individuals in 13 sub-counties in Masaka using a home based approach. For this study we selected data from three of those sub-counties based on population size and testing coverage. A census of all residents was conducted and all households visited by a clinical team offering counseling and testing to residents older than 18 months of age.

Results: A total of 93,512 individuals, 49% of whom were adults (15 years and older) was listed in the census. Out of the adult population, 32,489 (70.1%) were tested. Testing coverage was higher among women (75.2% of all censused women tested versus 64.6% of men) and in the age group 15-34 years (73.7% versus 65.1% in the group over 35 years). By sub-county, testing coverage ranged between 63.8% and 76.8%. Overall adult HIV prevalence was 3.8% (95% CI 3.6-4.0). Prevalence was significantly higher in women (4.0% versus 3.5% in men, p=0.02) and increased with age, reaching a peak earlier (6.9% at 25-29 years) than in men (7.1% at 30-34 years).

Conclusions: All the surveys conducted in the Masaka region since 1990’s have found prevalence above 8%. The last national survey documented an increase in prevalence (up to 10.6% in the Masaka area) due to longer survival of patients on ART and high incidence of HIV infection. Our testing results differ from those figures and show a prevalence of around 4%. These findings suggest that actual prevalence in the region may have decreased in the last years as a result of intensive efforts in HIV prevention implemented by AHF and other organizations in the ground.

Epidemiology of HIV in youth and adolescents

WEPEC618
HSV-2 and HIV infection among vulnerable adolescent girls in Zambia

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Background: Adolescent girls are recognized as having an elevated risk of STI and HIV acquisition in high prevalence countries, such as Zambia. The Adolescent Girls Empowerment Programme (AGEP) is an intervention that was designed to address the heightened vulnerability of 10,000 Zambian adolescent girls 10-19 by providing them social, health and economic assets through a ‘Safe Spaces’ model. Such assets can be drawn upon to reduce vulnerabilities and expand opportunities, increasing their delaying sexual debut, unintended pregnancy and acquisition of STIs.

Methods: Embedded within the AGEP intervention, a randomized cluster evaluation with longitudinal observation over 4 years is being implemented to obtain a rigorous assessment of the impact of AGEP. Girls were selected for the program and research based on a vulnerabil- ity indicator that captures household and individual deprivations. Baseline data collection was completed in 2014; survey information was collected from 5,241 adolescent girls 10-19. HSV-2
Preventing HIV in FSWs/clients is critical to the HIV response, even in countries labeled as generalized by existing approaches of appraising the contribution of sex work to HIV epidemics. A high proportion of women and men sell and purchase sex, and a disproportionately high burden of HIV transmission in Burkina Faso. However stigma and discrimination may prevent them from seeking healthcare services.

Methods: FSW practicing sex work as the primary source of revenue and MSM reporting anal intercourse with another man within the past 12 months were recruited in Bobo-Dioulasso, Burkina Faso by respondent driven sampling. All participants were aged ≥18 years and lived in Bobo-Dioulasso for ≥3 months. Perceived healthcare stigma was defined as being afraid to go to health services or avoiding going to health services. Stigma related to police, social support or past experience of healthcare stigma as well as baseline characteristics were examined as potential risk factors.

Results: A total of 350 FSW and 330 MSM were recruited and consented to participate in the study. The prevalence of perceived healthcare stigma was 17.4% and 32.7% in FSW and MSM, respectively. Experienced healthcare stigma was much lower in both groups (3.1% in FSW and 5.2% in MSM). Longer years of being FSW or participating in any HIV prevention or community group were significantly associated with higher odds of perceived healthcare stigma among FSW. In multivariate analysis, perceived healthcare stigma was associated with higher odds of verbal harassment due to selling sex (OR=3.91 95% CI 1.06, 9.43) as well as being forced to have sex (OR=2.04; 95% CI 1.06-3.93) and feeling rejected by friends (OR=2.53; 1.27-5.06) among FSW. Similarly, MSM who reported perceived healthcare stigma had a higher odds of being forced to have sex (OR=3.07; 95% CI 1.38-6.82) and were more likely to experience police refusing to protect them or being arrested, being scared to walk in public places or being blackmailed.

Conclusions: In these two key populations, perceived healthcare stigma was high and associated with experienced stigma, mainly being forced to have sex as well as social stigma among FSW and stigma from police and general public among MSM. Interventions to increase utilization of health services in these key populations may need to be targeted with different strategies.

Epidemiology of HIV in MSM

WEPEC621
Factors associated with high incident HIV in a high-risk cohort in Lima, Peru

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Background: HIV incidence in Latin America is concentrated among men who have sex with men (MSM) and male-to-female transgender women (TW). Despite substantial documentation of increased HIV prevalence in these populations, HIV incidence estimates and factors associated with incident HIV are rare.

Methods: We conducted an observational cohort study among MSM and TW recruited based on high-risk characteristics including having condomless sex with a male partner in Lima, Peru. Blood samples were collected and tested for HIV infection at baseline and then every 3 months, using an algorithm that included a 3rd generation HIV antibody rapid Point of Care (POC) (Determine, Alere Medical Co, Japan) and a 4th generation Ag/Ab HIV EIA serum test (Genescreen ULTRA HIV Ag/Ab, Bio-Rad, Redmond, WA) with Western Blot (WB) confirmation (Genetic Systems HIV-1 Western Blot, Bio-Rad, Redmond, WA). HIV positives at baseline were excluded from this analysis. Variables considered for the analysis included socio-demographics and risk behaviors. Cox regression was used to examine baseline factors associated with HIV incidence; for the multivariable model all variables with a bivariate p-value 0.2 were included. All analyses were conducted in Stata 13.1.

Results: During the 222 years of follow-up included in the cohort, there were 22 cases of incident HIV infection, yielding an HIV incidence of 9.9 cases per 100 person years (95% CI 5.9 - 13.8). In multivariable analysis the risk of HIV infection decreased with age (aHR 0.90, 95% CI 0.84 - 0.97) and increased if participants reported having had anal sex 2-3 times in venues.
Conclusions: The HIV incidence among MSM/TMV documented in this study was substantial. Within this high-risk group, standard individual-level risk characteristics may not be associated with HIV incidence. The identification of risky venues and behaviors associated with incident HIV infection suggest targeted locations for HIV prevention interventions such as testing, condom promotion and referral for PrEP.

WEPEC623
HIV and syphilis among male clients of male sex workers in China: the hidden epidemic
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Background: High risk of HIV/syphilis transmission from male sex workers (MSWs) was emphasized in recent studies; still male clients of these MSWs (MCM) were never studied. A detailed investigation was thus called for: to determine the burden and socio-behavioral determinants of HIV and syphilis among these MCM and compare them with other men who have sex with men (MSM) in China.

Methods: In a multi-center cross-sectional study, using respondent-driven and snow-ball sampling, 2958 consenting adult MSW were recruited, interviewed and tested for HIV and syphilis. Distribution of socio-demographics, behavior and HIV/syphilis prevalence were determined along-with comparison between MCM and other MSM regarding these parameters using SAS-9.3.

Results: Among recruited MSM, 5.0% (n=148) were MCM. HIV prevalence for MCM and other MSM were 7.4% and 7.7%, while syphilis prevalence were 15.9% and 14.2%, respectively. Condomless anal intercourse (CAI) was reported among 59.5% MCM and 48.2% MSM. Multivariate logistic regression revealed that compared to other MSM, MCM were more likely to have less education [for elementary level, adjusted odds ratio (aOR)=3.13, 95% confidence interval (95%CI)=1.42-6.90], higher income (for >$500/inm, aOR=2.97, 95%CI=1.53-5.77), found partners at bar/restroom (aOR=4.01, 95%CI=2.34-6.85), reported CAI (aOR=1.49, 95%CI=1.92-5.9.10), larger network (for ≥10, aOR=2.70, 95%CI=1.44-5.37) and higher odds of syphilis (aOR=1.54, 95% CI=1.00-2.38).

Conclusions: Compared to other MSM, similarly high prevalence of HIV and higher burden of risk behaviors and syphilis were observed. Our study indicated that HIV/syphilis prevention programs in China need to address MCM as a separate sentinel group especially focusing on their education, venues, network size and condom use.

WEPEC624
Factors associated with sex at “high parties” in men who have sex with men, Bangkok
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Background: Studies have demonstrated that drugs and alcohol are often associated with sexual practices that may increase the risk of HIV acquisition or transmission. We describe factors associated with having sex while under the influence of (being “high” on) drugs or alcohol in the Bangkok Men Who Have Sex with Men Cohort Study (BMCS), Thailand.

Methods: From April 2006 to November 2010, we enrolled Thai men aged ≥18 years from the Bangkok metropolitan area who reported penetrative oral or anal sex with another man in the past 6 months. Men were followed-up every 4 months with HIV testing and audio computer-assisted self-interview behavioral questions. Men were asked if they had participated in a “high party”, defined as “a party when two or more men come together to have sex while high on drugs”. We evaluated factors associated with high party using logistic regression.

Results: Among 1337 men aged 18-56 years (median age of 26 years), 223 (16.7%) had participated in a “high party”, defined as “a party when two or more men come together to have sex while high on drugs”. Male clients of these MSWs (MCM) were never studied. A high party was defined as “a party when two or more men come together to have sex while high on drugs”. We evaluated factors associated with high party using logistic regression.

Conclusions: These results highlight the potential vulnerability of Asian MSM to HIV upon arrival to Australia. The evidence that Asian-MSM were more likely to be diagnosed on their first test suggests less routine testing when compared to Australian-MSM, and require a need to focus on access to HIV prevention, testing and care among this group.
WEPEC625

HIV incidence in young men who have sex with men exposed to club drugs and ‘high parties’ and associated risk factors from the Bangkok MSM cohort study, Thailand, 2006-2014

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Conclusions: MSM engaged in riskier sexual practices in close partnerships than anonymous ones while travelling internationally. They more often knew the partner’s HIV serostatus and disclosed their own serostatus, which may be related to ease of communication. The findings suggest that interventions to reduce HIV transmission while travelling need to focus on partnerships that are established and recur in a foreign country rather than on partnerships that consist only of one-time sex encounters.

WEPEC627

HIV incidence estimates from repeat testing are closely related to trends in HIV risk behaviour and can identify epidemic changes earlier than HIV notifications


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Background: In high-income countries, trends in HIV notifications and behavioural risk are widely used in the evaluation of population-level HIV prevention programs. Direct estimates of HIV incidence are the ideal indicator for this purpose but can be difficult to obtain. We estimated trends in HIV incidence among gay, bisexual and other men who have sex with men (GBM) using repeat testing data from a large clinical network and compared it to trends in GBM risk practices and passive HIV notifications.

Methods: Our analysis utilised HIV test data extracted from a network of 33 sexual health clinics in New South Wales (NSW) from 2007 to 2013. HIV incidence among GBM was calculated based on those who had an initial negative test for HIV followed by a repeat test during the study period Annual HIV notifications associated with male homosexual exposure in NSW were obtained from Australia’s national registry. The behavioural indicator of ‘condomless anal sex with casual partners in the past 6 months’ was sourced from annual cross-sectional community surveys of GBM. Spearman’s statistics were used to assess correlations between pairs of indicators.

Results: Between 2007 and 2013 there were 150 incident infections of HIV in GBM at participating clinics. During this period, HIV incidence increased significantly from 0.78/100PY in 2007 to 2.18/100PY in 2009 (p<0.03) before decreasing at a non-significant rate to 1.77/100PY in 2013 (p=0.13; see Figure 1). The trend for condomless sex with casual partners was remarkably similar and from 2007 to 2013, HIV incidence was strongly correlated with this behavioural indicator (r=0.93, p=0.02). HIV notifications, however, were not correlated with other indicators until we introduced a 3-year lag to the notification data, after which strong correlations were observed between HIV notifications and condomless sex (r=0.95, p<0.05) and HIV incidence (r=0.95, p<0.05).

Conclusions: Trends in HIV notifications reflect changes in transmission that occurred up to three years prior. HIV incidence calculated using repeat testing methods is a more immediate indicator for evaluating the impact of HIV prevention programs.
WEPEC628
HIV prevalence among men who have sex with men in Malawi: informing national strategies through research from seven urban and rural districts

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Background: The nation of Malawi has made great progress in efforts to prevent HIV and provide treatment those living with HIV in the general population. Key populations remain at high risk of infection and only recent, limited research studies have been conducted among men who have sex with men (MSM). Though same sex practices are criminalized, national HIV programs have sought to understand the population to inform programmatic decisions and resource allocations.

Methods: A cross-sectional study of MSM living in Malawi was conducted between 2011 and 2014 in urban and rural districts: Blantyre, Lilongwe, Mzuzu, Nkhata Bay, Mangochi, Chikwawa, and Mulanje. Data collection was implemented by a local community-based organization. A total of 2,454 MSM (350/site) were recruited via respondent-driven sampling to participate in a sexual behavior survey and HIV and syphilis testing. Unique object multiplier and wisdom of the crowd methods were used for population size estimation. Bivariate and multivariable regression analysis to investigate correlates of HIV infection.

Results: Across the districts, the estimated sizes of the MSM populations were heterogeneous. Overall, the MSM population was estimated to represent 1.84% (95%CI: 0.65%-6.2%) of the male population, aged 20-39 years in Malawi. HIV prevalence was also heterogeneous and ranged from 5.4% in Mzuzu City to a high of 24.9% in Mulanje. Two to 8.7% of MSM had an active syphilis infection. In all but one low prevalence district, at least 90% of MSM living with HIV were unaware of their infection. Lifetime history of HIV testing ranged from 22.7%-62.7%. Correlates of infection were diverse across districts and related to behavioral and structural risks, including: sexual identity, young age of first same sex intercourse, inconsistent condom use with male partners, use of condom incompatible or no lubricants during anal sex, and lifetime history of jail/prison.

Conclusions: HIV prevalence among MSM is high and geographically heterogeneous. Geographic patterns are reflective of the general adult population, though relatively higher. The majority of MSM who are living with HIV are unaware of their infection status, largely reflective of low lifetime history of HIV testing. Findings provide insight into gaps and opportunities for informing future, national HIV prevention programs.

WEPEC630
Gendered vulnerabilities: HIV prevalence and correlates of transgender and feminine gender identity among natal males who have sex with males in Burkina Faso, Gambia, Lesotho and Malawi

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Background: Where data is available, it indicates that transgender women worldwide bear a heavy and disproportionate burden of HIV, with an estimated prevalence of 19% and 49 times the odds of infection compared to the general population. However, data are notably missing from sub-Saharan Africa, the region with the heaviest overall burden of HIV. This study examined the prevalence and correlates of gender diversity and HIV in at 6 sites in 4 African countries.

Methods: This cross-sectional analysis included participants from integrated HIV bio-behavioral surveillance (IBBS) studies with natal males who have sex with males in Burkina Faso (n=673), Lesotho (n=530), Gambia (n=206), and Malawi (n=338). Regression modeling was used assess the relationships between gender identity, HIV vulnerabilities, and HIV status by site. Correlates were not assessed in Gambia due to the low number of gender variant participants (n=4).

Results: The proportion of respondents identifying as women included 23% in Bobo-Dioulasso, 19% in Blantyre, 8% in Maseru, 7% in Ouagadougou, 6% in Maputo, and 2% in Banjul. In the three sites where asked, the proportion of transgender-identified respondents were 13% in Maseru, 9% in Maputo, and 3% in Blantyre. Across sites, gender variance was significantly associated with greater likelihood of reporting discrimination, such as rejection by family or friends, verbal harassment, physical assault, and forced sex. Women-identified participants were more likely to report problem alcohol use, depressivememtive symptoms, receptive anal sex, and a higher number of male partners. Condom use was lower in all sites except Bobo-Dioulasso. Laboratory-confirmed HIV prevalence was much higher among gender variant respondents in all sites, but only reached statistical significance in Lesotho (60-64% versus 28-33%).

Conclusions: These data suggest that women-identified and transgender natal males may represent a considerable proportion of the “MSM” included in current IBBS studies and that they differ from male-identified participants in structural HIV vulnerabilities, HIV risk behavior, and HIV prevalence. Filling the gap in understanding gender diversity in Africa is essential to the ability to accurately measure and interpret data as well as develop appropriate interventions for the prevention, care, and treatment of HIV.

Epidemiology of HIV in transgender persons

WEPEC629
“Testing machines can lie and be faulty”: perceptions of serodiscordance and ART by Ugandan serodiscordant couples and their communities

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Background: The primary driver of the HIV epidemic in sub-Saharan Africa remains heterosexual transmission. Serodiscordant couples in long term relationships represent a significant source of new HIV infections in this region. However, serodiscordance is often poorly understood in those affected. This study investigated perceptions and attitudes of serodiscordance and ART among women-identified participants in structural HIV vulnerabilities and HIV status by site. Correlates were not assessed in Gambia due to the low number of gender variant participants (n=4).

Methods: In-depth, gender-matched interviews were conducted from June 2013 to December 2014 with 28 heterosexual, initially serodiscordant couples (57 participants) attending The AIDS Support Organization in Jinja, Uganda as part of an ongoing study of serodiscordant couples and treatment as prevention. 14 of the HIV negative participants in these couples seroconverted by the first of 5 in-depth interviews. Thematic framework analysis of the baseline interview transcripts resulted in dominant themes regarding prevention methods, attitudes and knowledge about serodiscordance and antiretroviral treatment (ART).

Results: Participant ages ranged from 27-71 years. Couples were mixed regarding disclosing their serodiscordance, but those who had not cited stigma as a dominant factor in not disclosing. Almost all couples had adequate access to condoms, but adherence to-and use of condoms varied widely. Inconsistent condom use was felt to have contributed to seroconversion in some cases. Participants’ understanding of serodiscordance was varied, and many cited extensive education and multiple tests as positive factors. However, there were misconceptions about whether serodiscordance is possible, exemplified by the belief in “strong” or “heavy” blood which can resist HIV infection. Individuals cited that their communities’ understanding of discordance was limited, and many members dismissed the concept of discordance entirely. ART is perceived negatively by many community members stating it comes with “shoves and axes” (burial tools), although individuals on ART acknowledge benefits. Beliefs were varied as to whether ART could prevent HIV infection.

Conclusions: Although affected individuals in a serodiscordant relationship have a fair understanding of serodiscordance and treatment, stigma and misinformation remains widespread in the community. A focus on further education about serodiscordance and the benefits of ART should be considered in efforts to minimize heterosexual transmission, and accelerate the destigmatization of HIV and serodiscordance.
Epidemiology of HIV in other populations

WEPEC631
HIV prevalence and sexual behaviours among people with disabilities (PWD) in four states in Nigeria

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Background: PWD have often been overlooked in the context of HIV risk, prevention, and services as it is commonly assumed that they are not at risk for HIV. However, PWD are indeed at risk for HIV and have been found to be at equal or greater, risk for HIV compared to non-disabled persons.

This study measured prevalence of HIV, sexual behaviors and identified barriers to access and use of HIV prevention services among people with hearing, vision, and physical impairments in specialized schools and in the community.

Methods: A cross-sectional survey with HIV testing was conducted among PWD recruited through staff of Disabled Persons Organizations (DPO) from specialized schools and the community in Lagos, Calabar, Kaduna and Benue states in Nigeria.

Results: A total of 624 individuals (53.7% females and 46.3% males) participated with median age of 25.0 (IQR: 20.0—31.0) years. Two-thirds had at least secondary level education (67.6%), were single (69.9%), and resided in urban (63.2%) areas. Nearly half lived with at least one parent while 32.4% lived on their own. Seventy-one percent had ever had sex of which 74.4% had sex in the last year and nearly 20% had their sexual debut before 15 years. In the last year, 26% males and 17% females had multiple sex partners and 15% engaged in transactional sex. Only 63% ever used a condom, 36% currently used and 50% used condoms during higher-risk sex. PWD displayed low comprehensive knowledge and self-perceived risk of HIV and a high level of gender-based violence was reported by female PWD. Only 43% ever tested for HIV and received their results. Overall, HIV seroprevalence was 2%, higher among females (2.4%) than males (1.4%).

Conclusions: This is the first study to estimate the sero-prevalence of HIV and risk behaviors among PWD in Nigeria. It highlights that PWD are sexually active and they engage in behaviors that increase their vulnerability to HIV. While the HIV prevalence is lower than in the general population in Nigeria (3.4%), 2% is not negligible. This study also found that female PWD experience sexual violence that put them at risk for HIV.

WEPEC632
Factors related to seeking prison-based medication assisted therapy for opioid addiction

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Background: Criminalization of drug use in Malaysia has led to a concentrated epidemic of HIV and substance use disorders within prisons. In response, Malaysia introduced prison-based medication assisted therapy (MAT) programs to treat opioid dependence, reduce risk behaviors, and prevent relapse to drugs post-release. Despite the introduction of this program, MAT uptake has been suboptimal in prison settings. Therefore identifying individual-level factors related to seeking prison-based MAT initiation is key to improving uptake.

Methods: A total of 200 incarcerated individuals with a history of opioid use in the 12 months prior to incarceration were enrolled in a study to identify attitudes and behaviors associated with MAT initiation. Inclusion criteria were: 18 years of age or older, current incarceration for at least 30 days, and the ability to speak English or Bahasa Malaysia. Sampling was stratified by HIV status (HIV-positive=96; HIV-negative=104).

Results: Only 18 (9.0%) patients were currently enrolled in the MAT program and 69 (39.9%) were interested in enrolling in the MAT program. Pre-incarceration poly-substance use (OR=1.92) and injecting drug use (OR=2.80) were both associated with greater likelihood of enrolling into MAT (p<0.05). In regards to psychosocial factors, greater addiction severity (OR=1.20) and depression (OR=1.70) were associated with greater MAT seeking (p<0.05).

Additionally, those with greater treatment knowledge and more positive attitudes towards MAT were 1.50 times more likely to seek MAT (p<0.001). Age, ethnicity, religion, marital status, education, and income were unrelated to MAT-seeking. Those without previous incarcerations, however, were 5.80 times more likely to seek MAT when compared to those with prior incarcerations (p<0.005).

Conclusions: Results show that interest in MAT initiation is largely driven by risky drug use behavior, treatment knowledge and attitudes, and prior incarceration history. Incarceration provides a unique window of opportunity to initiate MAT, and previous findings suggest that prison-initiated MAT is associated with greater treatment retention and anti-retroviral (ARV) adherence post-release. Further investigation into how pre-incarceration drug use behavior affects MAT interest is warranted, especially in the context of prisons. Despite efforts to introduce MAT into the prison system, successful uptake of MAT will not be possible without addressing how treatment knowledge and attitudes impair MAT seeking.

Epidemiology of sexually transmitted infections (STI) and HIV co-infection

WEPEC633
Factors associated with HIV and syphilis co-infection among men who have sex with men in Brazil

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Background: HIV and Syphilis share many common factors and syphilis may increase the likelihood of HIV transmission. Syphilis is increasing among men who have sex with men (MSM) in several countries. This work aimed at assessing the prevalence and factors associated with HIV-syphilis co-infection, HIV only, or syphilis only among MSM in Brazil.

Methods: Respondent Driven Sampling cross-sectional study of 3738 MSM aged 18 years or older residents in ten large Brazilian cities. Data on sociodemographic and behavioral characteristics were collected using hand-held devices. HIV and syphilis serology were performed using standard methods. Estimates were weighted by the inverse of the probability proportional to the size of the social network and the proportion of MSM in each city. Number (n=5) and type of sex partners (commercial, fixed, casual), and irregular condom use during anal intercourse in the past year were combined into a sexual risk score. Weighted prevalence rates with 95% confidence intervals (95% CI) were estimated. Observations with missing data on HIV or syphilis serology were excluded. The magnitude of the associations with HIV only, or syphilis only, or HIV-Syphilis co-infection, each compared to participants with no infection, was estimated by the prevalence rate ratio (PRR) using Poisson regression, with a significance level of 0.05.

Results: Prevalence rates and Adjusted PRR are shown in Table 1. Older age and past history of syphilis were independently associated with all outcomes. Not knowing one risk of acquiring HIV was strongly associated with HIV only or with co-infection. Median risk score was 4 (range 0-36), while moderate-high sexual risk score (≥ 2) was associated with co-infection only. Prior HIV testing and sex with men only was associated with HIV infection only.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HIV-Only</th>
<th>Syphilis Only</th>
<th>HIV-Syphilis Co-Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence Rate</td>
<td>6.7% (5.8 - 7.5)</td>
<td>9.5% (8.5 - 10.5)</td>
<td>4.4% (3.7 - 5.0)</td>
</tr>
<tr>
<td>PRR (95% CI)</td>
<td>2.61 (1.20 - 5.69)</td>
<td>4.10 (1.91 - 8.78)</td>
<td>8.46 (4.92 - 16.0)</td>
</tr>
<tr>
<td>History of syphilis</td>
<td>1.76 (1.02 - 2.90)</td>
<td>2.39 (2.40 - 4.37)</td>
<td>4.85 (2.92 - 18.25)</td>
</tr>
<tr>
<td>History of Any STD</td>
<td>2.80 (1.01 - 2.74)</td>
<td>2.51 (1.41 - 4.46)</td>
<td>-</td>
</tr>
<tr>
<td>Not knowing one risk of acquiring HIV</td>
<td>4.11 (2.69 - 6.29)</td>
<td>-</td>
<td>4.10 (1.91 - 8.78)</td>
</tr>
<tr>
<td>Sex with men only</td>
<td>2.06 (1.11 - 3.82)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Prior HIV Testing</td>
<td>2.50 (1.38 - 4.50)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Conclusions: The prevalence of HIV and syphilis, alone or as co-infections, was high among this RDS sample of MSM in Brazil. Despite availability of free treatment and access to testing within the public health system in Brazil, treatment and prevention efforts may not be reaching those at higher risk. Public health workers and non-governmental organizations should be aware of the rising number of syphilis cases and co-infection among MSM to improve prevention and treatment nationwide.
WEPECE634
Sexually transmitted infection (STI) incidence in men who have sex with men (MSM) followed since primary infection stage in the French ANRS-PRIMO cohort
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Backgrounds: In France, in a context of rising at-risk sexual behaviour in MSM, we estimated the incidence rate of STIs in HIV-infected MSM followed since primary HIV infection. We compared these incidence rates according to the viral load of patients at the visit preceding the STI diagnosis.

Methods: In 1996-2014, 1,226 MSM have been enrolled in the ANRS-PRIMO cohort during primary HIV-infection. Patients are followed every 6 months. At each visit, a clinical questionnaire is completed with lab measurements, antiretroviral treatment and clinical information including STI occurrence since the last visit. We focused on syphilis, gonorrhea, Chlamydia trachomatis infections, and other suspected bacterial infections such as unspecified urethritis, rectitis, epididymitis, orchitis and balanitis. We assumed that two episodes of the same STI were distinct infections if separated by ≥3 months and by ≥1 for years. We assessed the evolution over time in incidence rates and their association with the viral load of the patients measured at the visit preceding the STI diagnosis with a regression model of Poisson taking into account longitudinal data.

Results: We observed 412 incident STIs in MSM, i.e. an incidence rate of 6.67/100 patient-years (PY) (95% CI: 6.07-7.34), including 215 syphilis (incidence rate: 3.16/100PY [3.14-3.18]) and 197 other bacterial STIs (incidence rate: 3.19/100PY [2.77-3.60]). The syphilis incidence rate was null before 2000 and increased afterwards of 9% per year on average (p<0.001) up to 4.91/100PY in 2013. As well, the other STIs incidence rate increased over time of 4% per year (p=0.006) up to 4.40/PY in 2013. Considering all STIs together throughout 1996-2014, the incidence rate during the periods when MSM had an undetectable viral load was lower compared with the periods with detectable viral load (6.08/100PY versus 7.72/100PY, p=0.02).

Conclusions: In these HIV-infected MSM, STIs incidence has risen over calendar time, in syphilis as well as in other bacterial infections. Although they may be underestimated because of under-reporting or under-diagnosis, these incidence rates were high, particularly when the viral load is detectable. With the diffusion of the concept of Treatment as HIV Prevention, efforts should be done to help MSM to prevent transmission of other STIs.

WEPECE635
Prevalence of STI and HIV RNA levels in anogenital compartments among Thai MSM and transgender women after antiretroviral therapy: implication for treatment as prevention program
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Background: Sexually transmitted infections (STI) are very common among men who have sex with men (MSM) and transgender (TG) women, especially in those with HIV infection. Prior to antiretroviral therapy (ART) initiation, we previously demonstrated the correlation between STI and HIV RNA detectability in anogenital compartments among Thai MSM and TG. We evaluated this correlation again after 12 months of ART.

Methods: Thai MSM and TG aged ≥18 years who tested HIV-positive at enrollment were offered immediate ART. Syphilis serology, oropharyngeal/rectal swab, urine collection for gonorrhoea and chlamydia nucleic acid amplification testing, and HIV RNA measurement in blood, semen and rectal samples were performed at baseline and after 12 months of ART.

Results: Of 111 HIV-positive MSM/TG who reached month 12 after ART, median (IQR) age was 23 (22-26) years. At month 12 after ART, median (IQR) CD4 count was 484 (361-611) cells/mm³, 16% reported having ≥1 partners and 15% did not use condom in the past month. 32% had reactive syphilis serology, 18% had gonorrhoeal infection (oropharyngeal 12%, rectal 12%, urethral 1%) and 30% had chlamydial infection (oropharyngeal 7%, rectal 23%, urethral 1%). At baseline, detectable HIV RNA (≥50 copies/mL) was found in 100% of blood, 61% of semen and 67% of rectal samples. At 12 months after ART, detectable HIV RNA was found in 3.5% (3/86) of blood, 1.2% (1/83) of semen and 1.4% (1/72) of rectal samples. No participant had detectable HIV RNA in more than one compartment. STI was not found in participants with detectable HIV RNA in semen or rectal sample. Higher proportion of participants with detectable HIV RNA after ART had HIV RNA >100,000 copies/mL in blood at baseline (100% vs. 42%, p=0.02), had <9% ART adherence (75% vs. 23%, p<0.05) and had baseline resistance mutations to first-line ART used (20% vs. 2%) than those with undetectable HIV RNA. Conclusions: HIV-positive MSM/TG continued to have high prevalence of STI after ART. ART effectively reduced HIV RNA in all compartments. Correlation between STI and detectable HIV RNA in ano-genital compartment was not seen after ART. Adherence remains crucial to achieve the prevention benefit of ART.

Epidemiology of viral hepatitis and HIV co-infection
WEPECE636
Elevated hepatitis C incidence among young, women co-infected with HIV/STIs and sex workers who use crack cocaine in Vancouver, Canada: gaps and opportunities for HCV prevention and treatment
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Background: Given the dearth of incidence data on hepatitis C virus (HCV) among female sex workers, potential for dual sexual and drug risk pathways, and the opportunities posed by new HCV therapies in 2014, we aimed to characterize incidence and predictors of HCV infection among female sex workers (FSW) who use and do not use substances in Metropolitan Vancouver, BC.

Methods: Data were drawn from a prospective cohort of 723 SWs recruited through street, indoor and online outreach (“An Evaluation of Sex Workers’ Health Access”) from 01/2010 - 08/2013. At baseline and semi-annually, participants completed questionnaires and volunteered HCV, STI and HIV testing by a project nurse with education and referrals to HIV, STI and HCV prevention, treatment and care. Cox regression was used to longitudinally model predictors of time to HCV seroconversion.

Results: Of 715 SWs included in the analysis, HCV prevalence was 43.6%, with higher odds of HCV infection among women who were HIV-positive, had a recent acute STI infection, older, of Aboriginal/indigenous ancestry, engaged in sex work for longer, and solicited clients outdoors (vs. indoor/online). HCV incidence density and predictors of time to infection were calculated among 256 SWs who were HCV-seronegative at baseline and had at least one follow-up visit. During the 3.5-year observation period, the HCV incidence density was 4.28 events/100 person-years (95% CI: 2.73-6.72), with highest rates among SWs who inject drugs (SW-PWID) (24.05 events/100 person-years, 95% CI: 13.57-42.63) and SWs who use non-injection drugs (7.02 events/100 person-years, 95% CI: 4.39-11.21). In a multivariate Cox model, age (Hazard Ratio [HR]: 0.91, p=0.04), STI co-infection (HR: 3.45, p=0.04), and non-injection crack use (HR: 4.24, p=0.05) remained independent predictors of time to HCV seroconversion; in a separate model, HIV co-infection also independently predicted time to HCV seroconversion.

Conclusions: While HCV incidence was highest among SW-PWID, STIs and non-injection stimulant crack use appear to be major pathways to HCV infections, suggesting dual sexual and drug transmission of HCV. Younger women and those co-infected with HIV/STIs face enhanced risk of HCV acquisition, highlighting the need for integration of HCV services within sexual health and HIV/STI programmes for youth, women and sex workers.

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Benzodiazepine use is a risk factor for hepatitis C infection in a prospective cohort of persons who inject drugs

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Background: Intravenous drug use is associated with an increased risk of acquiring blood-borne infections such as HIV and hepatitis C (HCV). While the diversion and abuse of prescription drugs has been the source of growing public health concern, benzodiazepines have received relatively less attention in comparison to prescription opioids. Therefore, the present study examined for a possible association between benzodiazepine use and HCV infection in a prospective cohort of persons who inject drugs (PWID).

Methods: The Vancouver Injection Drug Users Study is a prospective cohort of PWID in Vancouver, British Columbia. In the present study we investigated the relationship between benzodiazepine use and HCV seroconversion using a Cox proportional hazards regression.

Results: Between May 1996 and November 2013, 441 participants were included in our study sample. At the time of enrollment the median age of participants was 29.5, 300 (68.0%) were male, and 253 (57.4%) were Caucasian. 271 (61.5%) reported benzodiazepine use within the past 6 months. In a multivariable Cox regression model, after adjusting for potential confounders, benzodiazepine use remained independently associated with an increased risk of HCV seroconversion ([Adjusted Hazard Ratio = 2.42, 95% Confidence Interval = 1.59 - 3.69].

Conclusions: This study highlights the high prevalence of illicit benzodiazepine use in a population of PWID, and demonstrates an independent association with increased risk of HCV infection. These data highlight the need for physician education regarding the limited evidence-based clinical indications for benzodiazepine prescription and greater recognition of the safety concerns related to benzodiazepine diversion.

Epidemiology of Serious Non-AIDS events

WEPEC638

No association between HIV serostatus and risk of non-fatal overdose among people who inject drugs within the ACCESS and VIDSU2 cohorts in British Columbia

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Background: HIV infection among people who inject drugs (PWID) may contribute additional risk of experiencing an accidental drug overdose. A 2012 meta-analysis, which found a positive association between HIV infection and overdose, summarized possible causative pathways for this association, including immunosuppression and poorer physical health. We sought to replicate this finding by estimating the association between HIV serostatus and risk of non-fatal overdose (NFOD) using seven years of data from two community-recruited cohorts of PWID positive and negative PWID.

Methods: Data were collected from the ACCESS (HIV-positive) and the VIDSU2 (HIV-negative) parallel open prospective cohorts in Vancouver, Canada. We included all participants who completed at least one baseline or follow-up questionnaire during the study period (2006-2013). During each follow-up assessment, participants were asked whether they had experienced an NFOD (i.e., “a negative reaction from using too much drugs”) within the past six months. We plotted the proportion reporting at least one NFOD during each assessment, stratified by HIV status

(Figure 1). Then, bivariate and multivariable generalized mixed-effects regression models were used to determine the longitudinal unadjusted and adjusted association between HIV status and likelihood of NFOD.

Results: 1769 participants completed at least one questionnaire, producing 15,070 unique assessments. Among these observations, 649 (4.3%) included a report of a NFOD within the previous six months (4.4% among seropositive and 4.3% among seronegative individuals). Results of the bivariate analysis of serostatus and risk of NFOD were null (Odds Ratio [OR] 1.05, p=0.853). This persisted in multivariable analysis adjusted for potential confounders such as ancestry, risk behavior, and exposure to violence ([Adjusted OR [AOR] 1.19, p=0.474]. Additionally, secondary multivariable analysis estimating the association between detectable plasma viral load (compared to undetectable or negative serostatus) and NFOD yielded a null result ([AOR 1.30, p=0.250].

WEPEC639

Transmission clusters among newly diagnosed HIV patients in the country of Georgia

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Background: For years the HIV epidemic in Georgia was driven by injection drug use (IDU). Recent trends indicate an increase in sexually acquired infections, including emergence of an epidemic among men who have sex with men (MSM). We aimed to characterize the molecular epidemiology of HIV in Georgia and identify possible transmission clusters.

Methods: Multiple alignments of HIV-1 pol sequences were created with CLUSTAL W and phylogenetic analyses were conducted using MEGA software. The Neighbor Joining method and Kimura two-parameter model with reliability estimated from 1000 bootstrap replicates were used for tree construction. Branches consisting of ≥2 sequences showing bootstrap value of ≥70% and intra-cluster genetic distance ≤0.015 were considered reliable and defined as “cluster”.

Results: Among 218 newly diagnosed HIV patients included in the study the median age was 35 years and 138 (63.3%) were men. Slight majority (53%) were infected via heterosexual contact, IDU accounted for 37.6% and MSM to 6.9% of cases. 195 (89.4%) patients carried subtype A virus, 15 (6.9%) had subtype B and 6 (2.7%) had subtype G viruses; there was a single case each of subtype F (0.5%) and recombinant form AB_03 (0.5%). Overall 93% of IDUs and heterosexually infected persons had subtype A and 60% of MSM had subtype B. All viruses within subtypes A and B formed major clusters, with bootstrap values of 86% and 98% respectively. A total of 49 sequences grouped into 17 smaller clusters, the majority of which (71%) were pairs. The largest cluster of 8 sequences was dominated by MSM. There was significant clustering between viruses from IDUs and heterosexually infected females. Viruses from MSM and IDUs did not cluster together. In multivariate analysis, factors associated with membership in a cluster included: age < 25 (RR 2.44, p<0.014), MSM (RR 2.16, p<0.015), subtype B virus (RR 2.56, p=0.002).

Conclusions: Our study shows that subtype A is predominant HIV strain circulating in Georgia. Our findings confirm surveillance data showing emergence of HIV in the MSM population. There is strong linkage between IDU and heterosexual epidemics. Viruses from IDUs and MSM do not cluster together, thus suggesting independent evolution of epidemics in these populations.
WEPEC640

Genetic characterization of a large panel of diverse HIV-1 strains at six international sites

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Background: Genotyping for HIV-1 subtypes and drug resistance are determined by many international surveillance groups including the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) network. However, results from different sites are variable. A systematic approach to compare genotyping results from these sites is needed to determine if a standardized protocol is required for consistent and accurate data analysis.

Methods: A panel of well-characterized viruses (N=50) from the External Quality Assurance Program Oversight Laboratory (EQAPOL) was assembled for evaluation at six international sites (Brazil, South Africa, USA [2 sites], China, and Malaysia). The panel represented 7 subtypes, 6 circulating recombinant forms (CRFs), 9 unique recombinant forms (URFs) and 3 group O viruses. Seven viruses contained 10 major drug resistance mutations (DRMs). The virus isolates were prepared at 10°c/mL, compiled into blinded panels. Genotypes and DRMs were determined with partial pol sequences at five sites or whole genome sequences generated by next generation sequencing (NGS) at one site. Results (genotypes, DRMs and sequences) were reported, decoded, and compared to full-length genome sequences generated by EQAPOL.

Results: Five sites targeting partial pol gene obtained positive PCR products from the majority (93.4%-93.6%) of all 47 group M viruses. 95.1%-98% of the viruses were genotyped correctly for the partial pol sequences. However, many viruses contained additional recombination at unsequenced regions that could not be predicted by the partial pol sequences. At 10 major DRMs in 7 viruses were correctly detected at these 5 sites. All 50 viruses were also analyzed by NGS by one site. Four group M viruses were not amplified, and 3 recombinant viruses were not genotyped correctly. In addition, NGS missed 5 major DRMs but detected one additional major DRM. No group O viruses were amplified, except at one site that used additional PCR primers specific for group O viruses.

Conclusions: While major DRMs in protease and reverse transcriptase can be detected by partial pol sequences, the PCR conditions and subtyping program should be standardized to more efficiently amplify diverse viruses and more consistently assign virus genotypes, which is critical for accurate global subtype surveillance.

WEPEC641

Molecular analysis of HIV-infected individuals in a network-based intervention (TRIP): phylogenetics identify HIV-infected individuals with risk links

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Background: TRIP is a three-city network-based intervention which aims to decrease HIV spread by the recently infected. Here we estimate patterns of viral spread among persons who inject drugs (PWID) involved in TRIP Athens, and explore correlations between transmission links as estimated by phylogenetic analysis and risk networks.

Methods: Phylogenetic trees were inferred from HIV sequences generated from TRIP participants using as references, sequences from PWID sampled during the HIV outbreak (2011-2014) in Athens. Highly supported clusters (subnetworks) are those received >75% bootstrap support. Risk network links were determined based on standard network survey methods.

Results: We recruited 339 individuals (89% PWID) including negative controls; recently infected persons; long-term infected controls; and the first and second degree risk network members of recently infected and controls. Among them, 143 were HIV+. To date, we have sequenced 96 HIV(+) individuals (males 77%, mean age 38.8 years). We identified three categories of phylogenetic clusters. Those whose members belong to previously identified PWID transmission networks in Athens outbreak (n=78, 82.1%: CRF14_BG, CRF35_AD, subtypes A and B), unique recombinant forms consisting of partial sequences from previously-identified PWID clusters (n=10, 10.4%), and whose sequences are tied to non-PWID transmission trees (n=8, 8.3%: CRF96_gpx, subtype A). Further phylogenetic analyses in all sequences suggested the existence of nine phylogenetic clusters (subnetworks) including 2-5 individuals in each cluster. We identified 24 (25.0%) PWID within the subnetworks. Five of these subnetworks included 15 people who also had risk ties with at least another member of their cluster (figure). Specifically, one subnetwork consisted of people who were all homeless or incarcerated.

Geographical information systems and HIV

WEPEC642

A geographic approach to better understand HIV at a sub-regional and sub district level in Tanzania

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Background: Significant variations in adult HIV prevalence have been observed at a Regional level in Tanzania, however variations in HIV disease burden at a sub-regional and sub district level are not well understood. We describe a pragmatic approach for examination of variations in HIV burden, identification of potential hotspots and cold spots, as well as ART coverage at a sub-district level through the use of routinely collected clinic level program data from PMTCT and ART clinics.

Objectives:

1. Describe sub district level variations in estimates of HIV prevalence derived from 2013 PMTCT clinic level data.
2. Describe variations in estimates of ART coverage as of June 2014 at the following levels of aggregation (District level and clinic catchment level).

Methods:

HIV positivity data was obtained from 523 PMTCT clinics located across 2 regions of Tanzania. 104 clinics which tested less than 50 women and were excluded from the analysis. Annual HIV positivity in 2013 for women attending PMTCT clinics was calculated at each of the remaining 419 PMTCT clinics along with estimates of clinic level HIV prevalence through adjustment with the 2011 population based survey. The geocodes of the clinics were linked to the program data and HIV clinic level prevalence estimates were plotted. Interpolation of clinic level HIV prevalence using universal kriging was performed to create a predicted map of HIV prevalence in 2013. This gridded map of HIV prevalence was multiplied by a gridded map of population to obtain estimates of people living with HIV at a 1km2 resolution. Hot and cold spot spots were determined through the use of the Getis and Gi statistics tool. ART coverage estimates were then calculated at each clinic catchment area.

Results: Significant district level and sub district level variations in HIV prevalence were observed.

Conclusions: This approach allows an examination of variations in HIV burden at a very fine level of granularity through the use of routinely collected clinic level data. When thinking about resource allocation it is also important to also take into account population distribution and absolute numbers of PLHIV. It helps provide an evidence base that allows for appropriate targeting of resources.
WEPEC643

Interpolation of HIV estimates using off the shelf options, what's the difference?

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Background: Understanding disease burden at the lowest level of aggregation is important to enable an appropriate response to managing HIV. Prevalence surveys provide estimates at a national level or provincial level and routinely collected clinic data can provide reasonable estimates of HIV prevalence at a clinic level. To obtain a smoothed surface of HIV prevalence point prevalence estimates can be converted to pixel based estimates through a process known as interpolation.

We evaluated two interpolation methods to examine how the various interpolation methods affect estimates of PLHIV.

Methods: Using routinely collect PMTCT clinic data from 216 PMTCT clinics in the Tanga region of Tanzania, HIV positivity among women in 2013 was calculated and after adjustment, estimates of HIV prevalence among adults were generated. Two interpolation methods (IDW and Universal Kriging) were used to create a smooth surface of HIV prevalence and then two gridded population surfaces of PLHIV were calculated. Performance of the two interpolators was evaluated through two internal validations (Partitioned data holdback and leave one out cross validation). Results were aggregated to the district level and absolute differences in PLHIV examined.

Results: The two interpolation methods produced relatively similar results when the information was aggregated up to the district level. Differences observed in the numbers of PLHIV at the district level ranged from a low of five in Pangani district to a high of 511 in Tanga.

Conclusion: An appropriate interpolation method that provides the best estimates of PLHIV at a lower resolution is an important prerequisite for analysis that requires a detailed examination of HIV at a very fine resolution. Different methodologies, tools and models have been developed to estimate HIV prevalence from point data. These methods vary in complexity and accuracy in prediction. It is essential that a user select an interpolator that minimizes the prediction error and also provides an estimated errors of prediction. Our evaluation found universal kriging to be a more suitable interpolator.

Network studies of risk behaviours and their implications for prevention

WEPEC644

The organizing potential of risk behaviours: sexual risk behaviors as social cues that motivate where young black men who have sex with men (YBMSM) go to meet and socialize

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Background: HIV programs focus on social venues that MSM frequent as sites where risk behaviors are practiced and “hotspots” for intervention. But, the impact of established risk tendencies (e.g., sex-drug use) on venue visitation is not well understood. We determine the extent that three types of risk behaviors drive venue visitation amongst a population sample of YBMSM. Understanding the relationship between risk behaviors and venue visitation is critical for understanding how risk emerges in these settings.

Methods: From 2013-2014 data were collected from a respondent-drive sample (RDS) of YBMSM (16-29 years) in Chicago (N=623). The outcome of interest is a 623x15 YBMSM-to-venue visitation network (see Figure). Risk behaviors include inconsistent condom use, sex-drug use, and group-sex. To determine the likelihood of a visitation tie conditioned on YBMSM risk behaviors, we used exponential random graph models (ERGMs), a network analytic technique that examines the prevalence of specific patterns within the network by assessing their statistical likelihood.

Results: Of the 623 YBMSM, 46% used condoms inconsistently, 40% used sex-drugs and 21% engaged in group-sex. Clubs & bars were the most visited venues (61%); bathhouses were the least visited (9%). ERGM results reveal that venue visitation, when modeled as an oriented force. YBMSM-to-venue visitation network

Results: Of the 623 YBMSM, 46% used condoms inconsistently, 40% used sex-drugs and 21% engaged in group-sex. Clubs & bars were the most visited venues (61%); bathhouses were the least visited (9%). ERGM results reveal that venue visitation, when modeled as an oriented force, was no more or less likely to be informed by any of the three risk behaviors. However, when YBMSM who:

(a) used condoms inconsistently, or
(b) used sex-drugs, or
(c) engaged in group sex visited venues, they were statistically more likely in all three cases (p<.05) to choose places that attracted other YBMSM who practiced the same behaviors.

So, when the influence of other YBMSM is considered, risk behaviors emerge as a socializing force.

Conclusions: Findings demonstrate that sexual risk behaviors provide social cues that YBMSM draw from to make their visitation decisions. HIV prevention programs that target social venues for intervention should examine whether visitors’ desires to act on their risky tendencies by being with other MSM that behave similarly informs where they socialize. With this information, it becomes possible to see social venues on a spectrum of enacted risk versus risky in and of themselves.
WEPEC645
Some mediators contribute critically to transmit HIV-1 subtype B to various MSM communities in Japan
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Background: Investigation of transmission network features through conventional epidemiological method are of limited in HIV-1 which has a long incubation period between transmission and disease state and a low transmission rate per contact. To clarify an HIV transmission network of men who have sex with men (MSM) population in Japan, we conducted a phylogenetic-based transmission clustering followed by a network analysis.

Methods: Cases newly diagnosed as HIV-1 infected and registered in the Japanese Drug Resistance HIV-1 Surveillance Network between 2002 and 2012 were enrolled in the analysis. Protease-reverse transcriptase sequences from individuals newly diagnosed as HIV-1 seropositive were collected and their subtypes were determined. Phylogenetic relationships of subtype B sequences were inferred by 3 different methods: distance-matrix, maximum likelihood and Bayesian inference. Transmission clusters were identified based on the following criteria: >95% in interior branch test, >95% in Bayesian posterior probability and < 10% in depth-first searches for sub-tree partitions. Time of the most recent common ancestor (MRCA) of the transmission clusters were estimated by Bayesian inference. The transmission networks were estimated by linking two individuals (nodes) in a cluster whenever their sequences showed less than 1.5% genetic distance, and degree- and betweenness-based centrality indexes were calculated.

Results: Of 5018 cases collected between 2002 and 2012, 4398 (87.6%) were classified as subtype B. Of the 312 clusters found, 121 (38.8%) were large clusters with >5 individuals, and the largest cluster consisted of 256 individuals. 292 clusters (93.6%) showed a MSM behavior for their major transmission risk. Especially, all of 121 large clusters had the MSM risk. Most clusters had MRCA between 1996 and 2005, suggesting that subtype B virus expanded among MSM in the second half of the 1990s. Based on sample collection areas, clusters appeared to associate with specific geographic regions. Node centrality analysis of transmission networks in some large clusters revealed a few core individuals were connecting different communities.

Conclusions: Our study suggests that a few mediators connect different transmission networks. To prohibit further spread of HIV-1 infections and expansions of the transmission networks, such mediators and their communities should be targeted for prevention interventions.

WEPEC646
Sociocentric networks of urban Tanzanian youth enrolled in an HIV prevention trial
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Background: Sociocentric network studies can advance our understanding of the structure and function of social relationships, and the mechanisms through which social networks shape HIV risk behaviors. Compared to egocentric network studies, which depict relationships of an actor’s contacts and his/her perceptions of relationships between those contacts, sociocentric network studies aim to collect comprehensive data on the direct and indirect relationships between all individuals within bounded populations. This information may be leveraged to enhance the efficiency and effectiveness of HIV prevention efforts. Despite their potential for improving HIV prevention efforts, sociocentric network studies are lacking in sub-Saharan Africa. Our team is conducting a cluster-randomized HIV prevention trial with youth who socialize in urban social networks called camps in Dar es Salaam, Tanzania. Our objective is to describe the network structure of youth within these camps.

Methods: We defined the network boundaries through membership in one of our 60 study camps. Of the 9,500 individuals enumerated via camp rosters, 1,514 (77.9%) agreed to participate. Each participant was asked to identify all members known to him/her as well as members of their networks who they didn’t get along with. Network variables were created using the igraph R package.

Results: Networks had an average of 32.5 members (SD = 12.3) and contained 457 relationships (SD = 370). On average, the camp networks were closely connected, with an average density (representing the overall connectedness within networks) of 0.4 (SD = 0.19). The cohesion within camps was also high, with an average transitivity (a proxy for cohesion describing the probability that two camp members connected to the same individual are also connected to each other) of 0.7 (SD = 0.19). Finally, networks were fairly decentralized with an average degree centralization (a measure assessing the degree to which networks revolve around a single individual) of 0.35 (SD = 0.08).

Conclusions: The networks in our HIV prevention intervention trial are closely connected, cohesive, and decentralized, allowing for efficient transmission of HIV prevention information. Longitudinal network data will help us assess whether and how network structures mediate or moderate the intervention effect.
WEPEC648
Relationships between improvements in neighborhood conditions and sexual network dynamics among adults relocating from public housing
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Background: Extensive literature places risk of HIV acquisition and other sexually transmitted infections (STIs) in a socio-ecological framework, with social network and neighborhood characteristics associated with transmission. Instability and turnover in sexual networks have been associated with higher HIV risk behaviors, but few studies investigate the influence of neighborhood conditions on sexual network stability over time.

Methods: This longitudinal multilevel study uses seven waves of data (2009-2014) from a predominantly substance-using cohort of 172 adults relocated from public housing in Atlanta, GA, to determine the potential implications of post-relocation neighborhood change on the overall stability of sexual networks over time, and the extent to which sexual network members enter and leave participants’ sexual networks. At each wave, individual- and network-level characteristics were captured via survey; administrative data from the US Census Bureau and local agencies were analyzed to describe the census tracts where participants lived. According to the distribution of each outcome, multilevel logistic regression was used to model overall sexual network stability; multilevel poison regression was used to model the number of new sexual partners entering sexual networks; and multilevel binomial regression was used to model the number of new sexual partners leaving sexual networks.

Results: On average, participants relocated to neighborhoods that had less economic deprivation, social disorder, and enter-occupied housing, and to neighborhoods that had greater racial diversity and more equitable male-to-female sex ratios. No place characteristic was associated with overall sexual network stability over time. Reduced alcohol outlet density was associated with lower rates of new partners entering participants’ sexual networks between waves (beta=0.03, CI=-0.001, 0.058, p-value=0.05); this association was borderline statistically significant. Reduced perceived community violence was associated with a higher probability of participants leaving sexual networks between waves (beta=0.113, CI=-0.236, 0.010, p-value=0.07), this association was also borderline statistically significant.

Conclusions: Improvements in social context may lead to lower sex partner turnover. Research should be expanded to investigate the impact of neighborhood characteristics on social network characteristics, a key determinant of HIV/STI epidemics.

Determinaton of HIV incidence
WEPEC650
A new method for estimating HIV incidence that uses optimization to reconcile and validate two models based on independent data sources for the same population
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Background: HIV incidence is difficult to estimate due to the long asymptomatic disease stage which delays diagnosis. We developed an optimization-based method utilizing surveillance data and HIV genetic data to simultaneously estimate incidence and validate these estimates.

Methods: Mathematical models were developed for estimating HIV incidence for British Columbia (BC), Canada during 2000-2009, a time period preceded and followed by major expansions in antiretroviral coverage. The approach is summarized in the figure. First, a differential equation for the diagnosed proportion of the HIV-positive population. A Monte Carlo simulation was used to estimate seroconversion time at individual level for assessing temporal changes of HIV incidence is difficult to estimate due to the long asymptomatic disease stage which delays diagnosis. We developed an optimization-based method utilizing surveillance data and HIV genetic data to simultaneously estimate incidence and validate these estimates. A new method for estimating HIV incidence that uses optimization to reconcile and validate two models based on independent data sources for the same population.

Methods: Longitudinal clinical data of patients in Hong Kong were collected from HIV specialist clinics where almost all reported HIV cases are managed. A combination of methods was used to determine the seroconversion time. The mid-point of the interval between last HIV-
Results: Monthly time series were generated for free parameters from both models, which were used to produce a single time series for the proportion of diagnosed infections and HIV incidence. Our model suggests that HIV incidence (new infections per year) declined from 594 ± 2.3 in 2009 to 534 ± 2.3 in 2009 in BC. Our estimates are consistent with independent estimates by the Public Health Agency of Canada.

Conclusions: Our method for estimating HIV incidence from routinely collected surveillance and patient-monitoring data is potentially widely applicable. A particular advantage of the approach is that it integrates an internal validation method through reconciling models based on independent data sets.

WEPEC561

HIV incidence in Recife, Brazil, 2013, through the application of laboratory testing algorithm for detection of recent HIV infections


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Background: In the context of expansion of antiretroviral treatment to HIV-infected individuals, and resulting increased survival, the data that best reflect recent changes in patterns of transmission come from studies that consider the number of incident cases in a given period. In this study, we estimated HIV incidence in Recife, Brazil, 2013 through the application of laboratory testing algorithm for detection of recent HIV infections.

Methods: We used the LAg Avidity EIA testing algorithm in the majority of HIV positive tests performed in the public sector for a period of 12 months during 2013-2014 to classify infections as recent or long-standing. This included all HIV tests performed at primary care health units, family health units, HIV testing and counseling centers, mobile units and public hospitals. A sample of HIV positive tests performed in the private sector were also considered in the study. Incidence of HIV in Recife at period was estimated using a statistical approach with adjustment for the probability of an undiagnosed HIV positive person tests in 2013 and the probability that a newly diagnosed person has a LAg -Avidity result. We used a window period of 141 days.

Results: An estimated 538 individuals were diagnosed with HIV in 2013 in Recife. Of the 485 HIV positive specimens tested using the LAg Avidity assay, 48 (9.9%) were classified as recent infections. Based on statistical sample extrapolations from these data, the estimated number of new infections for Recife in 2013 was 553, which represents an estimated incidence rate of 34.6 per 100,000 population.

Conclusions: This study provides the first direct estimates of HIV incidence in a Brazilian city using laboratory assays. Results were corroborated with estimation of HIV incidence, 2013 in Recife based on information of the first CD4 count from the Laboratory Tests Control System (SISCES). Therefore, it is a possible approach for monitoring HIV incidence routinely in large Brazilian cities.

Methods for estimating incidence using cross sectional samples

WEPEC652

Estimating the distribution of new HIV infections by key determinants in generalised epidemics of sub-Saharan Africa using a validated mathematical model

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Background: Estimating the distribution of new HIV infections according to identifiable characteristics is a priority for programmatic planning in HIV prevention. We propose a mathematical modelling approach that uses robust data sources to estimate the distribution of new infections acquired in the generalised epidemics of sub-Saharan Africa and validate it against cohort data.

Methods: We developed a predictive model that represents the population according to factors that have been demonstrated to be powerfully associated with risk: gender, marital status, geographic location, key risk behaviours (sex-work, injecting drug use, male-to-male sex), sero-discordancy within couples, circumcision and ART status. Incidence rates obtained from large trials or inference methods are applied to estimate the number of new infections in each group in the next year. The model is applied within a Bayesian framework whereby regional prior information on demographic and epidemiological characteristics is updated, where possible, with national and local data. Uncertainty is propagated to model predictions. We trained and tested the model following an iterative process against cohort data from Manicaland, Zimbabwe. We developed a transmission module which builds on the results from the acquisition model to illustrate likely sources of transmission consistent with the estimated distribution of new infections. The model was applied to six countries in the region to investigate potential differences in incidence patterns.

Results: Without training using the site-specific data, the model was able to predict the pattern of new infections with reasonable accuracy. 95% credible intervals were substantially overlapping and the rank ordering of groups with new infections was consistent. With additional training using site-specific data, and tests on a further round of data from the same site, the accuracy of predictions improved further and credible intervals narrowed. When applied to the six countries in the region the model showed variation in the distribution of infections between and within countries consistent with the data on prevalence (see Fig. 1).

Conclusions: It is possible to accurately predict, in broad terms, the distribution of new HIV infections acquired using data routinely available in many countries in the Sub-Saharan African region. This tool can complement additional analyses on programmatic planning and data collection priorities.
**HIV testing and diagnostic strategies**

**WEPEC653**  
Attitudes and acceptability on HIV self-testing (HIVST) among key populations: a literature review  
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**Background:** Globally, approximately 40% of new adult HIV infections occur among key populations (KP). Yet, uptake of and access to HIV testing among KP is suboptimal. HIVST has potential to reduce existing disparities in coverage and access to HIV testing, particularly among KP who may be more reluctant to attend services. We examined values and preferences around HIVST among KP.

**Methods:** We systematically searched electronic databases, including peer-reviewed literature, conference abstracts and gray literature January 1995 to July 2014. Review was restricted to reports on acceptability, values and preferences among KP. Extracted data was analyzed by country income, type of specimen collection (oral fluid-based or blood-based), level of support offered, and other qualitative aspects.

**Results:** 23 studies met inclusion criteria; 14 reported acceptability (Figure 1). Most studies identified were from high-income countries and were among men who have sex with men (MSM), who found HIVST acceptable. MSM were interested in HIVST because of its convenient and private nature. Several studies identified MSM prefer access to HIVST over-the-counter and via the internet. Willingness to pay varied across setting. Participants in high-income settings, and for unsupervised HIVST approaches, were willing to pay more (≤ US$ 20 to US$ 50) Concerns, such as lack of counseling accompanying HIVST, possible user error and poor accuracy were identified. No adverse events were identified. Five studies report linkage to care; most participants (range: 81.6%-100%) stated if they received a reactive HIVST result they would seek confirmatory testing and treatment.

**Conclusions:** Although some concerns remain, HIVST is acceptable among MSM across all settings. Acceptability, values and preferences were similar across studies, regardless of whether HIVST is provided through a supervised or unsupervised approach or using oral fluid or blood-based RTD. Data among other KP groups, particularly in low- or middle-income settings was limited. To fully understand values and preferences of KP regarding HIVST, future research should include people who inject drugs, transgender people and sex workers.

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**WEPEC654**  
Diagnosis of earlier stage disease observed with expanded HIV testing in Vancouver, Canada  
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**Background:** The STOP HIV/AIDS three year pilot program was launched in March 2010 with the goal of improving early diagnosis and timely engagement in HIV care as a model for reducing transmission in British Columbia. Prior to STOP, from 2003-2010, greater than 80% of new HIV diagnoses in Vancouver occurred among individuals with a CD4 count less than 500 cells/μl. Here we describe historical, pilot phase and post-pilot temporal trends in disease stage at diagnosis.

**Methods:** To monitor and evaluate the STOP program, relevant outcome measures, including CD4 at HIV diagnosis as well as patient characteristics, were collected from laboratory testing sources and authorized linkages between public health and clinical databases. Indicators of disease stage from the post-STOP period (July 1, 2013 - June 30, 2014) were compared to the STOP period (July 1, 2010 - June 30, 2013) and a historical period (January 1, 2008-June 30, 2010). Early stage diagnosis was defined as a CD4 count greater than or equal to 550 cells/μl or acute stage disease and late stage diagnosis was defined as a CD4 count less than 200 cells/μl.

**Results:** In the post-STOP period, early stage diagnosis comprised 53% of new diagnoses compared with 45% during STOP and significantly greater than 40% historically. Furthermore, late stage diagnoses declined from 22% historically, to 21% during STOP and 15% post-STOP. During this time, the average regional testing volume increased 53% over the average observed during STOP and 106% over historical averages. Men aged 20-29 had the highest diagnostic yield (1.1%) in the post-STOP period unlike the preceding periods where men aged 40-49 had the highest diagnostic yield (0.9% - 1.6%).

**Conclusions:** Testing promotion activities part of the STOP program, including a city-wide HIV testing strategy in acute and primary care, lead to substantial and sustained increases in HIV testing in the region, and has coincided with the greatest proportion of early stage diagnoses since HIV became reportable in British Columbia in 2003.

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**Surveillance of HIV (youth and adults)**

**WEPEC655**  
Increases in the proportion of HIV among foreign-born individuals in King County, dates of HIV diagnoses and the impact on HIV prevention  
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**Background:** An estimated 13% of Americans and 16% of U.S. residents diagnosed with HIV are foreign-born. The National HIV Surveillance System (NHSS) collects data on nativity, but defines cases as newly-diagnosed based a first documented HIV positive test, usually one in the U.S. However, many of these people may have been diagnosed prior to immigration.

**Methods:** We used 2004-2013 King County, WA data from NHSS and supplemental surveillance activities to assess trends in the percentage of people identified as newly diagnosed with HIV infection who were foreign-born and how often these individuals self-reported HIV diagnoses prior to U.S. immigration.

**Results:** A total of 3,032 KC residents were diagnosed with HIV over the period, including 775 (26%) foreign-born. Foreign-born cases increased nearly 50% over the decade—from 22% in 2004 to 32% in 2013 (p< 0.001). Foreign-born individuals included 39% from Africa, 34% from Mexico or South/Central America, 18% from Asia, 6% from Europe, and 2% from Canada. Foreign-born cases were less likely than U.S.-born cases to be men who have sex with men (40% vs. 83%, p< .0001). Self-reported date of first HIV diagnosis was available for 2,041 (67%). Foreign-born cases were five times as likely as U.S. born cases to self-report HIV diagnosis >1 year prior to NHSS diagnosis date (20% vs 4%, p< .00001). We had date of entry to the U.S. for about one-quarter of foreign-born cases; of these, 3% entered the U.S. after their HIV diagnosis in NHSS, however 34% entered the U.S. after a self-reported HIV diagnosis. Misclassification of diagnosis date of foreign-born cases led to an estimated 11% over-estimate of new HIV diagnoses in 2013.

**Conclusions:** A growing percentage of presumptively newly diagnosed HIV infections - almost one-third of 2013 King County HIV - occur in people born outside of the U.S. Approximately one-third of these cases were likely diagnosed prior to U.S. entry, leading to a substantial overestimate of the number of new diagnoses. These findings highlight the need for data on nativity, HIV testing history, and immigration dates from people with newly diagnosed HIV, and emphasize a growing need for prevention addressing the needs of foreign-born populations.
Surveillance of behaviour

WEPEC656
Prevalence of physical activity in patients with HIV over time: the Swiss HIV cohort study (SHCS)

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Background: The prevalence of cardiovascular risk factors is high in patients with HIV. While there is growing evidence that physical activity (PA) is both safe and effective in improving cardiorespiratory fitness, metabolic profile and quality of life in patients with HIV, it is however not clear whether physically active patients with HIV are. The aim of this study was to provide population-based estimates of the level of PA in patients with HIV and to see whether this level is changing over time.

Methods: We included all patients from the Swiss HIV Cohort Study (SHCS) who completed at least one report of PA between December 2009 and November 2014 during routine clinical follow-up (scheduled every 6 months). Changes in the level of PA over time were explored with summary statistics and graphs where we divided time since December 2009 into 12-month periods. Data were taken from the first completed report within each period. We used rido analysis to assess the relationship between the degree of PA and numerous demographic or disease related factors.

Results: During the study period, 10417 patients completed at least one report of PA. Except for the first year with a higher non-response rate, the percentage of patients reporting free-time PA at all gradually declined from 49% to 44% over the four years (Table). At the same time, the percentage of patients reporting sedentary activity at work increased from 24% to 26% over the four years. In contrast, the percentage of individuals reporting no sports activities at all in the “Sport Switzerland” surveys of the general population was estimated to be much lower and seemed relatively stable over time (2005: 27%; 2014: 26%). Average ridits (with 95% confidence intervals) by time period and age suggest no strong trends in free-time PA over time but obvious differences in profiles between women and men, with young men being more active than young women (Figure).

Conclusions: Patients with HIV in Switzerland engage in much less free-time PA than the general population. Thus, increasing PA could be a behavioural change that helps patients with HIV reduce their risk of cardiovascular disease.

WEPEC657
Comparison between the first and the second round of the biological behavioral surveillance survey among male injecting drug users in Cairo

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Background: FHI 360/Egypt and Ministry of Health and Population conducted two rounds of Biological and Behavioral Surveillance Survey to track trends among Key Population, including Male-Injecting Drug Users (IDUs).

Methods: The two rounds were conducted in 2006 and 2010 respectively. Respondent driven sampling was applied to select male IDUs (sample size ranged from 413 in the first round and 275 in the second round). Participants were interviewed by their peers using a standard questionnaire and HIV status was measured by Elisa and Western Blot.

Results: Literacy rate among male IDUs was high, 95.0% in 2006 and 92.3% in 2010 reported attending school. More than half of them reported ever married to a female (55.5% in 2006 and 56.4% in 2010). More than half of the male IDUs in 2006 (53.0%) and almost one-third of them in 2010 (30.7%) reported injecting drugs with used needles in the past month. Almost one third in 2006 and about one quarter in 2010 reported sharing needles with or more partners in the past month (32.2% and 22.9% respectively). Almost all the male IDUs reported ever having had sex with a female (96.2% in 2006 and 94.9% in 2010). Having had a commercial sex partner in the last year was reported by 13.3% in 2006 and 13.1% in 2010. Having had a regular non-commercial sex partner in the last year was reported by 12.8% in 2006 and 33.6% in 2010. Having had sex with a male was reported by 9.2% of the male IDUs in 2006 and 14.3% in 2010. Condom use was very low among IDUs in the two rounds, 11.8% in 2006 and 12.2% in 2010, reported condom use at least once with commercial sex partners. HIV prevalence among male IDUs was 0.6% in 2006 and 6.8% in 2010.

Conclusions: HIV prevalence among male IDUs increased 10 times between 2006 and 2010. Links with the general population through marriage and an overlap of risk behaviors were common among male IDUs in Cairo. A combined approach including safer sex and safe injection is essential to overcoming the growing HIV epidemic among Male IDUs in Egypt.

WEPEC658
Gay sex-seeking mobile application in China: results from an online survey

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Background: Substantial increases in gay sex-seeking mobile application (gay app) use may facilitate sex partner turnover and HIV transmission. The goal of this study was to compare Chinese MSM demographics and sexual behaviours between gay app users and non-users.

Methods: In October 2014, we recruited individuals (≥18 years old, ever engaged in sex with men, agreed to provide cell phone number and agreed with the inform contents) from three Chinese gay web platforms. Information regarding socio-demographics, sexual behaviours and gay app use history were collected.

Results: Overall, 1723 participants did not meet eligibility criteria and were excluded, while1424 (45.2%) completed the online survey. In the last six months, 800 (56.2%) used gay apps for sex partner-seeking. Most participants were aged < 30 years (77.5%), never married (53.8%), and self identified as gay (72.9%). Among gay app users, 72.8% found two or more sex partners in the last six months, and three quarters (74.9%) met their partners within one week after met on gay app. Among those who found new sex partners through mobile apps, 25.4% did not use a condom during the last anal intercourse with a partner. Gay app users

[Figure. Average ridits by sex, time period and age]
were more likely to have condomless anal intercourse in the last three months (aOR=1.52, 95% CI: 1.19-1.94), and ever experienced intimate partner violence (aOR=1.43, 95% CI: 1.15-1.78). Gay app users were less likely to have sex with female (aOR=0.67, 95% CI: 0.51-0.89). Among HIV-infected individuals (<65y), gay app users were less likely to receive antiretroviral therapy compared to non-app users (aOR=0.13, 95% CI:0.03-0.56).

Conclusions: Millions of gay men in China meet new sex partners through gay apps. Contrary to other literature, our data suggest gay app users may have riskier sex compared to non-gay app users. Further research and programs about the use of social media and unsafe sex are urgently needed.

WEPEC659
Prevalence and correlates of sexual risk behaviours in Cross River State, Nigeria
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Background: A recent Mode of Transmission (MoT) Survey in Cross River State, Nigeria revealed that 23% of new HIV infections will occur among casual heterosexual groups and that 42% of new infections will come from low risk heterosexuals made up of people in a married or cohabitating relationship. We assessed factors associated with sexual risk behaviour among the general population in Cross River state.

Methods: The survey sampled females aged 15-49 years and males aged 15-64 years in Cross River State using probability sampling. Interviewer administered questionnaires were used to obtain data on sexual risk behaviours and assessed using a cross-sectional analysis. Logistic regression was used to identify factors associated with sexual risk behaviours while controlling for potential confounding risk factors.

Results: A total of 950 respondents (478 males, 472 females) were surveyed. Median age at first sex among young persons aged 15 to 24 years was reported as 21 for males and 17 for females. More males than females had more than one sex partner (50.3%, 19.2%) and engaged in higher risk sex (casual, non-marital partner) (23.2%, 14.2%). More females (17.6%) than males (7.3%) had sex in exchange for gifts/favours. When controlled for age, gender, educational status, marital status and location (urban vs. rural), females (AOR: 0.57; 95% CI:0.41-0.79) and those with at least secondary education (AOR:0.39;95% CI:0.20-0.73) were less likely to engage in multiple sexual partnerships while those with comprehensive knowledge (AOR:1.75; AOR:2.41) were more likely to engage in multiple sexual partnerships. Age, location and marital status, were not associated with multiple sexual partnerships.

Conclusions: Females were less likely to engage in multiple sexual partnerships indicating that targeted interventions are needed to reduce this risk behaviour among males as a means of mitigating HIV transmission. Those with comprehensive HIV knowledge were more likely to engage in multiple sexual partnerships and suggest a negative feedback in reducing risk behaviour. Knowing how to prevent HIV transmission may have triggered their involvement in risky behaviour as they feel they are well equipped to prevent their acquisition of HIV. Further research is required to understand factors driving the risk behaviour despite having comprehensive knowledge.

WEPEC660
Changes in the prevalence and risk of serosorting among Seattle men who have sex with men (MSM) 2002-2013: Is serosorting becoming safer?
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Background: Serosorting among MSM is common but data to describe changes in the prevalence and HIV risk of serosorting in the past decade are limited.

Methods: Data were collected as part of routine care for MSM attending an STD clinic 2002-2003 and a community-based HIV/STD testing center (Gay City Health Project [GCHP]; 2002-2013) in Seattle, Washington. MSM were asked about condom use with HIV-positive, HIV-negative and unknown status partners in the past 12 months. At the STD clinic, data were collected via face-to-face interview (FTFI) until October 2010 and thereafter via computer-assisted self-interview (CAS). All GCHP data were collected via FTFI. We classified behaviors reported at each visit into four mutually exclusive categories: no anal intercourse (AI); consistent condom use with partners of opposite or unknown HIV status (CCU); non-CCU with HIV-unknown or discordant partners (NCCU); and non-CCU with HIV-unknown or discordant partners (NCCAI).

Results: Behavioral data were complete for 49,912 clinic visits by 24,412 unique MSM. The proportion of visits during which MSM reported serosorting increased significantly among both HIV-positive and HIV-negative men over the study period (Figure). NCCAI significantly decreased, though this percentage stabilized among HIV-positive MSM after 2009 (Figure). Among HIV-negative MSM from 2002-2013, consistent condom use was relatively stable (12% for 2002 and 13% for 2013), though these behaviors declined among HIV-positive MSM (20% to 12% and 7% to 4%, respectively). MSM tested for HIV at 38,845 visits. Adjusting for time since last negative HIV test, the risk of testing positive during the study period decreased among MSM who reported NCCAI (7.1% to 2.8%; P=0.02), serosorting (2.4% to 1.3%; P=0.17) and no CCU (1.5% to 0.7%; P=0.01). Serosorting was associated with a 47% lower risk of testing HIV positive compared to NCCAI (aRR=0.53; 95% CI:0.45-0.62); this aRR did not significantly vary over the study period (P=0.48 for year*behavior interaction).

WEPEC661
Sexual behaviour and viral load in MSM HIV-diagnosed at primary infection stage and followed in the French ANRS - PRIMO cohort
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Background: From 2008, the diffusion of the concept of treatment as prevention (TasP) in the HIV-infected population may lead to an increase in at-risk sexual behaviour. We aimed to assess the evolution over time of sexual behaviour in HIV-infected MSM followed in the French ANRS-PRIMO cohort.

Methods: In 1996-2014, 1,226 MSM have been enrolled during HIV primary infection. At each visit (every 6 months), a clinical questionnaire including lab measurements is completed and a self-administered questionnaire collects data on sexual partners, and condom use during the past six months (reasons of inconsistent condom use are available since 2013). The evolution of sexual behaviour in 2002-2014 and the association with the viral load at the preceding visit (undetectable: yes/no) were assessed using GEE models taking into account longitudinal data.

Results: We analyzed 9,396 follow-up visits with completed data on partners and condom use. The proportion of visits where ≥1 casual partner was reported has significantly increased (3%/year from 2001 to 2010, and of 11%/year (p=0.0001) since 2011 to reach 68% of visits in 2013. In MSM reporting ≥1 casual partner, the frequency of inconsistent condom use with partners of negative or unknown HIV status has risen of 5% (year p=0.02) from 18% of visits in 2001 to 23% in 2010, and then of 18%/year (p=0.0001) up to 38% of visits in 2013. There was no difference in condom use according to the VL (p=0.52).

Since 2013, among the 94 MSM who did not use condom consistently with casual partners despite a detectable VL, 45% thought that they could not transmit HIV because they were treated or thought (wrongly) they had an undetectable VL.

Conclusions: In these MSM, inconsistent condom use has increased since the beginning of 2000s and more dramatically after 2010. We can assume that the concept of TasP is widespread in recent years and assign to it this kind of disinhibition in HIV-infected MSM, but no association was observed with VL. Efforts should be done to inform patients about the impact of treatment on HIV-transmission and the importance to know their VL.
Surveillance of HIV drug resistance (including in PrEP studies)

WEPEC662
Levels of transmitted drug resistance in HIV-1 patients in Cuba

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Background: Several factors in Cuba might have contributed to high drug resistance levels in the treated HIV-1 population, such as prescription of suboptimal regimens containing non-boosted PI, prolonged exposure to failing therapies due to limited access to laboratory monitoring and limited options for antiviral drug substitutions if required. This might also result in the subsequent spread of drug resistant strains and therefore, this study aimed to survey the levels and patterns of antiviral drug resistance in therapy-naive HIV-1 patients in Cuba.

Methods: Demographic, clinical and laboratory data were collected from drug-naive patients attending a clinical center in Havana from 2008 to 2013. The HIV-1 pol gene was sequenced using Sanger sequencing and drug resistance was interpreted according to the WHO surveillance drug-resistance mutations (SDRM) list, version 2009.

Results: Our study included 323 patients who were HIV-1 diagnosed between 1990 and 2013. The largest number of patients was from Havana City (67.5%). The average time between HIV-1 diagnosis and sampling for HIV-1 genotyping was 2.4 years. The median CD4 count and viral load at sampling was 333 cells/mm3 and 20,000 RNA copies/ml, respectively. Overall, 45 patients (13.9%) showed any evidence of TDR. Forty-nine percent of patients with evidence of TDR displayed a single SDRM. Around half of the patients with evidence of TDR displayed double class resistance against NRTI and PI (0.3%), and two patients triple-class resistance (0.6%). No significant change for the proportion of any TDR was observed over time. Four patients displayed double class resistance against NRTI and PI (0.3%), and two patients triple-class resistance against NRTI and NNRTI (22/45, 48.9%), whereas one patient displayed triple-class resistance against NRTI and NNRTI and PI (0.3%).

Conclusions: The prevalence of drug resistance in therapy-naive HIV-1 patients in Cuba was 13.9% in our study. Overall TDR remained stable during the investigation period, but double class NRTI and NNRTI resistance increased.

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Surveillance systems and methods

WEPEC663
A matter of perspective: comparison of the characteristics of HIV-infected persons in the United States from the HIV outpatient study, the medical monitoring project, and the National HIV Surveillance System

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Background: Owing to dramatic improvements in survival associated with use of cART and a steady rate of incident HIV infections each year, the cumulative number of persons living with HIV infection in the United States is increasing. Longitudinal HIV cohorts and surveillance projects collect more in-depth data on HIV-infected persons than routine HIV surveillance. We sought to describe how the characteristics of persons in these enhanced data collections may reflect those of all adults living with diagnosed HIV infection and thus inform HIV care and prevention nationally.

Methods: We compared the characteristics of HIV-infected persons included in three CDC-funded data sources in 2009, the National HIV Surveillance System (NHSS), a comprehensive prospective registry of all diagnosed persons in the United States whether in or out of HIV care, the Medical Monitoring Project (MMP), a nationally representative surveillance system collecting serial cross-sectional medical chart abstraction and interview data on a probability sample of HIV-infected adults receiving care in the United States; and the HIV Outpatient Study (HOPS), a prospective chart abstraction cohort of persons seen for HIV care at select U.S. specialty clinics.

Results: The median age of persons included was > 45 years across all data sources (Table), with only about one-quarter of persons aged 40 years or younger, and ≤ 3% persons aged 18-24 years. About three-quarters of persons were male. MMP and NHSS populations were more ethnically diverse than the HOPS (Table). Over 50% of persons in each data source were gay, bisexual, and other men who have sex with men (collectively referred to as MSM). The percentage of persons with AIDS diagnosis was 67% in MMP, 64% in NHSS, and 59% in NHSS. About 18% of persons in MMP and NHSS were diagnosed with HIV infection in 1996 or later versus 9% in HOPS.

Conclusions: Persons living with HIV in 2009 captured in three CDC-funded data sources were demographically diverse and the populations were qualitatively comparable across most characteristics. About three-quarters of persons were aged > 40 years, illustrating the need for HIV care and secondary HIV prevention services for older persons in the United States.

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WEPEC664
Near real-time tracking of localized HIV outbreaks using an automated phylogenetic monitoring system: implementation and translation to public health

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Background: The rapid evolution of HIV and routine use of genotyping make it possible to use the genetic similarity of new cases to detect newly evolving HIV outbreaks within weeks of diagnosis. We have implemented a monitoring program based on the automated analysis of HIV sequences collected for routine resistance genotyping at the British Columbia (BC) Centre for Excellence in HIV/AIDS (CFC).

Methods: The Drug Treatment Program at the CFE performs all HIV genotyping for BC. De-identified sequences are uploaded to an Oracle database (currently containing over 30,000 genotypes from over 8,000 individuals in BC) and linked to de-identified clinical, demographic, geographic and epidemiological data. The database is queried hourly; when new records are detected, the system retrieves and aligns all sequences, excludes codons associated with drug resistance, and reconsructs phylogenetic trees from 100 bootstrap samples of the alignment. Clusters comprising five or more closely-related infections are assembled from all pairs with a phylogenetic distance below a threshold in the majority of bootstraps. Reports on active transmission clusters are automatically generated and distributed to select CFE directors and individuals at Vancouver Coastal Health and the BC Centre for Disease Control (BCCDC).

Results: About 20-30 genotypes are uploaded to the CFE database every day. Presently, the system requires about two hours to re-process the entire database. While the growth of most HIV clusters has been slowing, our system detected a cluster in June 2014 that had ex-
panded by 11 new cases within 3 months involving individuals with a mean viral load of 4.9 log₁₀ copies/mL. Eight of these new cases carried transmitted HIV resistance to NNRTIs (K103N). This report corroborated population-level epidemiological trends monitored at the BCDCD, and prompted a formal outbreak investigation of this sub-population. This transmission cluster since expanded by a single new case in early August, with no other new cases by mid-January 2015.

Results: The implementation of this monitoring system has resulted in enhanced public health follow-up and engagement into care of individuals involved in a localized HIV transmission cluster. This serves as a model of how the systematic application of molecular phylogenetics can support more effective HIV prevention programming.

Conclusions: The implementation of this monitoring system has resulted in enhanced public health follow-up and engagement into care of individuals involved in a localized HIV transmission cluster. This serves as a model of how the systematic application of molecular phylogenetics can support more effective HIV prevention programming.

WEPEC665
Characterizing the continuum of care in a population-based sample to target programming in North West Province, South Africa

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Background: Losses along the HIV care continuum will slow potential gains in mitigating the HIV epidemic in South Africa. Determining where losses occur along the continuum will help target intervention strategies; however, population-based data to characterize the continuum is limited.

Methods: We conducted a population-based HIV seroprevalence survey including HIV rapid testing, dried blood spot HIV RNA testing, and point-of-care CD4 testing using a multi-stage cluster sample in two sub-districts of the North West Province between January and March, 2014. We estimated HIV prevalence, undiagnosed infections, linkage to and retention in care, ART adherence, and viral suppression using data from 1044 respondents aged 18-49 years, of whom 745 consented to sample collection. All estimates were weighted to the sub-district population and stratified by gender.

Results: Prevalence was 18.8% (95%CI: 13.7%-25.2%) for men and 26.2% (95%CI: 21.9%-31.1%) for women. Only 48.4% of HIV-positive men and 75.7% of women were aware of their serostatus, with one-third of newly diagnosed infections occurring among those reporting a recent negative result. Among those aware of their status, 90.8% of men and 98.8% of women reported having ever seen a clinician for HIV care (linked). However, because such a large portion of the population was unaware of their status, those linked to care represent only a small portion of the population was unaware of their status, those linked to care represent only the largest number of losses along the HIV care continuum occurs at diagnosis, which will hinder prevention efforts. Improved, early detection of infection must be prioritized, particularly among men. Under treatment is also a concern. While reported retention and adherence to medication is high, viral suppression remains extremely low; this discrepancy merits further investigation.

Conclusions: Despite testing campaigns and expansion of treatment in South Africa, the largest number of losses along the HIV care continuum occurs at diagnosis, which will hinder prevention efforts. Improved, early detection of infection must be prioritized, particularly among men. Under treatment is also a concern. While reported retention and adherence to medication is high, viral suppression remains extremely low; this discrepancy merits further investigation.

WEPEC666
Population level adult life expectancy in the era of antiretroviral treatment (ART) in rural Uganda

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Background: Information on population-level trends in Life Expectancy (LE) is essential for defining policy. Population-level LE in low-income settings has not been evaluated because most sub-Saharan African countries lack population data needed for accurate estimation. We examine LE by HIV-status in a rural Ugandan population cohort that has been under annual HIV and demographic surveillance since 1989.

Methods: We measured changes in adult LE from 1991 to 2012 using annual census, medical survey, and monthly vital registration from a general population cohort in Southwest Uganda. Life-table methods were used to quantify (a) population-wide changes in adult LE at 15 years, calculated as number of life-years gained since LE reached its lowest observed level, (b) LE trends by HIV status, and (c) trends in LE deficit due to HIV; that is, the difference in LE of known HIV-negatives and the whole population. All estimates are disaggregated by sex.

Results: From 1991-93 to 2009-12, overall female LE rose from 39.3 [95%CI=35.9-42.8] to 56.1 [54.0-58.5] years and male LE rose from 38.6 [35.4-42.1] to 51.4 [48.2-53.7] years. LE among HIV-positive individuals rose substantially between 2000-02 and 2009-12 (females: 13.0 [10.9-15.4] to 36.0 [30.8-46.0] years and males: 14.3 [13.6-20.6] to 34.3 [28.3-47.3] years), especially after 2004, coinciding with ART introduction. Among HIV-negative individuals there was no change in LE. Years-lost due to HIV decreased 3-fold among females (16.1 [12.1-19.0] to 5.5 [2.6-8.9] years) and 5-fold (16.0 [12.1-19.9] to 2.8 [1.2-4.8] years) among males. Contributions to adult LE gains by age-group between 1991-2003 and 2009-12 show that most of the 13.2 years gained in women and 8.8 years in men were in those of reproductive age, for women this occurred at younger ages than men.

Conclusions: Adult LE increased substantially in this population but not among HIV-negative individuals. This is attributed to ART introduction reducing mortality among HIV-infected adults. Despite the important recent gains in, the adult LE deficit remains substantial (particularly among women), implying that HIV/AIDS service provision and uptake needs further improvement. Interventions for: causes of most deaths in HIV-negatives; increasing the age of HIV infection among women; and reducing HIV-incidence are needed to improve LE.
Surveillance of Hepatitis C (HCV) and HIV co-infection

WEPEC667

Inferring the transmission dynamics of acute hepatitis C virus infection in HIV-positive MSM in Hong Kong

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Background: Sexual transmission of hepatitis C virus (HCV) infection has been increasingly recognized among men who have sex with men (MSM) in Western countries. Recently, there has been a marked rise of acute HCV infection in HIV-positive MSM in Hong Kong. The aim of our study was to characterize the transmission dynamic and genetic diversity of acute HCV infection in HIV-positive MSM in Hong Kong.

Methods: A retrospective analysis was carried out on HIV-positive MSM diagnosed with acute HCV infection between 2009 and 2014. Additional HCV RNA detection and genotyping were performed for all HCV seroconverters. Phylogenetic analysis of the HCV NS5B region was conducted by neighbor-joining method to examine the local molecular epidemiology of HCV co-infection.

Results: Of 24 HIV/HCV co-infected MSM, the median age at HCV infection was 32 years (IQR 27–41), and the median time from HIV to HCV diagnosis was 3.1 years (IQR 1.2–6.5). The majority of patients (87.5%) were Chinese, and 23 (95.8%) were on antiretroviral treatment. None of them reported history of injection drug use. Among 22 (91.7%) HIV-positive MSM with detectable HCV RNA, infection with HCV genotype 3a (63.6%) was the most common, followed by genotypes 1a (18.2%), 6a (9.1%), 1b (4.5%) and 2a (4.5%). Acute HCV infection identified before 2012 were mostly of genotypes 1a and 6a, whereas genotype 3a predominated in the majority of acute HCV cases diagnosed between 2013 and 2014. Phylogenetic analyses revealed a monophyletic cluster of HCV-3a lineage from 2013 onwards, and a homologous pair of MSM-specific HCV-6a strain that were separate from those circulating in local injection drug users.

Conclusions: Our study indicates the existence of MSM-specific networks that has contributed to the sexual transmission of HCV in HIV-positive MSM in Hong Kong. Recent finding of the emergence of an independent and non-infecting HCV-3a cluster further implicates the rapid spread and increasing burden of sexually acquired HCV infection within our local HIV-positive MSM community.

Innovations in the measurement of sensitive behaviours and adherence

WEPEC668

Behavior change, a critical step in HIV prevention: utilizing LQAS to monitor behavior change among youth age 15-24 years in East Central Uganda

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Background: In many regions of the world, new HIV infections are heavily concentrated among young people aged 15-24 years. It accounts for close to 40% of all new HIV infections globally. It is believed that the majority do not know that they are infected. Young people exhibit risky behaviours that expose them to HIV infections including: early sexual debut, none cohabiting sexual partner in last 12 months and used a condom at last higher risk sex improved from 84.9% in 2013 to 71.2% in 2014.

- Percentage of Youth 15-24 years who have had sexual intercourse before the age of 15 decreased from 12.5% in 2009 to 11.4% in 2014.
- Percentage of Youth 15-24 years who perceive low or no risk of getting HIV&AIDS infection improved from 30.1% in 2011 to 17.3% in 2014.
- Percentage of adults (15+) who can mention the 3 major ways of HIV/AIDS prevention improved from 58.7% in 2009 to 72.5% in 2014.
- Percentage of adults (15+) able to reject three of the major HIV/AIDS misconceptions (witchcraft, mosquito bites and sharing food) improved from 48.3% in 2009 to 68% in 2014.

Conclusions: Measurement of risky behaviors among young people using LQAS has shown positive behavior change among young people aged 15-24 years in East Central Uganda.

HIV testing

WEPEC669

Making it available is not enough: a qualitative study on MSM’ s views towards HIV self-testing

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Background: Despite controversies, HIV self-testing (HIVST) is a potentially useful approach to increase uptake of HIV testing among men having sex with men (MSM). Self-test kits are now available in many countries. This study aimed to explore the views on HIVST among MSM in Hong Kong where self-test kits can be accessible through purchases.

Methods: Email invitations to qualitative interviews were sent to 606 participants of an online survey. Two focus group interviews were successfully conducted with 15 HIVST-naive MSM, and key informant interviews were organised with 5 ever self-testers. Verbatim transcripts were analysed using a thematic analysis approach to identify a number of recurring themes related to views on HIVST and reasons for (not) choosing self-testing.

Results: In the focus groups, very few participants reported having heard about HIVST and most were skeptical about the accuracy of self-test kits. HIV was commonly described in terms of “social discrimination” and “death”. Therefore, privacy and the availability of support services were key considerations for participants when choosing an HIV test. Although most participants acknowledged the privacy provided by HIVST, this advantage was outweighed by their intense fear of facing test results alone and the uncertainties regarding HIV treatments and supports (“what if I test positive?”). Most participants were not interested in HIVST but felt that more formal information should be available to enable the community to make informed choices. For the self-testers, two distinct reasons for self-testing could be identified. Some self-testers were not satisfied with the current testing and counseling services; while others saw self-testing not as a health check, but as a convenient way to provide psychological comfort (to “prove one’s HIV negativity”). Even if they had doubts about the accuracy of the test, they would not go for another HIV test after a negative result.

Conclusions: Market availability of self-test kits alone is not enough to attract more MSM to receive HIV test and may even induce harm. Policy goals to increase uptake of HIV test by HIVST may benefit from taking account of fears of HIV and social discrimination, and concerns over the accuracy of HIVST held by the MSM community.

WEPEC670

Personal risk factors and HIV positivity among female sex partners of people who inject drugs (PWID) at voluntary HIV counseling and testing (VCT) sites in Vietnam, 2011-2013


Background: People who inject drugs (PWID) account for the largest proportion of HIV infections in Vietnam; 42% of cases reported in 2013 were among PWID, 95% of whom were male. Forty percent of male PWID report unprotected sex with regular partners in the last 12 months, suggesting that sex partners of PWID are at high risk for HIV. We assessed personal risk factors associated with HIV positivity among female sex partners of PWID.

Methods: We examined all records routinely collected during 2011-2013 from all 47 CDC-funded voluntary counseling and testing (VCT) sites throughout Vietnam. We analyzed records...
of female VCT clients who self-reported being sex partners of PWID. We used bivariate analysis to estimate associations between HIV positivity and clients' personal behaviors (including those with multiple risks) according to highest HIV transmission risk category (personal injection/sex work/having multiple sex partners/none of these).

**Results:** Of 11,419 female partners of PWID (figure), mean age was 29 years, 7,556 (66.5%) were married, and most had attended some high school; 10,143 (88.8%) reported not having previously tested for HIV. Regarding personal risk behaviors, 547 (4.8%) reported drug injection; 1,749 (15.3%) sex work, 1,006 (8.8%) having multiple partners; and 8,117 (71.1%), none of these (table).

Overall, 632 (5.5%; 95% confidence interval [CI]=5.1-6.0) tested HIV-seropositive. HIV positivity was 16.8% (95% CI=13.5-20.2) among those reporting personal drug injection, 3.7% (95% CI=2.9-4.7) among those reporting sex work, 7.1% (95% CI=5.6-8.8) among those reporting multiple partners, and 5.0% (95% CI=4.5-5.5) among those reporting none of these. Compared with sex partners of PWID reporting no personal behavioral risks, HIV positivity was greater among those reporting drug injection (prevalence ratio [PR]=3.4, 95% CI=2.8-4.2) and multiple sex partners (PR=1.4, 95% CI=1.1-1.8).

**Conclusion:** The uptake of universal BBV testing was 27% in the ED. Among clients who self-reported being sex partners of PWID, testing for HIV was offered at 23% higher rate compared with routine testing. The effective cost of detecting one new case was £1,062 for HCV, £1,351 for HBV, and £2,478 for HIV.

**WEPEC671**

‘Going Viral’: a universal blood-borne virus (BBV) testing campaign for HIV, hepatitis B and C in ten UK Emergency Departments

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**Background:** The CDC recommends universal HIV testing in 15-64s and targeted screening for Hepatitis C (HCV) and B (HBV). UK guidelines recommend HIV testing where the diagnosed prevalence is >21/1000, and targeted screening for HBV/HCV in 1 in 4 people attending ED in England annually (18 million in 2012), of whom 13% have bloods taken—a significant testing opportunity. Few hospital-based universal BBV screening initiatives have been described. ‘Going Viral’ is a multi-ED universal BBV testing campaign.

**Methods:** During 13th-20th October 2014, 10 UK ED departments serving populations with a diagnosed HIV prevalence of ≥21/1000 for 2014-2015 took part in an opt-out BBV screening programme, providing the data. Staff offered BBV tests to patients >16 years having bloods as part of routine care. HCV Ab, HBV Surface Ag & HCV Ab were tested by local labs. Uptake was defined as those ED attending bloods who were also tested for BBV’s. Demographic data were extracted from electronic records, analysed with R (CRAN). New and known positives were contacted and linked to care.

**Results:** 2124 individuals had the BBV test and 69 infections were diagnosed (3.2%), 31 new: HCV 37 (14.4%), HBV 17 (6 new), HVB 15 (11 new). Of those aged 25-54 had the highest prevalence: HCV 2.45%, HIV 1.36%, HBV 1.09%. Testing uptake 2124/7961 (27%) range 17.4%-60.5%. Uptake was 1/3 higher in hospitals with high diagnosed HIV prevalence (>61000 population, 29.4% of 20.5%). Women had lower odds of accepting testing than men (OR 0.85) and the odds of accepting testing decreased with each successive 10 year increase in age (OR 0.91). Assuming the cost per test as £7 for each virus, the cost per new case detected is £1,062 for HCV, £1,351 for HBV and £2,478 for HIV.
WEPEC672
Community-based HIV testing and linkage to care. Efficacy of multi-country testing initiatives during European testing week 2014
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Background: HIV testing and early detection remains a challenge in Europe. Of the estimated 2.3 million PLHIV in Europe, approximately 30% are unaware of their status. As a consequence, almost half (49%) of all newly reported cases in Europe in 2013 were late presenters (CD4 cell count < 350/mm3). Increasing uptake of testing will require innovative and community-based approaches to ensure that HIV testing services are targeted at, accessible to and used by those people who are most at risk of infection.

Methods: During the European HIV Testing Week, 21-28 November 2014, AHF Europe selected 12 community-based organisations in 11 countries (6 EU and 5 non-EU) to conduct testing using AHF Rapid Testing Model. They received small grants to cover direct and indirect costs to conduct rapid testing for key populations. The organisations received technical assistance on unified data collection, reporting and key elements of the model. They provided rapid testing, counselling and referral with linkage to care. Full linkage and late presentation data will be available in March 2015.

Results: 4200 people were screened for HIV at on-site and off-site events (median age 34; 68% male, 18% MSM, 13% SW). 56% had never tested for HIV before. 167 received reactive results; including 107 (2.5% (95% CI: 1.9-3.1)) self-reported new cases. 70% of new cases were among men. Overall, the results in different populations were: MSM: 3.6% (29); PUD: 15.7% (113) and SW: 1.8% (8). New cases across different populations included: MSM: 3.5% (27) PUD: 7.4% (57) and SW: 1.5% (8). 91% (152) of all positive cases referred to care attended their appointment. The average AHF Europe investment per test performed including direct and indirect costs was USD66.75 (USD55.86-78.38). The median cost per test was USD63.39 (USD133.33-350).

Conclusions: There is a pressing need to increase uptake of HIV testing among key populations and promote earlier diagnosis and linkage to care. Community-based HIV rapid testing interventions demonstrate a potential to reach people who have never been tested or those who know their status but are not in care, ensure efficacy and effective linkage to care.

WEPEC673
Expanding HIV testing and counselling (HTC) coverage through integration of community and facility strategies in an informal settlement in Kenya
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Background: Knowledge of HIV status is often the first step in the management of HIV/AIDS. People living in informal settlements, often low income earners are unique and require innovative approaches to spur their interest in HIV testing. AMREF has integrated community and facility strategies to expand coverage of HTC services. We hereby share our experiences, key challenges and successes.

Methods: The project is implemented at four Health Centers situated within Kibera Informal settlement, which is the largest urban slum in Africa. We analyzed data on testing strategies employed both at clinics (Facility based testing) and community level strategies, for cohort starting October 2013 and September 2014. Facility based testing strategies include Provider Initiated testing and counselling (PTCT) and Client Initiated Testing and Counselling (CITC), while the community approaches are mainly Home Based Counselling and Testing (HBTC). We used univariate and multivariate analysis to compare the outcomes of both approaches and determine the predictors of positivity and hereby present results of both testing strategies.

Results: A total of 19,591 patients were tested during the cohort period. About 73% (13,485) were tested at the 4 facilities with the remainder tested in the community. Within the facilities, PTTC accounted for 83% (11,015) of the clients with the remaining 20% tested through CITC. Individuals at the outpatient unit were provided with health education and appropriately referred for testing. HBTC contributed 5,106 (27%) clients and was mainly through door to door campaigns, community mobilization and referrals. Positivity for those tested at the facilities was 7% versus 1% among those tested in the community. Couple testing was better done in facility based testing and counselling centers. Major challenges with HBTC were difficulties linking HIV positive individuals to care, difficulties getting couples at home, couples refusing testing, high costs incurred, yet few positive clients identified and dispute of results among clients.

Conclusions: Though facility based testing and counselling is better in identifying HIV positive individuals, integration of both community and facility testing model, helps in capturing otherwise healthy HIV infected patients and expands testing coverage.

WEPEC675
Confidence in HIV testing ability is associated with higher HIV testing frequency and likelihood to self-test among test-confirmed gay and bisexual men
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Background: Regular testing of high-risk individuals is central to biomedical and behavioral prevention strategies, and specifically crucial to decrease time between infection and diagnosis. Little research has been conducted on ‘self-efficacy’ in relation to perceived ability to undertake HIV testing among gay and bisexual men (GBM). We examined self-efficacy in relation to HIV testing frequency and likelihood to self-test among GBM.

Methods: Participants were HIV-negative Australian GBM at increased risk of HIV (>5 partners or unprotected anal intercourse in previous 3 months) in a randomised controlled trial of HIV self-testing (FORTH). We constructed a HIV testing ‘Self-Efficacy’ scale (HTSE) measuring confidence in one’s perceived ability to undertake HIV testing comprising 8 items (responses: ‘not at all confident’=0 to ‘completely confident’=4; Cronbach’s α=0.81). Total HTSE score consisted of the sum of scores for all items. Prior to the trial (and self-testing) commencing, a cross-sectional analysis was conducted including survey with complete responses on HTSE items. Factors associated with past HIV testing frequency and perceived likelihood to self-test in the future were determined using logistic regression.

Results: A total of 352 GBM were included. Median age was 33 years (inter-quartile range [IQR]=28-41), and 63% were Australian-born (n=227). Overall, 95.4% reported having previously tested for HIV (n=336): 65.3% in the last 12 months (n=230) and 64.2% reported being ‘very likely’ to self-test for HIV (n=231). The median HTSE score was 26 (IQR=23-29, range=8-32). In multivariate analysis, independent factors associated with ≥3 HIV tests in last 12 months were: higher HTSE score (adjusted odds ratio [AOR]=1.1 for increase in score by 1, 95%CI=1.02-1.13;p<0.006); and >5 partners in last 6 months (6-10 partners AOR=2.7, 95%CI=1.3-5.80;p=0.008; 11-20 partners AOR=3.0, 95%CI=1.48-6.22;p=0.002; ≥21 partners AOR=6.5, 95%CI=3.03-13.73;p<0.001). Only HTSE score was associated with high perceived likelihood to self-test (odds ratio=1.1,95%CI=1.03-1.13;p<0.001).

Conclusions: Self-efficacy in relation to HIV testing is independently associated with HIV testing frequency and likelihood to self-test. Improving GBM’s confidence in HIV testing such as by improved knowledge and greater experience may lead to higher testing frequency. Future longitudinal analysis will provide information about the causal pathway direction between HTSE, testing frequency and actual self-testing measured in the FORTH trial.
WEPEC676
Increasing HIV testing and re-testing without declining HIV positivity among gay and bisexual men attending public sexual health clinics

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Background: Gay, bisexual and other men who have sex with men (GBM) are a risk group most affected by HIV in Australia. Mathematical modelling suggests that reducing the time between infection and diagnosis can lead to reductions in population incidence. Public sexual health clinics (SHCs) implemented a range of initiatives to increase HIV testing including express clinics, after-hours and drop-in services, online booking, rapid testing, and reminders. We measured the impact of these strategies on HIV testing among GBM attending SHCs in the state of New South Wales (NSW).

Methods: We utilised routinely collected data from 33 large SHCs in NSW. The analysis was restricted to HIV-negative GBM from 2007-2013. We calculated the following indicators: unique GBM attendance; proportion of attendees tested at least once in a year (tested/attended); proportion of attendees re-tested within 1-12 months (re-tested/attended). We also calculated annual HIV positivity defined as the proportion of attendees testing positive for HIV (positive/attended). We also calculated the proportion of attendees re-tested within 1-12 months (re-tested/attended). We also calculated the proportion of attendees re-tested within 1-12 months (re-tested/attended). We also calculated the proportion of attendees re-tested within 1-12 months (re-tested/attended). We also calculated the proportion of attendees re-tested within 1-12 months (re-tested/attended). We also calculated the proportion of attendees re-tested within 1-12 months (re-tested/attended).

Results: From 2007-2013, 20,542 unique HIV-negative GBM had 117,796 visits and 42,360 HIV tests. The median age at first visit was 31 years (inter-quartile range 25-40). In 2007, 4,202 unique GBM attended, 69.4% had an HIV test and 27.2% were re-tested within 12 months (see Figure). In 2013, 7,387 unique GBM attended (76% relative increase from 2007), 85.1% had an HIV test (23% increase) and 44% were re-tested within 12 months (61% increase) with a significant increasing trend in all indicators over time (p<0.001). Testing uptake was greatest in higher-risk GBM and increased from 79.6% in 2007 to 93% in 2013. Overall, HIV positivity fluctuated (0.9%-1.6%) with no significant trend over time (p=0.264).

Conclusions: Public SHCs in NSW have successfully increased attendance and HIV testing among GBM, and prioritised testing in higher-risk men. The HIV positivity data suggest that the increase in testing has remained well targeted, and not extended into a group at lower risk of HIV. There is potential to further improve testing uptake and re-testing to decrease the time between infection and diagnosis.

WEPEC677
Clinic-based supervised oral self-testing for HIV is feasible and accurate in rural KwaZulu Natal, South Africa

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Background: Key to decreasing HIV incidence is promoting people’s awareness of their HIV status and initiating eligible people on ART. This study examines the feasibility of oral self-testing (OST) in a primary healthcare environment as a step towards wider access to HIV counseling and testing (HCT). Confirmatory testing and linkage to care are key elements to be implemented as per Médecins Sans Frontières/UNAIDS recommendations on OST, and are ensured in our study setting.

Methods: Recruitment took place in two clinics in iLhukwula district, KwaZulu Natal, from June 2014 to January 2015. Potential participants were approached at the waiting areas, performed OST under the supervision of a counsellor, and read their results. Confirmatory blood-based rapid-tests were done for all participants.

Results: 1,001 (26%) among the 3,955 clinic attendants sensitized accepted to enroll in the study. Median age of the 259 (25.8%) men and 742 (74.1%) women participants was 28.7 (IQR 22.5-36.0) and 25.0 (IQR 21.0-32.6) respectively. 933 (93%) had a HIV test before, but only 53 (5.3%) had ever heard of OST. Counselor-participant concordance in results interpretation was 99.7%. A sensitivity-specificity of 99.55% and 99.87% was observed, with positive and negative predictive values having the same values. A total of 222 (22.2%) participants were confirmed as HIV-positive by the finger-prick rapid-test.

Conclusions: The use of supervised OST is feasible in rural clinics in KwaZulu Natal and with diagnostic performance observed in this setting being very similar to that of the rapid test. OST can be a feasible option to improve uptake of HCT at clinic level, and rural clinics in KwaZulu Natal need support to roll-out OST in their HIV testing services to increase awareness of HIV status among population who regularly do not access conventional HCT. Further research is needed to assess feasibility of unsupervised self-testing in settings outside of health facilities.

WEPEC678
Gay men’s awareness of pooled nucleic acid amplification testing (pNAAT): examining diffusion among networks and influence on testing following implementation and promotion in Vancouver, Canada

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Background: In 2009, pNAAT was implemented at 6 clinics accessed by gay men in Vancouver, Canada. This introduction was accompanied by social marketing campaigns and led to the increased detection of acute HIV infection (AHI) over time. We aimed to understand if and how awareness of pNAAT testing diffused among gay men following implementation, and whether this awareness influenced testing patterns.

Methods: Men identifying as having sex with men and testing HIV-negative at 1 of the 6 clinics were enrolled into a prospective cohort between June 2011 and March 2012. Participants self-completed questionnaires at 7, 30, 180, and 360 days that spanned domains including personal/social background, HIV testing and sex life. We used baseline data to explore outcomes related to awareness of pNAAT, diffusion of knowledge, and influence on testing behavior. Chi-squared analyses were used to identify variables associated with the outcomes.

Results: 166 men completed the baseline questionnaire. The mean age was 32 years and the majority self-identified as gay (88%), were Caucasian (67%), and resided in Vancouver (84%). Awareness of pNAAT was high (72%) across all sociodemographic groups. Most men reported talking to sex partners (53%) or gay friends (66%) about the test but fewer heard about the test from these sources (8% and 35%, respectively). Men who talked to sex partners about the early test were more likely to report asking for sex among friends of friends, friends, and ex-boyfriends (34.5% vs. 14.6%, p<0.02) and discuss HIV status with their sex partners (74.5% vs. 47.9%, p<0.005). Almost half (41%) of participants reported that awareness of pNAAT availability influenced them to test earlier than normal. Of reasons given for testing, men who reported they wanted pNAAT were also likely to report testing due to a sexual event that risked HIV transmission (p< 0.001), suggesting awareness was correlated with earlier testing after a risk event.

Conclusions: Awareness of pooled NAAT was high among this sample of gay men in Vancouver, discussion of pNAAT in sexual and social networks was common, and awareness appeared to contribute to earlier testing. Efforts to promote AHI testing are an important component of increasing AHI diagnosis capacity.
WEPEC679
Self-reported satisfaction and intent to retest among adolescents tested for HIV in a pediatric emergency department

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Background: Routine HIV screening of youth starting 13-15 years of age has been recommended in healthcare settings including Emergency Departments (EDs). Children's National Health System's (CNHS) ED provides universal, opt-out HIV screening for adolescents ≥13 years. Few studies have assessed the satisfaction and experience of young people approached and screened for HIV in a pediatric ED setting. This study was conducted to evaluate patient satisfaction and perceived impact on patients' future HIV testing following HIV screening at the CNHS United Medical Center (UMC) community hospital pediatric ED.

Methods: A voluntary, anonymous survey with multiple choice questions assessing patient satisfaction and experience with HIV testing was administered from March 2013 to August 2014 to adolescents who tested negative for HIV after they received their results. Adolescents with positive HIV test results were excluded from participating in the survey. Descriptive statistics were used to assess patient perception and satisfaction of ED HIV screening.

Results: A total of 405 adolescents (median age=18 years) completed the survey. The majority were female (70%; n=285) and Black (96%; n=395). The large majority of adolescents were “satisfied” or “very satisfied” with their HIV testing experience (86%; n=349) and with the way the test results were presented to them (97%; n=395). The majority of adolescents (66%; n=268) were also “satisfied” or “very satisfied” with the time spent on HIV education and reported increased awareness (72%; n=293) about the risk factors for acquiring HIV. Approximately half (56%; n=225) of adolescents reported that they would encourage their partners to get an HIV test and would retest themselves in 3 months (47%; n=191) or 6 months (27%; n=110).

Conclusions: In addition to identification of an infection, HIV screening provides an opportunity for adolescents to increase their awareness about HIV. High levels of patient satisfaction were observed among adolescents tested for HIV in the UMC ED. Most importantly, testing for HIV appears to have motivated almost half of adolescents to consider encouraging their partners to test for HIV and to retest themselves for HIV within 3 months although the intent to retest for HIV appeared to decrease at 6 months.

WEPEC680
The impact of HIV counseling and testing on HIV acquisition: a systematic review

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Background: Each year, millions of people in sub-Saharan Africa receive HIV counseling and testing (HCT), a service designed to inform persons of their HIV status and, if HIV-uninfected, reduce HIV acquisition risk. However, the impact of HCT on HIV acquisition has not been systematically evaluated. We conducted a systematic review to assess whether HCT was associated with reduced HIV acquisition in sub-Saharan Africa.

We conducted a systematic review to assess whether HCT was associated with reduced HIV acquisition in sub-Saharan Africa. We included all studies assessing the satisfaction and experience of young people approached and screened for HIV in a pediatric ED setting. This study was conducted to evaluate patient satisfaction and perceived impact on patients' future HIV testing following HIV screening at the CNHS United Medical Center (UMC) community hospital pediatric ED.

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WEPE841
The challenges with management of HIV infection where the law criminalizes MSM: a case study of MSM population in Abuja, Nigeria

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Background: The 2013 Same sex prohibition Act in Nigeria has severe impact on the HIV response in Nigeria. Prior reports have shown how this law has resulted in significant reduction (73.0%) in access of MSM in Abuja to HIV prevention services at a MSM friendly service outlet in Abuja. This report highlights the impact of the law on access to MSM to HIV treatment and the implication of this for the health and well-being of MSM in Nigeria.

Methods: The International Centre for Advocacy on Rights to Health - ICARH, documented the medical history of 899 MSM who access HIV services at the clinic between 2011 and 2014. Of these, 359 clients are HIV positive and 129 (35.9%) are on ARV. We specifically reviewed the profile of MSM who access treatment services in the Clinic for year 2014 following the promulgation of the same sex marriage prohibition Act in Nigeria.

Results: In 2014, 260 MSM enrolled into ICARH MSM HIV prevention, care and support programme. Of these 86(33.1%) tested HIV positive of which 84 were placed on first line ARV and two were on placed on second line ARV. One of the two MSM on second line ARV commenced second-line drugs directly as initial treatment, having had a positive drug resistance test. The second MSM on second line ARV was due to default of treatment resulting from fear of violence when he shows up at the clinic for treatment access. Also, eight other HIV positive MSM in care of ICARH died in 2014 due to their drop out of HIV care due to concerns about violence that could result from public reactions to the promulgated law.

Conclusions: The impact of the promulgated same sex prohibition Act in Nigeria has significant impact on the health and well-being of MSM in Nigeria. The law drives MSM from access to ARV currently largely placed within the previse of public health centers. With low national investment in MSM programmes in Nigeria, the long-term welfare of MSM living with HIV would be a challenge.
WEPE842

Decentralizing HIV care and treatment to improve primary health centers in Lesotho: results from a national patient file audit

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Background: The use of antiretroviral treatment (ART) has substantially decreased morbidity and mortality in people living with HIV/AIDS. In order to reach patients across countries with high disease burden, task shifting from physicians to nurses and decentralization of HIV treatment services are needed to support growing ART programs. Retention of HIV-positive patients in treatment programs remains central to the success of treatment outcomes. However, there is paucity of data on where retention was dependent on health facility level (hospitals or lower-volume health centers). In Lesotho, the Elizabeth Glaser Pediatric AIDS Foundation conducted a patient care audit to assess the difference in retention between hospital clinics and primary health centers (HC).

Methods: We carried out a cross-sectional descriptive review of patient clinical cards of patients ever enrolled in HIV care and treatment in Lesotho in the last ten years (2004-2014). We compared patient outcomes between patients attending ART clinics based in hospitals and those attending in HC in Lesotho.

Results: Overall, 88,768 clinical cards were reviewed; 49.3% (43,728/88,768) patients enrolled into ART in hospitals and 50.7% (45,038/88,768) in HC. Retention was better in HC than hospitals: 66% (30,826) patients starting ART in HC at still active at the time of the review compared to 59% (25,896) in hospitals (p<0.001). Baseline CD4 availability at enrolment was similar in hospitals and HC: 91% and 88%, respectively; baseline median CD4 was 215 and 180 in hospital and health center respectively. Availability of a recent CD4 was 56% and 83% of patients in health center and hospital respectively for those with CD4 available, most recent median CD4 was 449 for hospitals vs 445 for HC. Mortality was higher in HC, 11% (5,096/45,038) compared to 7% (3,191/43,728) in hospitals (P<0.001).

Conclusions: Decentralization of HIV treatment to primary HC can improve retention in active care, likely due to easier clinic access in settings closer to the patient. It may be necessary to scale up point-of-care CD4 at HC to improve treatment monitoring. Further research is necessary to define clear targets as Lesotho develops strategies to achieve the global call for "90-90-90" that is 90% of PLHIV know their status, of whom 90% are initiated on treatment and out of whom 90% are virally suppressed.

WEPE843

Clinical outcomes of patients in 10 years of national antiretroviral therapy scale up in Lesotho: results from a national patient file audit

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Background: Lesotho introduced ART in public facilities in 2004 and country has significantly scaled-up the HIV treatment program. By August 2014, nearly 150,000 HIV-positive people initiated ART at 190 clinics. Yet, patient health outcomes have remained somewhat unknown over the years.

Methods: EGPAF conducted a cross-sectional review of patient clinical cards of all patients enrolled in HIV care and treatment in 21 public hospitals and 103 health centers across Lesotho, from August 2013 through August 2014. The aim of was to use cumulative data from the patient care audit to improve program quality and patient outcomes. Age at enrolment, gender, CD4 at various points, drug regimen, treatment failure, clinical outcomes (active on treatment, transferred out, default and loss to follow-up) were extracted. Data were entered into MS Access, cleaned and transferred into Stata 11.0 for analysis to generate frequency and cross tabulation. Chi square test of significance was done.

Results: 114,854 records were reviewed and analyzed: 64% were female; 95% were adults with a mean age at enrolment of 37.5 years, and 5% were children with a mean age at enrolment of 5.6 years. The mean duration on treatment for all patients enrolled on treatment was 3.8 years. Overall, 63% of patients enrolled on ART were still active at the time of the review, 28% were lost to follow-up, and 9% were dead. The overall retention was higher in children (69% compared to adults at 63% (p<0.001)). Of patients enrolled on ART, 86% were still active within one year, declining to 75% for those enrolled for 2 years; 61% for those were enrolled for 5 years and 43% of patients stayed active on ART for 10 years. Baseline CD4 was preformed among 80% of patients.

Conclusions: Lesotho’s national ART program achieved good retention at one year which gradually declined over the years. The results of this audit can and should be used as baseline to define clear targets as Lesotho develops strategies to achieve the global call for “90-90-90” that is 90% of PLHIV know their status, of whom 90% are initiated on treatment and out of whom 90% are virally suppressed.

WEPE844

Evaluation of ART program outcomes: a comparison of public and private ART facilities in Maseru District

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Background: A number of evaluations have been conducted on national antiretroviral therapy (ART) programs in Africa to assess clinical outcomes or discern lessons learned, but few have evaluated outcomes in private ART clinics. Private health facilities usually offer services to more privileged populations; they have a smaller population reach and care is generally tailored toward patients’ convenience. Many private sector providers pioneered the provision of HIV-related care in developing countries, but they have largely been overlooked in program implementation science. In Lesotho, the Ministry of Health mandated that private care providers should receive free antiretroviral from the national system, to distribute free ART to their patients. The Elizabeth Glaser Pediatric Foundation Lesotho Program compared key clinical and program outcomes in private versus public facilities in Maseru district.

Methods: EGPAF-Lesotho carried out a national, cross-sectional review of clinical cards of all patients enrolled in HIV care and treatment in Lesotho over a period of ten years (2004-2014). Clinical and program outcomes from private and public health facilities in Maseru were compared for clinical outcomes including mortality, retention on treatment, and CD4 counts.

Results: Overall, 88,768 patients were enrolled in ART at public facilities compared to 1,896 at private facilities. Retention on ART was better at private than public health facilities: 74% (1,340) patients starting ART were still active at the time of the review vs 64% (56,522) in public health facilities (P<0.001). While baseline median CD4 count was higher in patients seen at public health than private facilities (225 vs 192, respectively), the most recent CD4 was similar at both facility types (411 in public health vs 406 in private facilities). Mortality was higher in public health facilities, 11% (8,287/88,768) compared to 5% (911/1,896) in private facilities (P<0.001).

Conclusions: In high burden countries like Lesotho, innovative strategies to provide free ART to accredited private sector providers who provide ART to clients at no cost are useful in complementing public ART services. Although patient numbers in private sector facilities were low, the public sector could benefit from an exploration of approaches employed by private facilities to attain better outcomes.

WEPE845

Antiretroviral (ARVs) prescribing outcomes among physicians: a rural-urban comparison in British Columbia (B.C.) Canada in 2013

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Background: Disparities in HIV care between rural and urban settings, including access to physicians who prescribe ARVs (hereon ART Physicians), have been recognized globally. The profile and prescribing patterns of ART Physician can provide a better understanding of educational and programmatic needs of each geographic area and address the disparities in the care and treatment of HIV-positive patients.

Methods: We analyzed data from the B.C. HIV/AIDS Drug Treatment Program (DTP) collected between January 1, 2013 and December 31, 2013. The DTP is a centralized program that provides access to ARVs free-of-charge to all HIV-positive individuals residing in B.C. We compared characteristics of ART Physician in rural and urban areas using Pearson’s chi-squared test. Experience in ART prescribing was defined as having treated more than 6 HIV-positive patients in the past since DTP was initiated in 1996.
Results: In 2013, 894 physicians completed at least one ARV prescription (7.9% of the total general practitioners [GPs] and specialists in B.C.), and among them 749 (83.8%) only completed ARV refill prescriptions but did not initiate or change any ARV regimen, 8 (0.9%) only initiated or changed ARV and 137 (15.3%) performed both initiation/change and refill prescriptions. 93.4% of the ARV Physicians were GPs, 2.8% were infectious disease specialists, 1.9% were internal medicine specialists and 1.9% were other specialists. Physicians prescribed ARVs for a mean of 11.4 and median of 1 (interquartile range=1-3) patients each. There were 105 (11.7%) ARV Physicians practicing in rural areas and 789 (88.3%) in urban areas. In rural areas, significantly fewer ARV Physicians were specialists when compared to urban areas (1.0% vs. 7.4%, p<0.001), and a larger proportion of ARV Physicians only refilled ARVs in rural areas (93.3% vs. 82.5%, p=0.007). Also, a significantly larger proportion of urban ARV Physicians were experienced in HIV care compared to their rural counterparts (30.9% vs. 9.5%, p<0.001).

Conclusions: A smaller proportion of ARV Physicians in rural areas were experienced in HIV care and fewer of them initiate and/or change medication compared to their urban counterparts. These results suggest the need to support and train GPs in HIV care and treatment, particularly in rural areas.

WEPED846

The roles of implementation leadership and implementation climate in provider attitudes toward HIV prevention EBPs in Mexico

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Background: The use of evidence-based practices (EBPs) for HIV prevention and intervention is associated with more favorable patient outcomes. Service provider attitudes toward EBPs is associated with increased use of EBPs in health, mental health, and substance abuse treatment. However, service provider attitudes can be impacted by the organizational context in which they work. Specifically, leadership and organizational climate are associated with provider attitudes to EBPs. We examined the extent to which implementation leadership affected HIV prevention worker attitudes to EBPs as mediated by implementation climate.

We hypothesized that stronger implementation leadership and implementation climate would be associated with stronger provider attitudes toward EBPs and that climate would partially mediate these effects.

Methods: The Mujer Segura HIV prevention study is a Hybrid Type 1 effectiveness/implementation trial taking place in 13 women’s reproductive health clinics in eight states in Mexico. WePeD846

We hypothesized that stronger implementation leadership and implementation climate would be associated with stronger provider attitudes toward EBPs and that climate would partially mediate these effects.

Methods: The Mujer Segura HIV prevention study is a Hybrid Type 1 effectiveness/implementation trial taking place in 13 women’s reproductive health clinics in eight states in Mexico. Participants were N=49 clinic employees including outreach workers and counselors. Measures included the Implementation Leadership Scale, Implementation Climate Scale, and Evidence-Based Practice Attitude Scale. All measures were completed by clinic employees and data were nested at the clinic level. We utilized Mplus to conduct a multilevel path analyses examining the impact of implementation leadership on implementation climate and their associations with provider attitudes to EBPs while controlling for the nested data structure.

Results: Results indicated a significant positive path between implementation leadership and implementation climate (β=0.51; p<.001). The path from implementation climate to attitudes to EBPs was also significant (β=0.30; p<.01). The direct path from implementation leadership to provider attitudes to EBPs was also significant (β=0.19; p<.05). We conducted a Sobel test for mediation which was significant (z=2.17; p<.05) indicating significant partial mediation.

Conclusions: This is the first test of the new constructs of implementation leadership and implementation climate in an HIV prevention study. Findings suggest that clinicians should consider improving leadership and climate as avenues for improving provider attitudes to EBPs and this is consistent with emerging work in other public health and allied health settings that have shown that provider attitudes predict increased adoption and use of EBPs.

[Table 1: Barriers to Care for Truck drivers]

<table>
<thead>
<tr>
<th>Primary barrier to care</th>
<th>TOTAL</th>
</tr>
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<tbody>
<tr>
<td>No time, always on road</td>
<td>34 (68%)</td>
</tr>
<tr>
<td>Services not convenient times</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>TD attitude not seek services</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Unfriendly providers</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Unsure where to access care</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Services not available</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

Conclusions: Mobile populations face significant barriers to HIV care in rural Malawi. This study provides the foundation for designing effective and accessible services to prevent and treat HIV among this vulnerable population.
We conclude that regular use of mHealth technology (weekly text messaging) improved ART adherence, and that this improvement (283%) is sustained for 12 months. Our study has important implications for the design and evaluation of mobile health interventions globally, and for the integration of such interventions into routine care for HIV treatment and care.
WEPE851
Dose-response relationship between methadone dose and adherence to antiretroviral therapy among HIV-positive persons who use illicit drugs
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Background: For HIV-positive individuals who use illicit drugs, engagement in methadone maintenance therapy (MMT) can contribute to improved HIV treatment outcomes. However, we have no understanding of the role of methadone dose on adherence to antiretroviral therapy (ART) that has not been investigated. We sought to examine the relationship between methadone dose and ART adherence among a cohort of persons who use illicit drugs.

Methods: We used data from the ACCESS study, an ongoing prospective cohort of HIV-positive persons who use illicit drugs, who we confidentially linked to comprehensive HIV treatment data. Using generalized estimating equations (GEE) we evaluated the longitudinal relationship between methadone dose (≥ 100 mg < 200 mg/day and ≥ 200 mg/day) and the likelihood of ≥ 95% adherence to ART among ART-exposed participants during periods of engagement in MMT.

Results: Between December 2005 and May 2013, we recruited 207 individuals on MMT who were followed for a median of 42.1 months. In adjusted GEE analyses, MMT dose ≥ 100 mg/day was independently associated with optimal adherence to ART (adjusted odds ratio [AOR] = 1.06 per 20 mg/day increase, 95% CI: 1.00 - 1.12, p = 0.041).

Conclusions: Our results demonstrate a dose-response relationship between increasing MMT dose and improved adherence to ART. These findings underscore the need to optimize methadone access and dosing practices for illicit opioid use in an effort to enhance ART adherence and improve HIV outcomes.

WEPE852
Using ART experienced patients to tackle the challenges of attrition from ART in the resource constrained setting. A before-after retrospective cohort study in 10 randomly selected health facilities in Ethiopia
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Background: Retention has been declining among patients on ART in Ethiopia in the last 5 years from 82% to 70%. Use of ART experienced and trained PLHIV to prepare and re-engage patients is recommended, and many countries including Ethiopia have started the program, but its effectiveness has not been adequately assessed. In this study, we evaluated the effectiveness of use of ART experienced patients in preparing and re-engaging those who are lost to follow-up.

Methods: A retrospective cohort study with random selection of 10 facilities as clusters was done to compare key outcome measures before and after the initiation of the adherence supporters program. Survival analysis was used to examine time to 1st lost, and time to restart after being lost to follow-up.

Results: 18,635 records were originally available out of which records with missing values were excluded (4.36%) leaving 17,897 records for analysis. Observation period ranged from 1 day to 6.1 years (median follow up time was 1.25 years). The incidence of first instance of lost to follow-up was 22.2 per 100 person-years (21.7-22.7). The risk of being lost to follow up was high after initiation of the program (HR =1.22, log rank p-value: 0.000), which may be explained partly by the fact that all patients who are lost to follow up are identified immediately by the adherence supporters. The incidence of restarting after being lost to follow up was 23 per 100 PY (95% CI 22.2-24.1 per 100 PY). The chance of restarting after being lost to follow up was 4 times higher during the period adherence supporters were present (log rank p-value: 0.0000). Patients who stayed longer in care before being lost to follow-up were more likely to restart treatment than those who were lost sooner after ART initiation (5.66 times higher chance of restarting comparing time at first lost at 12 months to at < 3 months, log rank p-value: 0.0000). Time to restarting treatment was also shorter (median 37 vs 115 days).

Conclusions: Adherence supporters were effective in improving re-engagement after patients were lost to follow up, but preventing lost follow-up remains a challenge.

WEPE853
Short-term comprehensive case management support can contribute to long-term ARV adherence for complex clients
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Background: In Vancouver, BC, a multi-disciplinary case Management (CM) team was implemented as a key component of a region-wide Treatment as Prevention (TasP) initiative. The CM team consists of Nurses, Social Workers, Outreach Workers, Peers, and Housing Workers, and engages in outreach-based support to assist individuals who face multiple barriers to antiretroviral (ARV) adherence. The CM team works with clients to develop and execute a care plan to strengthen connections to primary care, mental health and addiction services, stabilized income and housing, and psycho-social supports. Discharged clients are either transitioned to less intensive programs, or assessed as capable of meeting healthcare needs independently.

Methods: Between November 2010 and September 2014, 481 clients were discharged from the clinical case management team. A chart audit was conducted of a random sample of 135 clients who had been discharged for a period of ≥6 months. Plasma Viral Load (pVL) data was examined to determine whether discharged clients had successfully achieved viral suppression (pVL<200), suggesting improved ARV adherence.

Results: Clients within the sample ranged in age from 24-65 years, with a median age of 46. The median period of time the clients were supported by the CM team was 193 days. At intake, 67% (n=90) of clients were linked to a primary care provider and at discharge, 99% (n=133) of the clients were linked. At intake 39% (n=63) of clients had pVL ≥200, and at discharge 67% (n=91) of clients had pVL ≤200. In the sample of clients at least 6 months post-discharge, 80% (n=108) of clients had a pVL ≤200 at most recent measurement.

Conclusions: Results suggest that providing complex clients with comprehensive community-based outreach support that addresses housing, income and psycho-social supports, along with strengthening engagement with primary care, is an effective intervention toward achieving long-term health stabilization. In the months following discharge the clients continued to show an improved trajectory, as the number of clients with suppressed viral load continued to increase. An assessment of on-going needs of clients who did not achieve suppressed pVL post discharge is needed to develop interventions to meet the needs of this group.

WEPE854
The value of strategies to address attrition from care within an HIV treatment program in East Africa
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Background: Attrition from HIV care and treatment threatens gains achieved as a result of the scale-up of antiretroviral therapy (ART) across Africa. Attrition rates vary substantially between settings. Since many patients who are lost are, in fact, dead, retention programs may be an inefficient use of scarce resources. We sought to establish the rate of attrition within a HIV treatment program in East Africa and to ascertain the value and cost-effectiveness of the implementation of a retention program within it.

Methods: We used a micro-simulation HIV model in order to account for attrition dynamics. Attrition event rates from an East African treatment program (Academic Model for Prevention and Treatment of HIV [AMPATH]) were assessed and utilized. We analyzed the health impact and value of enhancing retention in care directed activities within this setting. We compared this to simulation derived estimates of expansion of ART services to all patients in care with a CD4 count ≤500 cells/mm3 as a measure of the potential health benefits forgone (e.g., opportunity cost) that could be gained by applying resources to other resource-constrained decisions. The analysis was considered from a payer perspective using a lifetime horizon.

Results: The impact of retention focused interventions is seen in the table. An outreach program that seeks to re-link those patients who do not return for routine follow up care is associated with an incremental cost effectiveness ratio (ICER) of $1800/QALY. A strategy consisting of a retention focused intervention and outreach effort is associated with an ICER of $900. The value of retention programs was strongly influenced by costs of second-line ART and cost of the interventions.

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Life Years</th>
<th>QALYs</th>
<th>Cost</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>No intervention</td>
<td>19.1</td>
<td>10.6</td>
<td>$10,420</td>
<td>—</td>
</tr>
<tr>
<td>ART ≤500 cells</td>
<td>19.8</td>
<td>11.0</td>
<td>$10,780</td>
<td>$900</td>
</tr>
<tr>
<td>Outreach</td>
<td>20.8</td>
<td>11.3</td>
<td>$11,710</td>
<td>$1,800</td>
</tr>
<tr>
<td>Reduce attrition + Outreach</td>
<td>29.6</td>
<td>13.5</td>
<td>$33,130</td>
<td>$7,900</td>
</tr>
</tbody>
</table>

[Impact of retention focused interventions]
Conclusions: In a setting where HIV-infected persons present to care with advanced disease, retention programs may have a greater health benefit than expanding treatment access, though this may not provide these health gains in a more cost-efficient manner. Further research is needed to assess the factors associated with retention focused strategies that can maximize population health.

WEPE855
Access to stable housing and adherence support services improve antiretroviral adherence among HIV and hepatitis C co-infected individuals in British Columbia

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Background: Hepatitis C virus (HCV) is both a risk factor for and common comorbidity associated with HIV. Individuals with HIV/HCV co-infection face serious health challenges including risk of end-stage liver disease. The purpose of this study was to compare sociodemographic and clinical characteristics between HIV/HCV co-infected and HIV mono-infected individuals and to determine covariates of optimal ART adherence among co-infected individuals enrolled in a large cohort of HIV-positive individuals in British Columbia, Canada.

Methods: The study utilizes survey data from the Longitudinal Investigations into Supportive and Ancillary Health Services (LISA) study collected between 2007 and 2010 across British Columbia. This cross-sectional data is linked with longitudinal clinical data through the provincial Drug Treatment Plan (DTP). HCV co-infection status was obtained through self-report. Optimal ART adherence was defined as ≥95% based on pharmacy refill compliance. Multivariable logistic regression models compared optimal adherence between HIV/HCV co-infected and HIV mono-infected individuals, as well as independent covariates of optimal ART adherence among co-infected individuals.

Results: Of 912 included participants (28.2% women), 536 (58.8%) were HIV/HCV co-infected. In adjusted multivariable analysis, co-infected individuals were significantly more likely to have a history of IDU (adjusted odds ratio [AOR]: 20.8; 95% confidence interval [CI]: 11.2 to 38.5) and incarceration (AOR: 2.52; 95% CI: 1.41 to 4.51), and less likely to be optimally adherent (AOR: 0.53; 95% CI: 0.28 to 0.99). Optimal adherence among HIV/HCV co-infected participants was associated with stable housing (AOR: 1.86; 95% CI: 1.14 to 3.05) and accessing an adherence support program (AOR: 4.76; 95% CI: 2.62 to 8.57).

Conclusions: HIV/HCV co-infected individuals exhibit significantly lower ART adherence than HIV mono-infected individuals, however, stable housing and adherence support services were associated with improved adherence within this demographic. The findings highlight the importance of integrating adherence support and social services, such as housing outreach, with ART treatment programs for HIV/HCV co-infected individuals.

Socio-economic challenges in implementing treatment as prevention strategies

WEPE856
Socio-economic and clinical factors associated with late initiation of antiretroviral therapy: preliminary results from the ENGAGE cohort study

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1BC Centre for Excellence in HIV/AIDS, Epidemiology and Population Health, Vancouver, Canada, 2Simon Fraser University, Burnaby, Canada, 3Oak Tree Clinic, Vancouver, Canada, 4Dr. Peter AIDS Foundation, Vancouver, Canada, 5Hunter College, New York City, United States

Background: The purpose of ENGAGE is to identify socio-economic factors associated with late initiation of antiretroviral therapy (ART) among people living with HIV in the province of British Columbia (BC), Canada. Results will inform practices to improve linkage to care in a province where ART is provided free of charge.

Methods: People living with HIV and newly initiating ART (within the previous 6 months) were enrolled in ENGAGE, a prospective cohort study nested within the provincial Drug Treatment Program (DTP). Participants complete a 1-hour structured survey collecting demographic, ART attitudes and adherence behaviours, and use of healthcare and support services. CD4 cell count and plasma viral load were obtained via linkage to the DTP. The primary outcome, late initiation of ART, was defined as CD4 cell count < 500 cells/µL at time of initiation. Socio-demographic characteristics and adherence behaviours at baseline were compared using bivariate analyses (Wilcoxon rank-sum and Fisher’s exact tests) were used to test the association between late initiation and socio-economic characteristics.

Results: Since December 2013, 55 participants were enrolled in ENGAGE, representing 14% of the 389 eligible individuals. Enrollees were 15% female, median age of 40 years (IQR: 28-45), 27% reported Aboriginal ancestry, and had a median annual personal income of 13,332 CAD (IQR: 7,801-27,600). In addition, 24% reported ever being incarcerated and 25% a history of injection drug use. The median CD4 cell count at time of ART initiation was 500 cells/µL (IQR: 310-640). Overall, 55% of our participants were late ART initiators. In contrast, for all eligible individuals the median CD4 cell count at initiation was 410 cells/µL (IQR: 225-595; median age 40 [IQR: 31-50]) and 16% were female. Higher personal income was the only variable found to be negatively associated with late initiation (Odds ratio [OR] = 0.62, 95% Confidence Interval [CI] 0.40-0.98) per thousand-dollar increase). Female gender was marginally associated with late initiation (OR: 7.30, 95% CI 0.83-62.50) with a greater proportion of women (88%) initiating late than men (49%).

Conclusions: In this analysis, over half of the individuals initiated ART late, with disparities observed by income level. Continued efforts are needed to engage individuals in care earlier in order to fully benefit from high-quality HIV care.

WEPE857
Stigma fears undermine the scale up of HIV care and prevention in North West Province, South Africa

S. Treves-Kagan1, W. Steward2, L. Ntsware2, R. Haller1, J. Gilvydis3, H. Gulati3, S. Barnhart3, S.A. Lipman4
1University of California, Center for AIDS Prevention Studies, San Francisco, United States, 2University of Washington, International Training and Education Center for Health (ITECH) - South Africa, Pretoria, South Africa, 3University of Washington, International Training and Education Center for Health (ITECH), Department of Global Health, Seattle, United States

Background: Stigma is a known barrier to HIV testing and care. Because widespread availability of antiretroviral therapy reduces mortality, some scholars have posited that HIV-related stigma could also be reduced. This view, however, focuses on overt acts of discrimination (enacted stigma). Individual beliefs about the existence of prejudice (felt stigma) may continue to drive behavior. As part of a “situational analysis” to inform a combination HIV prevention program in high prevalence communities, we examined the impact of stigma on the uptake of services.

Methods: We conducted semi-structured interviews and focus groups with 677 individuals in four low-resource subdistrict districts in North West Province, South Africa, between April 2012 and September 2013. We subsequently coded all fieldwork notes; we also conducted a more in-depth transcription and coding of 31 recorded interviews. Using a grounded theory approach, we developed codes based on themes that emerged in the data. Stigma-related codes were subsequently categorized according to manifestation (enacted stigma, felt stigma). We then examined how people sought to manage stigma and the impact it had on accessing care.

Results: Findings suggested that stigma remains a barrier to care. Although participants reported less hostility toward people living with HIV, they also felt that HIV remains highly as-
sociated with promiscuity and infidelity. Participants described community members taking steps to avoid being identified as infected, including avoiding healthcare facilities entirely, using traditional healers, or paying for private doctors. Such behaviors led to delays in testing and accessing care, and problems adhering to medications, especially for men and youth who worried that there was no other health condition that could plausibly account for their utilization of medical services.

**Conclusions:** Despite significantly increased availability of treatment and care, stigma continues to pose a formidable barrier. Providing access to ART alone will not end HIV-related stigma. Individuals are hesitant to seek care and support as long as they fear that doing so will lead to unintended disclosure and prejudice and discrimination. It is critical to combat this trend by increasing cultural acceptance of being seropositive, integrating HIV care into general primary care and normalizing men and youths' utilization of health care.

**WEPED858 Sociodemographic barriers affecting adherence to HAART among elderly patients at a tertiary care centre in India**

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**Background:** Adherence to ART in geriatrics is affected by factors which are novel to this age group. The lost to follow up rates are very high. The impact of co-existing morbidities, the effect of toxic drugs on failing organ systems and dependency of this population to obtain medicines makes the management of HIV in this group complex. This study was done to estimate the sociodemographic barriers to HIV care among elderly patients (>55 years) at a Tertiary care centre in Pune, India.

**Methods:** Elderly patients (>55 years) on regular ART for more than a year (N=100) were selected from those attending OPD at BJMC, Pune. A 28 question questionnaire was administered and ART records were analysed subsequently conclusions were drawn.

**Results:** Study questionnaire was divided into two parts: A self assessment of drug adherence and common perceived barriers to adherence. Patients were divided into strictly adherent (<2 doses missed a month), adherent (<2 missed days) and poorly adherent (>2 missed days). Of all participants, 58 patients were on non-ART medications due to associated comorbid conditions with 25 patients currently on ART for pulmonary or extra pulmonary TB. Barriers to adherence were assessed under the headings of perception of HIV disease and treatment, self efficacy of treatment and follow up, adverse effects and social barriers to treatment adherence. Among the poorly adherent group, major barriers recognized were confusion due to multiple treatments, self efficacy of treatment and follow up, adverse effects and social barriers to treatment adherence.

Factors associated with good adherence were adequate information about drugs (87.88%), positive perception of disease outcomes (83.33%), less fear of ADRs (81.6%), and less travel time to obtain medication (88.9%).

**Conclusions:** Lost to follow up rates among geriatric HIV patients are high. Certain factors which resulted in poor adherence among patients were lack of adequate adherence counseling, requirement of multiple drugs, presence of comorbid conditions, fear of adverse effects and lack of social support structure, especially in case of widows. Modification of these factors could lead to improved adherence to ART in this population.

**Implementation of PMTCT Option B+ in various contexts**

**WEPED859 Six- and 12-month loss to follow-up among early implementation of Option B+: a systematic review**

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**Background:** Universal, lifelong provision of antiretroviral therapy (ART) for pregnant or breastfeeding HIV-positive women (Option B+) was adopted by the World Health Organization in 2013. Since then, 16 of the 22 Global Plan priority countries have endorsed Option B+ and moved towards implementation. However, uptake, retention, and clinical outcomes under Options B+ are not yet well understood. Women who feel healthy at the time of ART initiation may be more likely to be lost to follow-up (LT FU) than symptomatic women. We sought to review published literature reporting LT FU among pregnant or breastfeeding women at 6 and 12 months after initiating Option B+.

**Methods:** We searched PubMed, African Index Medicus, and relevant citations using the terms “Option B+” and “universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women.” Studies reporting loss to follow-up among women at 6 and/or 12 months after initiation of Option B+ were included. Heterogeneity in data sources, methods of ascertaining loss to follow-up, and follow-up time precluded statistical pooling of results.

**Results:** Of 99 citations that met our search terms, 9 were eligible for full study inclusion. Upon further review, one study was later excluded as inclusion was conditional on study retention through the breastfeeding period. Of the 8 studies included, 7 reported LT FU under Option B+. LT FU at 6 months ranged from 8-22%, LT FU at 12 months ranged from 6-23%.

**Abstract Book 1 6- and 12-month Option B+ LT FU Rates**

<table>
<thead>
<tr>
<th>Author, Year, Country</th>
<th>Setting</th>
<th>Study Population</th>
<th>Study Period</th>
<th>Study Design</th>
<th>Data source</th>
<th>n</th>
<th>6 mo LT FU</th>
<th>12 mo LT FU</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC, 2013, Malawi</td>
<td>all public clinics in Malawi</td>
<td>All women initiating OB+ in first quarter 2011 (1st quarter of implementation)</td>
<td>July 2011 - Sept 2012</td>
<td>Retrospective cohort</td>
<td>Registries</td>
<td>2,949</td>
<td>-</td>
<td>23%</td>
<td>-</td>
</tr>
<tr>
<td>Kieffer, 2014, Uganda</td>
<td>EGPAF-supported health facilities</td>
<td>Women accessing OB+ services</td>
<td>March 2013 - March 2014</td>
<td>Retrospective cohort</td>
<td>Aggregated service delivery data</td>
<td>9,805</td>
<td>12%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kieffer, 2014, DRC and Cameroon</td>
<td>EGPAF-supported health facilities</td>
<td>Women accessing OB+ services</td>
<td>2013 - March 2014</td>
<td>Retrospective cohort</td>
<td>Aggregated service delivery data</td>
<td>1,314 (DRC); 6,657 (Cameron)</td>
<td>21% (DRC)</td>
<td>-</td>
<td>89% at 90 days (Cameron)</td>
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<td>Kieffer, 2014, Malawi</td>
<td>EGPAF-supported health facilities</td>
<td>Women accessing OB+ services</td>
<td>August 2011 - March 2014</td>
<td>Retrospective cohort</td>
<td>Aggregated service delivery data</td>
<td>5,837</td>
<td>-</td>
<td>-</td>
<td>71% at 24 mo</td>
</tr>
<tr>
<td>Kooi, 2014, Malawi</td>
<td>All public ART clinics within one district (Karonga)</td>
<td>All ART patients; sub-group included all women initiating OB+</td>
<td>2005 - 2012</td>
<td>Retrospective cohort</td>
<td>Clinic registries</td>
<td>586</td>
<td>15% (12-18%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Price, 2014, Malawi</td>
<td>Karonga district</td>
<td>All recently postpartum women residing in DSS survey area</td>
<td>July 2011 - January 2013</td>
<td>Retrospective cohort</td>
<td>Interview &amp; clinic record review</td>
<td>495</td>
<td>-</td>
<td>-</td>
<td>19% LT FU at interview</td>
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<tr>
<td>Terhmani, 2014, Malawi</td>
<td>all public clinics in Malawi</td>
<td>Women initiating OB+</td>
<td>October 2011 - March 2012</td>
<td>Retrospective cohort</td>
<td>MoH routine data</td>
<td>21,959</td>
<td>17.1%</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Teeya, 2014, Malawi</td>
<td>Largest ANC clinic in Lusungu, Malawi</td>
<td>Women initiating OB+; those LT FU were interviewed to ascertain the cause</td>
<td>2011 - 2013</td>
<td>Prospective cohort</td>
<td>Clinic registries</td>
<td>2,353</td>
<td>-</td>
<td>-</td>
<td>20% missed 1 clinic visit by &gt;3 weeks</td>
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<td>van Lettow, 2014, Malawi</td>
<td>All PMTCT/ART facilities in 6 districts</td>
<td>Women initiating OB+</td>
<td>Feb - June 2013</td>
<td>Cross-sectional</td>
<td>Aggregated clinic registry &amp; health facility survey data</td>
<td>141 health facilities</td>
<td>Range 8-21%</td>
<td>Range 6-23%</td>
<td>-</td>
</tr>
</tbody>
</table>

**Author Index**

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**WEPE860**

**Option B+ in Mozambique: challenges to retention in care**

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Presenting author email: catiel13@uw.edu

**Backgrounds:** The objective of this implementation science intervention study was to develop and test a pilot intervention in six large public clinics in central Mozambique to improve implementation of new 2013 WHO “Option B+” guidelines that seek to start antiretroviral treatment (ART) among pregnant women at time of diagnosis. The “B+” approach was initiated by the Ministry of Health in selected sites in July 2013. Data from the 6 sites in this study indicate substantial loss-to-follow-up (LTFU) in the first 3 months after ART initiation. Major streamlining of links among ANC, PMTCT, and ART services is required. Results from the formative research from this study are described here. The intervention is currently being implemented in the six sites using a stepped wedge design.

**Methods:** The study includes a formative research, intervention design, and implementation phase. This formative research was initiated in early 2013 completed in early 2014 in each of the six study clinics and consisted of:

1. patient flow mapping,
2. collection of health systems data from ANC registries, pharmacy registries, and ART clinic databases, and staffing levels, patient waiting times, and patient flow data,
3. and patient and health worker individual interviews and focus groups.

**Results:** Performance at the six sites ranged from 1% to 79% of newly diagnosed HIV-positive women starting ART within 14 days of diagnosis. Only about 50% (ranging from 27% to 70%) at the six sites) managed to return for their first scheduled 30-day medication refill visit. There was little training, minimal workflow modification, and few new job aids to orient health facilities to the B+ roll-out. These data revealed major systemic bottlenecks that contributed to poor adherence and retention in the first month after ART initiation. Long wait times, short consultations, and poor counseling were identified as barriers.

**Conclusions:** Formative research findings indicate that improved retention requires:

1. workflow modification to redefine nurse tasks, shift tasks to community health workers, and enhance patient tracking; and
2. an adherence and retention package to systematize active patient follow-up, ensure home visits by community health workers, employ text messaging, and intensify counseling by health staff.

**WEPE861**

**Patient preferences for antiretroviral treatment during pregnancy under Option B+ in Zambezia, Mozambique**

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**Background:** Option B+, lifelong antiretroviral therapy (ART) for all HIV-infected pregnant women (PW), was implemented in Mozambique in 2013, to accelerate reductions of HIV vertical transmission. However, loss to follow-up of PW enrolled in Option B+ is a challenge, and the optimal approach for B+ implementation is unknown.

We conducted a survey to identify factors associated with disclosure and reluctance to start ART on the day of diagnosis.

**Methods:** We interviewed a random sample of HIV-infected women enrolled in HIV care in Mozambique’s Zambezia Province about demographics, HIV knowledge, stigma, and preferences for HIV care. We assessed factors associated with disclosure of HIV status and preferences for timing of ART initiation. Results were compared using chi-square and t-tests, and regression analysis was used to test factors associated with preference for timing of ART initiation.

**Results:** 1020 women participated in the survey; mean age was 29.3y; 48.9% were pregnant and 85.7% were on ART. Over 80% reported that they had disclosed their HIV status to their partner or family member. Women who disclosed were more frequent non-PW vs. PW (91.1% vs. 73.9%, p < 0.001), literate (71.9% vs. 59.7%, p < 0.01) and older (mean: 25.5y vs. 24.6y, p < 0.05). In addition, the partners to whom participants disclosed their HIV status were more frequently HIV infected (30.9% vs. 6.5%, p < 0.001). 74.5% of participants would prefer to initiate ART on the day of diagnosis vs. waiting until the next visit. PW were more likely to prefer starting immediately (78.3% vs. 70.7%). Endorsing stigma was associated with unwillingness to start immediately (OR 3.04, 95% CI 1.05-8.78).

**Conclusions:** Preliminary experiences delivering Option B+ indicate that loss to follow-up can be substantial, though some facilities are able to achieve high retention rates. Future research to define the characteristics of these high performing health facilities could be applied to maximize retention of women initiating Option B+. Gaining a better understanding of why some women remain in treatment while others are lost to follow-up will also be important to identify women who might benefit the most from efforts to reduce LTFU.

**WEPE862**

**HIV-free survival at six weeks in a cohort of children born to HIV-positive mothers enrolled in Option B+ in Kigali: the Kabeho study**

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**Background:** In April 2012, Rwanda began implementing a policy to initiate all HIV-positive pregnant women on lifelong antiretroviral treatment (‘Option B+’). In April 2013, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and Rwanda’s Ministry of Health began the Kigali Antiretroviral and Breastfeeding Assessment for the Elimination of HIV (KabeHo) Study. The study aims to assess HIV-free survival from birth to 24 months of age among HIV-exposed children with mothers enrolled in Option B+. Methods: HIV-positive women were enrolled from their third trimester of pregnancy until two weeks postpartum at 14 Kigali health facilities that serve > 50 HIV-positive pregnant women/year. At enrollment, HIV and ART history, medical care, and laboratory information were collected. Delivery information and birth outcomes were recorded from maternity units as soon as possible after delivery. At 6 weeks of age, PCR for HIV diagnosis was done by the National Reference Laboratory using Roche COBAS Ampliprep/TaqMan HIV-1 qualitative test. Positive results were confirmed on second specimen.

**Results:** Of the 608 infants born in the cohort, 9 (1.4 %) were still births, 10 (1.6 %) spontaneous preterm deliveries and 7 (1.2 %) infants had birth defects. Of the 572 infants with known birth weight, 33 (5.8 %) had birth weight below 2500 grams. By six weeks of age, 11 (1.8 %) additional infant deaths occurred and 7 (1.2%) of them died within the first 24 hours of life. Of the 588 children alive at six weeks, 2 (0.3%) were confirmed to be HIV-positive. The overall HIV-free survival at 6 weeks was estimated at 96.8% (95% CI 95.6%-98%).

**Conclusions:** Provision of ART to all KabeHo Study women resulted in low mother-to-child HIV transmission (0.3%) before six weeks of age, and mortality in this HIV-exposed cohort is much lower than the 2.7% neonatal mortality rate in the 2010 Rwanda Demographic and Health Survey (DHS).
Optimizing health information systems for Option B+ in Swaziland

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Background: The Option B+ approach for prevention of mother-to-child transmission (PMTCT) of HIV presents opportunities for streamlined treatment and retention for mothers and their infants. However, paper-based health information systems (HIS) are often redundant and poorly integrated across maternal-infant care. We examined documentation protocols and their implementation in the context of PMTCT.

Methods: ‘Stikutulwane Lesethiphi—Safe Gardens’ is an implementation science research study evaluating Option B+ outcomes in the Kingdom of Swaziland using routinely collected patient-level data. Facility and healthcare worker assessments were conducted at 10 PMTCT clinics to identify and describe PMTCT service documentation under Option B+.

Documentation source was tabulated against visit type, maternal and infant health indicators, and maternal and infant unique identifiers to evaluate: a) proportion of repeated data collected across documentation source, b) the burden of documentation at each visit type, and c) the presence or absence of maternal-infant linking through unique identifiers.

Results: Swaziland PMTCT HIS includes 12 documentation sources for maternal data and 4 sources for infant data. Multiple paper-based documentation sources are completed for each PMTCT visit (min 10, max 15). Many indicators are duplicated across these sources. For example, health workers must document maternal HIV status on eight separate forms for each PMTCT visit. Maternal HIV status is the only key variable routinely recorded on infant documentation source; maternal health and treatment status are not found on any infant record (Table 1). Unique identifiers are not used to link maternal-infant pairs on any documentation source (Table 1).

![Table 1. Documentation Sources](image)

<table>
<thead>
<tr>
<th>Documentation Source</th>
<th>Maternal Documentation Sources</th>
<th>Infant Documentation Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal HIV ANC Unique Identifying Number</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Maternal HIV Care Unique Identifying Number</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Infant Unique Identifying Number</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Maternal Outcome (Dead, Transfer, LTF)</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Infant Outcome (Dead, Transfer, LTF)</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Maternal HIV Status</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Maternal ART Status</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Infant HIV Status</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Key Information on Maternal & Infant Documentation*

Conclusion: The multitude and replication of maternal and infant documentation required for a single PMTCT visit burdens healthcare workers and increases risk for inconsistent, erroneous, and incomplete data. New approaches to Option B+ documentation, including introduction of electronic medical records, are urgently needed to facilitate and accurately record maternal-child health service delivery and PMTCT outcomes.

Acceptability of community-based mentor mothers among HIV-positive pregnant women and partners in the context of Option B plus in Kenya

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Background: Universal ART for HIV-infected pregnant and breastfeeding women (Option B+) holds promise for improving maternal and child health but key challenges remain in achieving long-term ART adherence and retention in HIV care. Mentor mothers (HIV-infected women who have been through PMTCT and who are tasked with providing peer education and psychosocial support) have been shown to increase uptake of services, but have generally been facility-based in Kenya. In order to optimize adherence and retention in the context of Option B+, we explored the acceptability of community mentor mothers (cMMs).

Methods: A total of forty gender-matched in-depth interviews were conducted separately with HIV-positive pregnant/postpartum women and their male partners at four health facilities in Western Kenya between September-November 2014. Transcripts were transcribed verbatim, translated and then coded using Dedoose software based on the literature, themes from the interview guides and the transcripts. Excerpts from broad codes were then fine-coded using an inductive approach.

Results: Major themes in the data indicated an overall acceptability of cMMs, ideal characteristics of a cMM and potential risks. The cMMs were thought to be beneficial for stigma reduction, as well as improving women’s clinic attendance and medication adherence. Participants’ ideal characteristics of a cMM included age over 30 years and they preferred someone they could see as both a confidant and a role model. The cMM should preferably wear unmarked clothing that would not identify her as an HIV-related worker. There were, however, mixed responses as to whether the cMM should work in the same community where she lives, with some respondents raising concerns about inadvertent disclosure. Risks of the cMM approach included potential breaches of confidentiality and inadvertent disclosure of HIV status.

Conclusions: The cMM approach was perceived as a potentially beneficial and acceptable strategy for supporting adherence and retention of pregnant and postpartum women on ART for life. However the design for cMM interventions should minimize risks of unwanted disclosure and stigma.

Impact of Option B+ on maternal ART initiation rates in Mashonaland Central, Zimbabwe

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Background: Zimbabwe’s PMTCT Program began its transition to Option B+ ‘test and treat for life’ strategy in September 2013. With an HIV prevalence of 15.9% among women in antenatal care (ANC), Option B+ presents an opportunity to improve maternal and child health through improved access to ART, reduced transmission to uninfected male partners and provide protection against vertical HIV transmission in future pregnancies in Zimbabwe. Our objective was to document changes in ART initiation rates among HIV positive women in ANC following transition to Option B+ in Mashonaland Central Province.

Methods: In April 2014, Option B+ was rolled out simultaneously to all 135 health sites in Mashonaland Central Province, serving a population of 273,372 women of childbearing age. Routinely collected data from the national PMTCT program on maternal ART initiation rates was analyzed descriptively 6 months prior and 9 months after roll out of Option B+ (Oct 2013-Dec 2014). Chi-square test was used to calculate statistical significance.

Results: The simultaneous, rapid roll out of Option B+ to all sites in Mashonaland Central resulted in significant, 45% increase in the number of HIV positive pregnant women initiated on ART in ANC χ²(1, N = 5300) = 2373.43, p<0.0001, from 6 months prior to 6 months after implementation of B+. In the last quarter of 2014 (Sept-Dec), among 362 women identified in ANC as HIV positive, 95.5% (n = 358) were initiated on ART (95% CI: 94.0% to 96.7%).

Conclusions: Implementation of Option B+ resulted in dramatic and significant increases in the number of HIV positive pregnant women initiated on ART in Mashonaland Central Province. Introduction of Option B+ saw an initial surge in maternal ART initiation rates as HIV positive women in care but not on ART were initiated under revised guidelines. Following this ‘ART catch-up’ phase, initiation rates stabilized proportionate to number of HIV positive women identified in ANC. With high ART coverage, there is need to enhance retention and adherence of mothers across the PMTCT cascade, including improved uptake of early infant diagnosis among HIV-exposed infants and timely ART initiation among infected children.
Immediate initiation of antiretroviral therapy in PMTCT programmes is not associated with non-adherence during pregnancy: a cohort study

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WEPED867

Viral load outcomes after ART initiation among women in a PMTCT B+ programme in Zimbabwe

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WEPED868

Utility of individual tracking tool in monitoring and evaluation of prevention of mother to child transmission of HIV, Maharashtra, India

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Abstract Book  I  www.ias2015.org
Health facility challenges to the provision of Option B+ in Kenya


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Background: Current World Health Organization guidance recommends lifelong antiretroviral therapy (ART) for all pregnant and breastfeeding women (Option B+) in settings with generalized HIV epidemics. We explored provider perspectives on potential barriers and facilitators in the provision of Option B+ in Kenya.

Methods: We conducted four focus groups with 30 health care providers between September and November 2014 to explore challenges that health facilities are facing in implementation of Option B+, which has recently been rolled out in western Kenya. Transcripts were coded using the Dedoose software; based on the literature, topics from interview guides, and emerging themes from transcripts. Excerpts from broad codes were then fine-coded using an inductive approach.

Results: Major themes that emerged included a preference for Option B+ over prophylactic regimens, with the major advantage cited being elimination of CD4 count testing as a requirement for treatment initiation. Shortage of drugs and staff, and the practice of same-day initiation into treatment were challenges raised. Providers expressed concern that pregnant women have little time to accept and disclose their HIV status when they are immediately initiated on treatment; this could potentially lead to stigma, conflict, or violence in the home. An additional challenge noted was the possibility of women disengaging from care if their care is provided to ART-negative at 18 months and they no longer feel the need to adhere to treatment to protect their child. Suggested facilitators for long-term retention and adherence included strategies for individual clients (continuous adherence counseling, tracing of clients who are lost-to-follow-up, and text messages), couple/group strategies (couple testing, assisted disclosure, treatment buddies, and support groups), community strategies (reducing stigma, community mentor mothers), and changes in service provision (integration of ART with other services and longer clinic hours of operation).

Conclusions: This study highlights important challenges at the health facility level related to Option B+ roll-out in western Kenya. Adaptation of identified facilitators may increase linkage, retention and adherence to lifelong treatment for pregnant women in Kenya, contribute towards elimination of mother-to-child HIV transmission, and improve maternal and child outcomes.

Interventions to improve retention in the PMTCT cascade, including early infant diagnosis

Using text messaging to maximize adherence and retention for women and infants in the context of Option B+ in Kenya


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Background: Key challenges in the provision of lifelong antiretroviral therapy (ART) to pregnant and breastfeeding women (Option B+) include achieving long-term ART adherence and retention in care. Evidence suggests these challenges may be addressed using mobile text messaging. However, the efficacy and acceptability of this intervention in context of Option B+ has yet to be ascertained. We evaluated the acceptability of mobile text messaging as a means of supporting women’s long-term ART adherence and retention in care as Option B+ is being rolled out in Kenya.

Methods: Forty in-depth interviews with 20 HIV-positive pregnant/postpartum women and 20 male partners, as well as 4 focus groups with 30 health workers, were conducted during the period September-November 2014 in rural Nyanza, Kenya. Transcripts were coded using the Dedoose software based on the literature, topics from interview guides, and emerging themes from the transcripts. Excerpts from broad codes were then fine-coded using a grounded approach.

Results: Themes that emerged in the data included overall acceptability, preferred content of messages, message sharing and potential risks of receiving HIV-related text messages. The overall acceptability of a patient-tailored mobile text messaging intervention was evident among most participants. They anticipated that the messages would provide useful and educational information, and proposed the content of messages include specific reminders for clinic visits and infant immunizations. In addition, participants recommended that messages encourage HIV testing for infants and HIV-negative partners, as well as promote “positive living” with HIV. Because mobile phone sharing was common, participants reported potential risks of inadvertent disclosure of HIV status. All participants emphasized the need to keep messages confidential. They suggested that disclosure between couples be required if partners received messages. To further reduce risk of involuntary disclosure, many participants preferred text messages be kept general and omit any specific mention of HIV.

Conclusions: Overall, mobile text-messaging was viewed as an acceptable intervention for promotion of long-term ART adherence and retention in HIV care among pregnant women. The findings are being used to refine a text messaging intervention for pregnant/postpartum women and male partners at sites rolling out Option B+ in Kenya.
WEPE872
Improving retention of young children and women on Option B+/ART at six months in Zimbabwe: a quality improvement approach

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Background: Retention of women and children on ART has long been a challenge in Zimbabwe, and yet is necessary for the success of Option B+. Quality improvement (QI) methods can optimize retention in HIV care and treatment. In 2014, EGPAF supported QI to optimize HIV care and treatment to obtain at least 90% client retention on ART at 6 months.

Methods: Thirty seven PMTCT District Focal Persons (DFP), a government cadre of health workers who oversee PMTCT functions, were trained and supported to coach 125 EGPAF-supported, facility-based QI teams across 62 districts. Between April and December 2014, 85 facility teams developed and implemented QI projects to improve retention of women on ART 6 months after ART initiation in ANC and 55 teams had projects to improve 6 month retention of children initiated on ART before 2 years of age. Each team was reviewed monthly coaching from the DFP. Interventions based on use of appointment diaries and use of peers or community based health workers to track clients who missed reviews were used in >90% of sites. Facility retention data were abstracted monthly and transmitted by DFPs to EGPAF for use in QI support through peer learning sessions for coaches and facility managers. Monthly cross-sectional analysis of women and child cohorts initiated on ART 6 months prior to each reviewing month were used to track retention.

Results: A review of progress after 3 months of implementation indicated that in QI sites, the proportion of women retained on ART 6 months post ART initiation in pregnancy increased from 77% to 81.6% and that of children retained on ART 6 months post initiation increased from 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of women retained on ART 6 months post ART initiation in pregnancy increased from 77% to 81.6% and of children retained on ART 6 months post initiation increased from 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of women retained on ART 6 months post ART initiation in pregnancy increased from 77% to 81.6% and of children retained on ART 6 months post initiation increased from 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months. The proportion of sites whose retention rates were above 90% for women increased from 46% before QI to 66% and retention of children had surpassed the 76.6% to 92% over 3 months.

Conclusions: Overall TAT in the national EID program remains far too long. The courier system and decentralization of EID have reduced TAT in the provinces served by regional labs. EGPAF is in process of working with MOHCC to further decentralize EID process and have more sites referring specimens to the regional laboratories.

WEPE873
Factors associated with HIV-related stigma in three African countries (Project ACCLAIM)

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Background: In 2013, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) undertook a baseline knowledge, attitudes and beliefs (KABP) household survey as part of a three-arm, community-based randomized trial to improve the uptake and retention of women in MCH and PMTCT services in Swaziland, Uganda and Zimbabwe. EGPAF also assessed social and behavioral factors including HIV-related stigma using eight selected validated stigma scales for community and individual attitude measures. In this analysis, we present factors associated with stigma in the three countries.

Methods: We surveyed randomly selected households using a structured questionnaire with data entered into a database on laptops. One adult (male or female) per household was randomly selected from eligible (18-66 years) adults. We analyzed demographic, socioeconomic and HIV testing factors in relation to the mean values of the stigma scales using general- estimating equations with a binomial distribution, a logit link function and the compound symmetry correlation structure. We used principal component analysis to identify the most discriminating stigma measures. Odds ratios (ORs) and 95% confidence intervals (CIs) were estimated along with p-values.

Results: Over 3,000 respondents were surveyed; 1099 in Swaziland, 1140 in Uganda, 1079 in Zimbabwe. Of the eight stigma measures, two were the most discriminating: “HIV/AIDS is the result of sinning”, and “It would be foolish to marry someone who is living with HIV/AIDs”. The latter adjustment for the covariates of age, gender, marital status, education, occupation and HIV testing; “country” was found to be significantly associated (p<0.001) with agreement with the statement “HIV/AIDS is the result of sinning”, and “It would be foolish to marry someone who is living with HIV/AIDS”. Results are presented for Swaziland, Uganda and Zimbabwe.

Conclusions: High levels of HIV stigma persist in the community. Evidence-informed approaches to prevent and mitigate stigma are needed.

WEPE874
Optimizing Zimbabwe’s National PMTCT Program: cost-effectiveness of a planned village health worker (VHW)-based intervention to improve mother-infant linkage to postnatal care

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Background: Low retention of mother-infant pairs in postnatal care (PNC) reduces the effectiveness of PMTCT programs offering Option B+ (lifelong ART). We projected the clinical and economic impact of a planned village health worker (VHW)-based intervention to re-engage mother-infant pairs who fail to link to PNC after delivery in Zimbabwe.

Methods: Using the Cost-effectiveness of Preventing AIDS Complications (CEPAC) model, we simulated a cohort of Zimbabwean women identified as HIV-infected and treated with ART during antenatal care and their infants (mean maternal age: 24 years, CD4: 451/µL, breastfeed duration: 18 months). We compared three strategies: no PMTCT program (comparator), current national program, and current program plus a VHW-based intervention to identify and re-engage in care mother-infant pairs who fail to link to PNC by 6 weeks postpartum. Based on the program and published data, we modelled successful 6-week PNC linkage with current plus VHW: 71.5%: 50% of traced defaults linked; VHW program costs were US$35/ mother-infant pair traced. Model outcomes included MTCT risk, maternal and pediatric life expectancy (LE), and lifetime healthcare costs (2013 US$). We calculated incremental cost-effectiveness ratios (ICERs) in US$/life-year saved (US$/LYS) from discounted maternal+pediatric LE and costs, defining “very cost-effective” as ICER < US$950/LYS (Zimbabwe 2013 per-capita GDP). Sensitivity analyses varied intervention effectiveness, intervention costs, and loss to follow-up after initial linkage to PNC (late-LTFU).

Conclusions: It is possible to optimize retention on ART under Option B+ through QI methods based on techniques to better track clients at sites and follow up with community health cadres. We recommend extension of these efforts beyond six months as cohorts mature.

[Figure 1. Retention of women initiated on ART during pregnancy and infants initiated before two years of age over six months of treatment]
Results: Compared to no PMTCT (not shown), the current national program was projected to reduce MTCT from 26% to 8.8%, increase pediatric LE from 48.70 to 57.37 years, and be cost-saving. The VHIV program further reduced projected MTCT risk to 7.2% and increased maternal and pediatric LE (by 0.8 and 1.9 years). The VHIV program increased total projected lifetime costs - including healthcare and ART costs - by $510/mother-infant pair, but was very cost-effective ($510/mother-infant pair). Projected MTCT risk reduction, increased total pediatric LE, and increased total lifetime costs - including healthcare and ART costs - by $510/mother-infant pair, but was very cost-effective ($510/mother-infant pair).

Methods: Using Fisher's exact test, we performed univariate analysis to assess the association between PMTCT service coverage and ART, linkage to Mentor Mothers and other key services/processes shown in Table 1. With PHCs providing high-ANC flow services, we initiated PMTCT services with: healthcare worker training, provision of Nevirapine (NVP) and appropriate Nevirapine (NVP) administration.

Conclusions: VHIV-based interventions to improve linkage to PNC will provide good value for investment in Zimbabwe. Long-term retention of mother-infant pairs is critical to realize these benefits and optimize outcomes of Option B+ implementation in Zimbabwe.

WEPE875
ANC-PMTCT integration at primary healthcare centers improves exposed infant service quality in a high-burden Nigerian State

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WEPE876
Telephonic defaulter tracing by mentor mothers for EMTC

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Abstracts
WEPED877
HIV early infant diagnosis (HEID): using IQSMS tool to track HIV-positive infants; an experience from Tanga region, Tanzania

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Background: HIV testing of exposed infants is the entry point to rapid HIV treatment, continuous follow up and monitoring from an early age. Innovative methods to track exposed infants in communities and facilities are important for successful treatment programs. To support national efforts of improving early identification and treatment of all HIV exposed infants, the Local Partners Excel in Comprehensive HIV and AIDS Service Delivery (LEAP) project, funded by the Centre for Disease Control under PEPFAR used International Quality Short Messages (IQSMs) to identify infants who were not tested at first clinic visit and six weeks after cessation of breastfeeding in 293 facilities in Tanga region for them to be tested.

Methods: The IQSMS server receives preformatted SMS monthly reports from health care providers through their mobile phones. IQSMS software is equipped with a feature used for reporting stock of HIV test kits, numbers of exposed infants, and whether they have been tested. The monthly reports submitted to the server are analyzed and lists of infants who have not been tested are sent to the respective facilities whereby a multidisciplinary teams, including home based care providers trace the untested infants using the infant’s mother/guardian home address, mobile phones or treatment supporters contacts retrieved from the facility register.

Results: Between October 2013 and September 2014, there were 1757 registered exposed infants from 293 facilities located in remote areas with limited resources in Tanga region. A total of 1749 (99.9%) were traced and tested for HIV within 12 months of their birth using DNA-PCR; of these 50 (2.9%) were diagnosed HIV positive. Of the identified positive 39(78%) initiated treatment, 6 were reported dead and 5 were lost to follow up.

Conclusions: IQSMS tool assists program implementation in areas where challenges are inevitable. The use of IQSMS to trace exposed infants has reduced infant lost to follow up rates and can be used in different areas for program monitoring.

Recommendations: IQSMS can be adapted by countries with limited resources. It is a fast, reliable and sustainable innovation critical to ensuring that children start treatment on time thus decreasing morbidity and mortality.

WEPED878
A highly successful massively early infant HIV testing campaign in rural Mozambique

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Background: Zambézia (Z), Mozambique’s 2nd most populous and principally rural province, is characterized by high HIV prevalence (12.6%), poverty, and suboptimal health service access and utilization. Significant antiretroviral therapy (ART) scale-up efforts are ongoing as part of the national “acceleration plan”, but as of the end of 2013, only 37% of eligible children nationally had been initiated on ART. Zambézia is among the poorest performing provinces with respect to ART coverage and implementation. In order to achieve the ART acceleration plan, the Zambézia Provincial Department of Health (DPS-Z) has implemented a Massive Testing Campaign (MTC) using the IQSMS tool in 293 facilities in Tanga region.

Methods: A Massive Testing Campaign took place between May 1st - November 30th, 2014, and it included: i) training of health care personnel at each health facility; ii) supply-chain support, increasing distribution of HIV rapid tests and provider-initiated HIV testing and counseling (PITC) registers; iii) expanded service provision, offering PITC to “at-risk” children in all service entry points with all infants testing positive immediately referred to the requisite exposed child services and ART clinics; and iv) weekly monitoring of pediatric indicators. Data presented include 5-month outcomes, July - November 2014.

Results: 177 (74.7%) of Zambézia’s 237 health facilities provide early infant diagnosis (EID) via HIV DNA PCR testing. Between July-November 2014, 78,760 infants greater than 2 months of age underwent HIV rapid testing with 2,549 (3.2%) testing positive. In addition, 6,221 exposed infants underwent EID with 836 (13.4%) testing positive. The majority (87.2%) of testing took place in pediatric triage clinic (53.4%) and healthy child clinic (33.3%) settings. Compared to the same period last year when massive testing campaign were not ongoing, we noted marked increases in proportion of children being linked to care (85.3%) as well as proportion of infected children (87.9%) being initiated on ART.

Conclusions: The DPS-Z led massive pediatric testing campaign was highly successful as evidenced by increases in identified and ART-initiated children. Consistent (weekly) monitoring as well as supply-chain (reagents, ART medications, etc.) and individual health facility-level support were integral to the success of this important initiative.

WEPED879
Women’s voices: perceptions, values and preferences of women living with HIV regarding early infant diagnosis

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Background: World Health Organization (WHO) is updating guidelines that currently recommend that all infants with known or possible HIV exposure undergo virological testing at 4-6 weeks old. Infants with an initial positive diagnosis should begin anti-retroviral therapy (ART) as soon as possible. Although the testing rate of infants exposed to HIV in the first two months of life has increased since these guidelines’ implementation, many still lack access to early infant diagnosis (EID), essential to timely ART initiation. WHO commissioned ICW and GP+ to conduct a qualitative study to understand the perspectives of mothers living with HIV regarding the causes of loss-to-follow-up in terms of EID and treatment.

Methods: During June and July of 2014, a judgment sample of women living with HIV who gave birth in the past three years (n=110), recruited by national networks of women living with HIV, participated in ten focus group discussions (FGD) held in Kenya, Namibia, and Nigeria, using the same FGD questionnaire. Standard qualitative thematic analysis was applied to the FGD transcripts.

Results: FGD participants shared the following:
1. Many pregnant women are not informed about EID nor asked to give consent before their babies are tested;
2. Participants support testing within 4-6 weeks of age, but had mixed feelings about testing at birth;
3. Barriers contributing to loss-to-follow-up on infant diagnosis include lack of understanding about EID, clinic distances, and fear;
4. Participants feared that integration of EID and immunisation programs may cause inadvertent disclosure of their and the child’s status;
5. Infant testing uptake depends on the quality and availability of education, peer counselling, and home/community-based testing;
6. Participants appreciate that immediately offering ART to infants can increase child survival, but raised concerns about the side effects, toxicity, drug resistance, and running out of treatment options at young age.

Conclusions: To ensure survival of infants exposed to HIV, prevention of vertical transmission programmes must provide essential information about EID to women and support them to take necessary action for themselves and their children. Providing rapid turnaround testing at point-of-care for infants is preferred. However, barriers to current EID methods must also be addressed.
Engaging men for eMTCT through men's health days: experiences from Mutare District, Manicaland Province, Zimbabwe
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Background: The Prevention of mother to child transmission of HIV (PMTCT) program in Zimbabwe advocates for male partner HIV testing together with women attending antenatal care (ANC). Male partner testing rates (17%) remain below national target of 20%. The ‘Men’s Health Days’ initiative is a strategy to mobilise male partner involvement in PMTCT programs and increase uptake of HIV testing and counselling (HTC) among men. Our objective was to assess male partner testing at health sites in Mutare district following implementation of ‘Men’s Health Days’.

Methods: Mutare district was purposively selected due to male partner testing rates consistently below 15%. Men’s Health Days (MHDs) intervention was developed collaboratively with Ministry of Health and community stakeholders to increasing rates of HTC among male partners of women in ANC. Held at health sites, the days were divided into three sessions:
1) community dialogue led by midwives to discuss pregnancy, child birth and the role of men;
2) Men’s health needs;
3) Provision of free HIV counselling and testing, doctor’s consultations and planning for men and health in the community.

Results: In October 2013, MHDs reached 1,539 men at 8 clinics over 10 days. A total of 402 men received HTC over 10 days approximated the number of male partners accessing HTC on an average per day. Men received HTC over 10 days approximated the number of male partners accessing HTC in the same period in 2012.

Conclusions: High attendance at Men’s Health Days demonstrates potential of community-led efforts to increase male engagement in PMTCT. Clinic-based Men’s Health Days are an effective strategy for reaching men for HIV prevention, treatment and care services. Future research should explore long-term impact on service utilisation and health outcomes among women, men and infants in communities where Men’s Health Days are held.
Conclusions: Through intensified case finding it is possible to find additional eligible children and initiate them on ART. These efforts need to be sustained to reach every eligible child for ART and support in identifying all “missed opportunities” for Pediatric ART.

**WEPED883**

**ART and pre-ART treatment outcome among adolescents in Zimbabwe, results from a routine program**

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**Background:** Adolescents have emerged as a priority group for HIV prevention and care services especially in sub-Saharan Africa. However, antiretroviral treatment (ART) outcomes for this age group are rarely reported and data on pre-ART outcomes are completely lacking.

**Methods:** All HIV-infected adolescents (aged 10-19 at time of presentation) presenting at a public sector hospital clinic in Bulawayo, Zimbabwe between February 2004 and November 2011 were included in the analysis. HIV care at the hospital was provided by the public sector in partnership with Medecins Sans Frontieres (MSF) and other organisations. Survival analyses were performed to calculate crude mortality, loss to follow-up and ART initiation rates. Proportions in care, dead and lost to follow-up stratified on ART or pre-ART were calculated for different time points.

**Results:** A total of 2255 HIV-infected adolescents presented to the HIV service. The median age was 13.2 (IQR 11.4; 15.3) and 1189 (53%) were girls. The median follow-up time was 1.57 years (IQR 0.62; 3.17). A baseline CD4 count was available for 49% (N=1098), median CD4 count was 220 (IQR 85-330). The crude ART initiation rate was 218/100PY (95%CI 208-228) with a median time to ART initiation of 21 days (IQR 6; 61). Crude mortality and loss to follow-up rates were 4.4 (95%CI 3.9-5.1) and 7.8 (95%CI 7.0-8.7) respectively. Proportions alive, lost to follow-up and dead at 4, 12 and 24 months are presented in Table 1.

**Conclusion:** Overall this program showed minimal delay in treatment initiation and the overall ART treatment initiation rate was high. However a considerable proportion of all loss to follow-up (50%) happened in the pre-ART period.

**WEPED884**

**Promoting paediatric antiretroviral treatment (ART) adherence and retention: outcomes of children receiving ART in family ART adherence clubs in Khayelitsha, South Africa**

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**Background:** Community models of care supporting long term retention are relevant not only for adult ART populations but also for children. Family ART adherence clubs (FCs) adjusted Medecins Sans Frontieres' adherence club model for family units. Fifteen children stable on ART and their caregivers (whether on ART or not) meet at the clinic every 2 months, receive support and ART supply in their club. Child disclosure forms a key part of group discussions. Children have their viral load (VL) taken twice a year with a follow-up clinical consultation. When a child has a raised VL, requires clinical follow-up, or neither child nor caregiver attends their scheduled club visit, they return to mainstream care, including enhanced adherence support.

**Methods:** Patients enrolled in FCs from March 2011-September 2013 were included. Study endpoint was 30 November 2014. Patient baseline characteristics; longitudinal VL data, retention in care outcomes and child disclosure status were collected from clinic records. Patients with no recorded clinic or FC visit for three months were counted as lost to follow-up (LTFU).

**Conclusion:** While this program showed minimal delay in treatment initiation and the overall ART treatment initiation rate was high, however a considerable proportion of all loss to follow-up (50%) happened in the pre-ART period.

**WEPED885**

**A comparison of the institutionalization of ART programs in four categories of health facilities in Uganda**

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**Background:** In 2004, Uganda commissioned a national antiretroviral therapy (ART) scale-up program with external donor support. There has been limited post-implementation research evaluating program sustainability since the trial roll-out phase. Without donor support, the sustainment of interventions is most likely to occur when they become an integral part of an organization. We sought to measure the extent of institutionalization of ART programs in health facilities in Uganda and compare institutionalization scores by health facility type.

**Methods:** Level of Institutionalization (LoIn) scales developed by Goodman, et al(1993) were used to measure the extent of institutionalization of ART programs at 195 health facilities in 42 districts of Uganda which received donor support between 2004 and 2009 to initiate ART services. Health facilities were categorized as Public, Private for Profit (PFP), Private Not for Profit (PNFP) and HIV Research Clinics. The 45-item questionnaire measured institutionalization based on four sub-“systems” theorized to make up an organization (Production, Maintenance, Supportive, Managerial) assessed against two levels of institutionalization; routines (lower) and niche saturation (higher). Data were collected between December 2013 and April 2014. Descriptive statistics were generated and used to describe organizational characteristics and calculate and then rank health facilities into quartiles based on their mean institutionalization scores.

**Results:** Of those children retained in clinic care, 15 (45%) exited the FC due to a high VL while the remaining 17 (55%) were suppressed and exited due to missing their scheduled club visit or for other clinical reasons. Median time in a FC until exit was 1.9 years (IQR 1.3-3.3). Of those children retained in FC care, 16 (100%) 7-10 years achieved partial disclosure and 57 (79%) older than 10 years achieved full disclosure.

**Conclusion:** FCs ensure quick access to ART for children and their caregivers stable on ART, supporting high rates of paediatric retention and adherence. FCs allow for family-centered HIV care with less interruption of daily family activities; promotion of school attendance; and an optimal setting for empowering caregivers to manage child disclosure.

**Building country ownership in HIV care and prevention**

**WEPED888**

**Retention outcomes of children in family clubs**

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Results: The overall mean institutionalization score for participating health facilities was 3.5 (Range, 1-4) and the mean score for niche saturation, the highest level of institutionalization, was 3.2 (Range, 1-4). Of the four systems, the production sub-system, concerned with ART product delivery activities, scored the highest mean component score. The Managerial sub-system, concerned with coordinating the operations of other sub-systems, had the lowest mean component score. PFP health facilities had the lowest mean institutionalization score. PNFP health facilities had a higher overall mean institutionalization score than Public facilities. There was a statistical significance in the correlation between institutionalization scores and health facility type (p-values < 0.05).

Conclusions: Programs aimed at enhancing the institutionalization of ART interventions in PFPs are recommended. ART program evaluation and supervision need strengthening across health facilities. Mainstreaming best practices from health facilities with the highest institutionalization scores could enhance sustainability of ART programs in Uganda and other resource-limited settings.

Changes in policy and practice

WEPEP886
Putting into perspective how criminalization of certain practices is impedining evidence-based policy formulation in Malawi

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Background: Policies based on local research evidence are critical in the management of HIV and AIDS. However, continued criminalization of certain practices discourages researchers from conducting research in populations which undertake those practices, thereby impeding evidence-based policy formulation. Approximately 50% of all health research in Malawi is conducted through the Malawi College of Medicine and its various affiliates. We investigated the amount of HIV/AIDS related research in gays, lesbians and commercial sex workers that has been conducted through the Malawi College of Medicine and its affiliates from 2012 - 2014, Malawi, one of the countries hardest hit by AIDS, still criminalizes same-sex partnerships and commercial sex work.

Methods: We used key words HIV, AIDS, ART, CD4, HTC, VCT, VMRC and their definitions, sex, partners and condoms to search the research study database for the College of Medicine Research and Ethics Committee (COMREC) for HIV/AIDS-related studies submitted for ethics approval from 2012 - 2014. We then cross-referenced the results with key words gay, men having sex with men, MSMs, homosexuals, lesbians, women having sex with women, commercial sex workers, CSWs, street girls, gay girls and prostitutes. We also manually read through all the titles of submitted studies. Where clarification was required, study investigators were contacted.

Results: In 2012 COMREC reviewed 158 studies, of which 36 were HIV/AIDS-related with 1 (0.9%) focusing on gays. The same study focused on lesbians and commercial sex partners. In 2013 COMREC reviewed 169 studies, of which 32 were HIV/AIDS-related, with no study (0%) focusing on gays, no study (0%) focusing on lesbians and 1 (3.1%) commercial sex workers. In 2014, COMREC reviewed 159 studies, of which 20 were HIV/AIDS-related, with 1 study (5.0%) focusing on gays, no study (0%) focusing on lesbians and no study (0%) focusing on commercial sex workers.

Conclusions: Far too inadequate research to guide evidence-based policy formulation for management of HIV/AIDS in gays, lesbians and sex workers is being conducted in Malawi. Health workers may therefore be using arbitrarily policies to manage HIV/AIDS in these populations.

WEPEP887
Economic and epidemiological impact of early antiretroviral therapy (ART) initiation in India depends on the HIV continuum of care

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Background: Recent WHO guidance advocates early ART initiation at higher CD4 counts to improve survival among people living with HIV and reduce HIV transmission. Models suggest early ART initiation in India is cost-effective, but have not considered that suboptimal engagement in care may limit potential benefits.

Methods: Our dynamic compartmental model of the Indian HIV epidemic replicates transmission, disease progression, and health system engagement among Indian adults (15-64 years), stratified by sex, HIV risk-profile, and serostatus. Primary outcomes were prevalence, incident cases, AIDS-related deaths, quality-adjusted-life-years (QALYs), and costs over a 20-year time horizon, assessing how the impact of early ART initiation was modified by the HIV continuum of care (i.e. screening, linkage, retention in care, ART usage).

Results: Assuming optimal levels of engagement in HIV care after diagnosis, we project 882,000 new HIV infections and 532,000 AIDS-related deaths in India over twenty years with current practice (ART delayed until CD4 ≤350 cells/mm³). In this idealized care continuum, earlier ART initiation could avert 306,000 new infections (36% reduction) and 79,000 AIDS-related deaths (15% reduction), at a cost-effectiveness of $384/QALY-gained. However, when incorporating realistic gaps in care (i.e. incomplete linkage and long-term retention), projections of 20-year outcomes (ART initiation at CD4 ≥350) rose to 1,277,000 new HIV infections and 999,000 AIDS-related deaths. In this more realistic setting, early ART initiation remained highly cost-effective ($688/QALY-gained) but averted only 230,000 new infections (18% reduction) and 54,000 AIDS-related deaths (9% reduction). Implementing early ART initiation with expanded screening for high-risk groups (i.e. test and treat strategies) offered only modest benefits at current rates of care-retention (283,000 new infections averted; 22% reduction). Alternatively, a 50% reduction in the rate of disengagement from care more than doubled the impact of early ART initiation, averting 445,000 new HIV infections (35% reduction) and 331,000 AIDS-related deaths (33% reduction).

Conclusions: Early ART initiation in India is highly cost-effective, but has modest absolute benefits in reducing new HIV infections and averting AIDS mortality if current rates of retention persist. Sustained economic investments and improved strategies to strengthen the HIV continuum of care are required to realize the full potential of early ART initiation.

WEPEP888
What does a national response to closing the gap in pediatric and adolescent HIV treatment cost? Zambian costing model for universal pediatric treatment

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Background: Zambia has set aggressive targets for its HIV treatment program. The recently adopted national guidelines call for access to treatment for all 149,000 HIV-positive children < 15 years and renewed focus on the 38,500 HIV-positive adolescents. These groups have lagged behind adults in treatment coverage. Zambia’s government needed to understand the cost of pediatric and adolescent treatment scale-up under these new guidelines for informed budgeting, forecasting and implementation decisions.

Methods: We conducted a macro-level cost analysis from the government perspective with realistic Early ART initiation and 50% reduction in rate of disengagement in care.

Results: Assuming optimal levels of engagement in HIV care after diagnosis, we project 882,000 new HIV infections and 532,000 AIDS-related deaths in India over twenty years with current practice (ART delayed until CD4 ≤350 cells/mm³). In this idealized care continuum, earlier ART initiation could avert 306,000 new infections (36% reduction) and 79,000 AIDS-related deaths (15% reduction), at a cost-effectiveness of $384/QALY-gained. However, when incorporating realistic gaps in care (i.e. incomplete linkage and long-term retention), projections of 20-year outcomes (ART initiation at CD4 ≥350) rose to 1,277,000 new HIV infections and 999,000 AIDS-related deaths. In this more realistic setting, early ART initiation remained highly cost-effective ($688/QALY-gained) but averted only 230,000 new infections (18% reduction) and 54,000 AIDS-related deaths (9% reduction). Implementing early ART initiation with expanded screening for high-risk groups (i.e. test and treat strategies) offered only modest benefits at current rates of care-retention (283,000 new infections averted; 22% reduction). Alternatively, a 50% reduction in the rate of disengagement from care more than doubled the impact of early ART initiation, averting 445,000 new HIV infections (35% reduction) and 331,000 AIDS-related deaths (33% reduction).

Conclusions: Early ART initiation in India is highly cost-effective, but has modest absolute benefits in reducing new HIV infections and averting AIDS mortality if current rates of retention persist. Sustained economic investments and improved strategies to strengthen the HIV continuum of care are required to realize the full potential of early ART initiation.
- varying treatment eligibility guidelines, pace of scale-up and drug regimen choices - were analyzed and compared in an Excel-based mathematical model.

Results: Under World Health Organization (WHO) HIV treatment guidelines, average cost per patient year is estimated at US$433 for children and US$269 for adolescents. If scale-up were to follow the aggressive rate needed to reach universal access (defined as 95% coverage) by 2015 and close the gap between coverage of adults and children, total program costs for pediatrics are estimated at US$48.5 million in 2014 and then on average US$60 million per year through 2018. Adolescent total program cost is estimated at US$5.8 million in 2014, growing steadily until US$9.8 million in 2019. The Zambian national guidelines have a higher estimated cost than WHO pediatric guidelines due to Zambia’s decision to include all children < 15 rather than all < 5 years, and drug regimen recommendations.

Conclusions: In Zambia, a modeling exercise provided policy-makers and planners with the evidence on costs to develop a budgetary roadmap that will allow them to expand HIV treatment to children and adolescents and raise treatment levels to soon reach that of adults and advance to full coverage. The model and process can be applied in new contexts where governments need to make informed policy and implementation decisions to efficiently scale-up HIV treatment.

WEPE889
From policy to practice? A comparison of national HIV policy implementation in six sub-Saharan African countries with generalized HIV epidemics
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Methods: A policy extraction tool was developed to review and compare 120 national HIV policy documents published in Kenya, Malawi, South Africa, Tanzania, Uganda, and Zimbabwe between 2003 and 2013, covering delivery of testing, prevention of mother-to-child transmission, and HIV care and treatment services. 139 purposefully-sampled health facilities in nine HDSS sites in six countries, we compared national policies on HIV testing, HIV care and treatment, and retention in care with survey data from health facilities serving the HDSS populations in order to assess policy implementation.

Results: Provision of HIV testing services closely followed national policy in all sites, with the exception of provider-initiated testing and counselling which was explicit policy in all countries, but not systematically implemented in all facilities surveyed. Malawi emerged as having the closest relation between its progressive HIV care and treatment policies, designed to maximize the numbers of infected persons accessing antiretroviral therapy, and their implementation. In contrast, Zimbabwe’s relatively detailed policies in relation to HIV testing and access to care and treatment did not translate into service provision across most of the facilities surveyed. There was wide variation between countries’ policies to encourage retention in care and treatment programmes, and also in relation to their implementation among the facilities surveyed in each country.

Conclusions: Wide variation was observed in the degree of implementation of HIV policies influencing service access and retention across the diagnosis-to-treatment cascade in the six countries which may contribute to HIV mortality differences between sites.

WEPE890
Evaluating pricing policies of pharmaceutical companies as a rationale for introducing measures related to removal of intellectual property barriers to scale up access to HIV treatment
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Methods: To evaluate the pricing trends for antiretrovirals, 5651 tenders were analyzed in 2012-2014. The key research parameter was minimal price. To evaluate the generic drug landscape, the official drug register was used; as search entries, international non-proprietor names were used. Two groups of drugs were selected based on the criteria of the presence/absence of generic versions. The choice of drugs is based on an already available analysis of the most popular drugs used in Russia. The patent landscape and the regulatory instruments available for use in Russia were analyzed using semi-structured interviews and literature review.

Results: We found that in the group of drugs with generics, the price decrease varied from 113% (abacavir, number of generics - 2) to 1946% for lamivudine (number of generics drugs - 6), whereas in the group of patented drugs without generic versions the price decrease varied between 1% (raltegravir, atazanavir and lopinavir/ritonavir) and 9% (darunavir). The interviews and literature review have shown that there is a range of tools related to IP available under the current regulatory framework to force companies to reduce prices, including compulsory licenses and patent opposition.

Conclusions: The study has confirmed that in the absence of generic versions, brand companies do not change their pricing policies voluntarily; in contrast, competition drives the prices down by a great margin. Based on the result of the drug procurement monitoring, interviews with experts and literature review, it is proposed to introduce measures related to removing IP barriers which can be used according to the current laws, such as compulsory licensing and patent opposition.

WEPE891
How to translate high level political targets into programmatic planning for key populations at country level?
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Methods: A conceptual framework of policy implementation was developed to identify and compare HIV policies and programme implementation by factors that influence HIV-related adult mortality across the HIV care continuum including i) service access; ii) quality of care; iii) service coordination and patient tracking; iv) patient support and v) medical management.

Results: Provision of HIV testing services closely followed national policy in all sites, with the exception of provider-initiated testing and counselling which was explicit policy in all countries, but not systematically implemented in all the facilities surveyed. Malawi emerged as having the closest relation between its progressive HIV care and treatment policies, designed to maximize the numbers of infected persons accessing antiretroviral therapy, and their implementation. In contrast, Zimbabwe’s relatively detailed policies in relation to HIV testing and access to care and treatment did not translate into service provision across most of the facilities surveyed. There was wide variation between countries’ policies to encourage retention in care and treatment programmes, and also in relation to their implementation among the facilities surveyed in each country.

Conclusions: Wide variation was observed in the degree of implementation of HIV policies influencing service access and retention across the diagnosis-to-treatment cascade in the six countries which may contribute to HIV mortality differences between sites.
Methods: A technical tool was developed to set targets and measure the availability, coverage, and quality for the recommended interventions. It also includes indicators for assessing the key factors related to the enabling environment and examining the outcome and impact of efforts to address HIV among KP. This tool was developed by reviewing relevant existing guidelines and in consultation with relevant stakeholders (UN agencies, academia, community representatives, programme managers, donors and implementers) to reach consensus on the proposed framework, indicators and indicative targets. The framework of this tool is based on the 2009 technical tool to set targets for PWID that was revised in 2012.

Results: By proposing indicative targets and a set of practical indicators with guidance on data collection and interpretation, this tool sets out to support national programmes and donor agencies to programme and monitor national HIV responses for KP.

Conclusions: It is widely acknowledged that an effective AIDS response needs to effectively include and address key populations. This tool provides countries with guidance to set ambitious, yet achievable, targets for each intervention of the essential package for KP and measure progress as countries work towards achieving the UNAIDS ‘90-90-90’ targets.

WEPED892
Addressing the unmet need for ART among HIV+ women and newborns in Cameroon through strengthening the supply chain of PMTCT commodities

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Background: The Government of Cameroon and its partners have made major investments in the last decade in prevention, treatment, and care of HIV-infected patients. However, unmet need for antiretroviral therapy (ART) among HIV-positive pregnant women remains high at 86%. Critical to satisfying this need is ensuring adequate availability of prevention of mother-to-child transmission (PMTCT) commodities for rollout of new Option B+ guidelines. The Cameroon supply system consists of a cost recovery system of essential medicines and other health commodities and a free-of-charge system for priority commodities including those for PMTCT and ART. This study examines options for improving the supply and availability of these commodities.

Methods: Supply chain (SC) operational data was collected in July 2014 from central (CENAME) and 4 regional warehouses (CAPRs); 10 district stores; and 30 service delivery points (SDPs), including ART and PMTCT sites. The study also included seven central private-sector logistics firms. In addition, SC cost data was obtained from CENAME and CAPRs financial statements audited in 2013. Data collected served for analysis of three options to improve effectiveness of delivering PMTCT commodities, based on the four variables detailed in Figure 1.

Results: Asset utilization within the cost recovery system ranged between 73% and 89% while inventory turnover was 1.5. Therefore, a reliable supply of medicines to SDPs is essential. However, for PMTCT and ART commodities, distribution to the SDPs was unreliable while inventory turnover was at 1.5. Therefore, a reliable supply of medicines to SDPs is essential. Moreover, its total cost and human resource requirements were more favorable.

[Figure 1: PMTCT and ART supply options analysis]

Conclusions: As a result of disseminating the findings, the Ministry of Health adopted Option 2: PMTCT free-of-charge commodities are also amenable to being managed within the existing effective cost recovery system.

WEPED894
HIV and STI prevalence among men who have sex with men in 3 major cities in Uganda

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Background: Although there is increasing evidence of the risks associated with HIV acquisition and transmission among MSW in Uganda, practically nothing is known about other sexually transmitted infections (STIs) in this population.

Methods: A total of 712 MSW were recruited between August and September, 2010 through respondent-driven sampling (RDS) from Kampala (43.3%), Masaaka (29.5%) and Mbarara (27.2%). In addition to information elicited about reported STI and risk behaviors, screening for Syphilis (S), Chlamydia trachomatis (CT), Gonorrhoea (GN) and Hepatitis B (HBV) were also conducted.

Results: Most of the MSW were aged 18-25years and a large proportion (>60%) reported having multiple male and female partners with whom they often had unprotected sex. Whilst 31% reported STIs in the past 12 months, only 28 (3.7%) reported STI symptoms at the time of the survey. Weighted prevalence of STIs ranged from 0.5-1.9% for syphilis, 4.2-8.9% for gonorrhoea, 0.4-3.5% for Chlamydia and 21.4-21.9% for hepatitis B. Population based estimates of HIV was highest in Masaaka (34.9%), followed by Kampala (15.2%) and Mbarara (11.3%). Overall, prevalence of STIs was low in Masaaka and Mbarara. However, in Kampala, prevalence of Chlamydia was highest among MSW who had casual sex partners [AOR=2.6 (1.2-5.5)] and among those who self-identified as homosexual [AOR=2.8 (1.3-6.0)]. Similarly, hepatitis B infection was more likely among the more educated [AOR=1.7 (1.0-2.7)] and MSW who had sex with men exclusively compared with those who had with both men and women [AOR=2.0 (1.2-3.3)]. This study afforded many MSM first time opportunities of being tested and treated for STIs.
Conclusions: There is a large unmet need for MSM in Uganda. This calls for an urgent need for targeted screening and vaccination to prevent the untoward squealed of STIs among MSM in Uganda.

WEPED895
Fleet management system: a useful tool in improving efficiency and effectiveness in PMTCT and pediatric ART service support in Elizabeth Glaser Pediatric AIDS Foundation Zimbabwe programs

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Background: In an effort to strengthen support to the national PMTCT and pediatric ART program, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) acquired 40 vehicles between 2011 and 2013 to enhance PMTCT and pediatric treatment service delivery. Thirty-seven vehicles were deployed to support all 62 districts throughout the country. Given the size and spread of the area covered, effective fleet management was a challenge. There was no independent way of verifying the trips made against the approved travel plans. Irresponsible driving, speeding, and general abuse of the vehicles was occurred. One major accident was reported and maintenance and service costs increased up to September 2013. Monitoring the position and use of the vehicles during site support trips with absolute accuracy from the EGPAF office in Harare became necessary.

Methods: Between September 2013 and April 2014, EGPAF installed a fleet management system with telematics, GPS tracking, and anti-theft mechanisms. The system allowed for real time tracking of vehicles, and it generated reports or alerts on reckless driving. All field vehicles were geo-fenced within their respective districts to control and monitor the trips made against approved plans. Manual vehicle logbooks were compared by the Logistics Team with an online logbook generated by the system in order to check if the program vehicles were utilised as planned and approved.

Results: Several benefits accrued as a direct result of the system. All vehicles were monitored at all times. In six months, maintenance costs were reduced by 12% for all vehicles. During the same period, fuel efficiency increased by 33% and no accidents were recorded after system installation. Speeding alerts decreased from 51 during the October 2013 (first month of system installation) to only one during the month of April 2014. Manual logbook recordings compared exactly with the online logbook system of approved monthly travel plans. In summary, the system sustained the vehicles in a roadworthy and usable state up to the end of the program.

Conclusions: The installation of the fleet management system strengthened efficient use of program vehicles, ensuring that donor resources achieved the maximum benefit in country program implementation.

WEPED896
Lesotho’s HIV clinical mentorship program from 2005-2015: a health systems strengthening approach

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Background: Clinical mentoring is a critical component of the Government of Lesotho’s comprehensive approach to scale-up of HIV prevention, treatment and care. It is the link between the gap from pre service training and clinical practice, allowing health care workers to practice new skills and develop confidence in their own clinical abilities with the support of an experienced clinician.

Methods: A retrospective review of a national HIV Clinical Mentorship Program, designed based on a 6-week implementation experience in 2005; five (5) expatriate clinical mentors from Namibia, Canada, and USA. Standard reporting tools allow each mentor to tailor on-site training and skills transfer, local mentor evaluation of their ability to impart new guidelines, referrals and linkages along the cascade of HIV prevent and care. Using monitoring and evaluation provides impact evidence to inform program planning and response-guided mentoring. The quality improvement model incorporates plan-do-study-act cycles (PDSA), this approach is where clinicians plot a change for improvement on a small scale, observe the results, and adjust or expand it based upon results. The methodology focuses on simple, low-cost solutions that can be implemented with limited resources to address implementation barriers.

Results: Promising practices at the individual, health systems and patient level resulted in improvements including:
1. Partnerships established with local health care providers to collectively address health system challenges;
2. Transition from an out sourced program to a national driven and owned program; and
3. Monitoring and evaluation tools contingent on mentor self reporting and health care provider responses.

Conclusions: Results from Lesotho’s HIV clinical mentorship program and interest from other countries suggest that individual, health systems, patient level and quality improvement with the model for improvement are interventions that increased quality of care in Lesotho. Using these methods, Lesotho’s HIV clinical mentors increase change at twice the rate of expatriate mentors and increases local country ownership. 10-years of country program implementation experience suggests HIV clinical mentorship is an essential in-service program that contributes to strengthened health system linkages and individual health care providers’ confidence to scale up new guidelines and is a high impact approach to high quality health care provider support.

WEPED897
An assessment of New York State (NYS) Department of Health HIV-HCV-STD clinical education initiative (CEI) online training program by healthcare providers

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Background: Since 2009, the NYS HIV-STD program has developed 238 multimedia learning modules, 97 online CME/CNE courses, 12 interactive case simulation tools, and various other resources. These resources are delivered to tens of thousands of New York State clinicians through web, mobile apps, email newsletters, and online social networks. CEI website has received 142,261 user sessions and 724,995 pagewviews from 170+ countries, ranked by Google as a top site for HIV-HCV-STD clinical education. Here we report an assessment of CEI online training program, focusing on clinicians’ evaluation of resources, their self-reported knowledge increase, intention to use knowledge, and analyses of clinicians’ professional/personal background.

Methods: We selected all 12 online courses from CEI’s new student portal, with an online questionnaire for evaluation.

Results: Promising practices at the individual, health systems and patient level resulted in improvements including:
1. Partnerships established with local health care providers to collectively address health system challenges;
2. Transition from an out sourced program to a national driven and owned program; and
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WEPED898
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Co-variant analyses showed:
1) clinicians from rural areas, with a small caseload (<10 patients/month), and not yet provid-
ing direct patient services (but planning to) had the most positive evaluations;
2) the individual courses taken, clinicians providing particular types of services, and years of practice had mixed responses, and,
3) clinicians’ demographics, education levels, professions, and employment settings made no differences.

Conclusions: Initial assessment has shown that the CEI online courses are very positively evaluated by its clinician audience. While certain responses may depend on individual courses and particular clinical services, clinicians from rural areas, with a small caseload, and new to the field of HIV-HCV-STD care are likely to have across-the-board benefits to participate in the CEI online training program to incorporate the learned into clinical practice.

WEPE899
Building capacity for implementation and sustainability of harm reduction training to prevent HIV transmission in Tijuana, Mexico

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Background: Policing practices (e.g., syringe confiscation) are pervasive HIV risk factors among people who inject drugs (PWID) in the Mexico-US border region and other settings. We sought to develop creative, cost-effective training tools to educate police officers about occupa-
tional and public health elements of HIV prevention in Mexico and other resource-constrained settings. The development of the training also served as an experiential learning exercise for forensic science students in a college setting.

Methods: Our binational team included faculty and graduate students from US and Mexi-
can universities, and the Department of Municipal Public Safety in Tijuana, Mexico. We devel-
oped basic educational modules that bundled harm reduction training with occupational safety
for active duty police officers in Tijuana. Training focused on policing behaviors and prevention of HIV and viral hepatitis risks related to needle-stick injuries. We piloted these educational materials with forensic science students, who then created original videos to enhance harm reduction messages for the police, using smart-phones. The educational modules and smart-
phone videos were then piloted with police academy instructors.

Results: Over a four-month period, 30 forensic science students received the educational
modules and created 3 videos: (1) inappropriate skiving that could expose to needle-stick injuries,
(2) on-site visits to drug treatment centers in Tijuana highlighting evidence-based drug treat-
ment, and;
(3) an in-depth interview with a rehabilitated drug user to generate awareness on the path to
rehabilitation and reduce stigma.
A total of 15 police academy instructors were trained. All enthusiastically embraced the content
of the training modules and provided feedback for refining materials. Approval was granted by the
Tijuana Mayor and Police Academy Director to integrate the training modules and videos into
regular police refresher training, offered by trained police academy instructors.

Conclusions: This multi-sectoral, binational collaboration led to low-cost approaches to
develop and sustain harm reduction training for active duty police officers. These modules
form the basis of a structural intervention for active duty police officers that aims to reduce the
incidence of needle-stick injuries as well as policing behaviors that are well-established drivers
of needle sharing among PWID.
WEPE901  

**m-Health: intervention to rapidly link Xpert MTB/RIF rifampicin-resistant patients to treatment initiation in South Africa**

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**Background:** GeneXpert technology has improved the rapid diagnosis of multi-drug resistant tuberculosis (MDR-TB) patients, however, the gap between diagnosis and treatment initiation and subsequently retention in care, remains large. m-Health is a promising solution to real time linkage to care and is being investigated for MDR-TB patients in South Africa through the development of a prototype MDR-TB android application (APP).

**Methods:** The MDR-TB treatment APP is named Treat TB and has been designed for android platforms by the National Priority Program of the National Health Laboratory Service in Johannesburg, South Africa, as an extension to the existing national network of 2960 bi-directional printers. The 'Treat TB' prototype has to date been implemented in one of eight trial sites in two districts of Johannesburg, using one Lenovo 3G enabled tablet placed within the clinic and two laboratory based Lenovo monitoring tablets. The following variables are being measured to determine the value of m-Health over existing laboratory-paper based clinical result reporting: time to treatment initiation, clinic workload reduction, ease of use, end-user value added satisfaction, training requirements, computer literacy and cadre of staff, impact of connectivity downtimes and patient identification mapping.

**Results:** The Treat TB required five months software development. Implementation training could be performed within one hour across staff cadres (one data capturer, two nurses, one social worker, two clinicians). Data capture through drop-down, selection boxes and minimum free text fields took on average 10 minutes per patient. One software upgrade has occurred requiring additional training. Sporadic and variable signal connectivity increased data capture delays and ease of use. Implementation currently is performed without real time automated result reporting: time to treatment initiation still takes on average 12 days from diagnosis.

**Conclusions:** The Treat TB APP was successful and shown to be easily implemented in an MDR-TB treatment initiation facility, however, requires real time automation to further reduce the turnaround time to treatment initiation. Access of this APP by all health care workers at all levels of the cascade of care may also be achieved through functionality available on personal smart phone devices.

WEPE902  

**Engaging aboriginal communities and organizations in research: lessons learned from stable homes, strong families**

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**Background:** Conducting research with Aboriginal communities necessitates developing positive relationships within the community long before data collection begins. This process is important to maximize leadership within communities and organizations that are critical to supporting the research process. Stable Homes, Strong Families (SHSF) demonstrates the successes and challenges of relationship building in community-based research (CBR). SHSF is a national project that aims to develop cultural understandings of housing and home amongst Aboriginal peoples living with and affected by HIV and AIDS in order to influence housing policy and programs.

**Methods:** Relationships were developed between Aboriginal HIV service organizations, academic researchers and community leaders prior to grant submission. Following receipt of funding, a strategy to hire, train and support local Peer Research Associates (PRAs) to plan and lead digital storytelling (DS) workshops along with the research team was developed. Five workshops were held with 22 participants across Canada from June 2013 to November 2014.

**Results:** Our CBR approach highlighted a number of important lessons for working in partnership with diverse Aboriginal communities across Canada and conducting research with PRAs who also bring diverse identities and experiences. Time must be invested to develop partnerships even before the grant is finalized and submitted. PRAs should be trained and supported in all aspects of the research. Early engagement with Elders, community supports and organizations is critical to understanding the needs of participants, to creating a safe space where the research will be conducted and ensuring local Aboriginal cultural protocols are respected.

**Conclusions:** Community engagement and partnership development are as important as generating data and are essential to effective, community-driven knowledge translation activities. Lessons learned regarding key considerations for partnerships between Aboriginal communities and researchers will critically inform our analysis of data from the DS workshops.

WEPE903  

**Challenges and facility-level solutions identified by frontline healthcare workers to scale up high quality paediatric HIV treatment and care**

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**Background:** There are an estimated 5.8 million HIV-infected children and young people in sub-Saharan Africa, yet only 24% of eligible children are receiving ART. Policy makers and programme managers require an informed understanding of service barriers and bottlenecks to providing paediatric and adolescent care at the frontline in order to translate health policies into more responsive practice.

**Methods:** The PATA 2014 Continental Summit was held in December 2014 to mobilize local action, share innovations and best practices, and disseminate guidance and technical updates. Thirty-seven health facilities from 15 sub-Saharan African countries, represented by 142 frontline HIV healthcare workers, five ALHIV and YPLHIV, and eight Ministry of Health representatives, participated in the summit which used expert plenaries, interactive workshops and peer-peer exchange to identify facility-level barriers, share best practices and generate concrete plans to take facility-specific action. Descriptive statistics and framework analysis were used to analyse reported barriers and planned facility interventions.

**Results:** The mean age of participants was 40 years, with a female majority (76%). Counsellors, community healthcare workers and social workers were most represented (28%). Collectively, health facilities cared for 53,048 children and adolescents in care (mean per facility, 427). Frontline healthcare worker and stakeholder groups reported key challenges and shared best practices along the continuum of care (Table 1).

<table>
<thead>
<tr>
<th>Theme</th>
<th>Key challenges</th>
<th>Best practices</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV case finding</td>
<td>Lack of entry points for testing children and adolescents</td>
<td>Routine HIV testing in high yield settings; Community education and demand generation</td>
</tr>
<tr>
<td>Linkage to HIV treatment and care services</td>
<td>Lack of child- or adolescent-friendly services; Stigma and myths</td>
<td>Healthcare worker training, mentorship, sensitization and job aids</td>
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<tr>
<td>Aherence and treatment</td>
<td>Poor caregiver support</td>
<td>Caregiver support</td>
</tr>
<tr>
<td>Community and multilevel engagement</td>
<td>Poor linkages and referrals with related health services; Staff shortages, negative attitudes and poor knowledge; Lack of child- or adolescent-friendly services</td>
<td>Community education and demand generation</td>
</tr>
<tr>
<td>Operational infrastructure and staffing</td>
<td>Staff shortages, negative attitudes and poor knowledge</td>
<td>Developing active linkages and referrals with related health services; Child- or adolescent-friendly services</td>
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</tbody>
</table>

**Table 1**

Healthcare workers designed 37 related quality improvement interventions to effect practical change at facility-level. Interventional activities and services focused on community health education and demand generation; healthcare worker training, mentorship, sensitization and job aids; and child- or adolescent friendly services. In summit evaluations, 96% of participants reported that expert input was valuable, peer-peer exchange helped in identifying bottlenecks and solutions, and intervention planning helped to clarify and define goals they could achieve over 12 months.

**Conclusions:** Frontline HIV healthcare workers and stakeholder groups identified major challenges in providing quality paediatric and adolescent HIV treatment and care, and developed practical solutions for implementation. Convening healthcare workers to provide capacity building, sensitization and support can motivate and inform facility-designed interventions and services that respond to the needs of children and adolescents living with HIV.
WEPEP904 Moving from theory to practice: ensuring capacity building and the application of GIPA/MIWA principles in conducting community-engaged research among women living with HIV in Canada

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Methods: This research aims to share the achievements in improved background: working in CHIWOS while balancing the need to protect HIV-status confidentiality; facilitating roles on the research team and community they are researching. lives while prioritizing professionalism; and supporting PRAs to navigate insider versus outsider for participating members.

Results: Comparison of cohort data representativeness between 2012/13 and 2013/14 demonstrated an increase of data availability from 18.4% to 54.7%. Training demonstrated the use of the ART monitoring system to support in-facility patient management and also provided guidance on the generation of reports to support management. The training supplied attendees with a sample agenda to guide the establishment of forums in each district and guide strength-ened data usage.

Conclusions: Training and support, as well as expanded implementation of the system from 1,296 facilities in Dec 2013 to 2,139 in October 2014, has increased data availability. Data representativeness increased by 36.3% (range 23.3% - 89.7%) in this reporting period. The DMF demonstrates the importance of data completeness and routine engagement with data to inform the management of the ART programme in the facility. It also creates an opportunity for facilities to share their best practices; to seek advice or support about how to manage a challenge they are currently experiencing; and facilitates the identification of facilities at risk for drop out.

WEPEP906 The utility of HIV support groups in advancing implementation research in resource-limited settings

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Methods: The utility of HIV support groups in advancing implementation research in resource-limited settings. WePeD906

Results: A variety of tensions were noted in moving GIPA/MIWA from theory to practice. Among these tensions were issues of meaningful participation of WLHIV Peer Research Associates (PRAs), including appropriate compensation: role clarity, recognition, and a sense of overall well-being. Among these tensions were: needing transparency around having WLHIV working in CHIWOS while balancing the need to protect HIV-status confidentiality; facilitating maximum involvement while ensuring proper recognition and compensation under budget constraints, engaging and being supportive given the time restraints on their personal lives while prioritizing professionalism; and supporting PRAs to navigate insider versus outsider for participating members.

Conclusions: The importance of recognizing these intersecting tensions is paramount to the shift from GIPA/MIWA as theoretical constructs to the practice of undertaking community-engaged research in Canada. In an effort to proactively address tensions which can emerge when moving GIPA/MIWA from principle to practice, research teams must embrace open, flexible, and creative approaches. Such approaches are aimed at recognizing and engaging WLHIV within the broader funding landscape, ongoing HIV-related stigma, including issue of disclosure, and the intersecting determinants of health all of which can negatively impact on ways in which we animate GIPA/MIWA principles. Recommendations for ways to address these tensions will be offered.

WEPEP905 The district monitoring forum: a forum to support data driven decision-making to inform patient management in the South African ART programme

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Background: The South African National Department of Health (NDoH) introduced a standardised ART monitoring system in 2011 comprised of standardised ART clinical records and a standardised in-facility monitoring tool. Whil implementation is still in progress data is now available for 1.3 million patients in the central data repository and the country has produced two annual reports presenting the programme outcomes. With an aim to strengthen the use of the system and improve data-driven decisions country-wide trainings were conducted to guide interrogation and use of the data. This research aims to share the achievements in improved reporting data use discussions: the district monitoring forum (DMF).

Methods: Twenty-eight trainings organised by the NDoH were prepared using data from each province and district where the trainings were held. Data was drilled down to the facility-level and included interpretations to demonstrate data usage and emphasise the importance of data completeness. A sample agenda was supplied to guide discussion in the DMF.

Results: Comparison of cohort data representativeness between 2012/13 and 2013/14 demonstrated an increase of data availability from 18.4% to 54.7%. Training demonstrated the use of the ART monitoring system to support in-facility patient management and also provided guidance on the generation of reports to support management. The training supplied attendees with a sample agenda to guide the establishment of forums in each district and guide strength-ened data usage.

Conclusions: Training and support, as well as expanded implementation of the system from 1,296 facilities in Dec 2013 to 2,139 in October 2014, has increased data availability. Data representativeness increased by 36.3% (range 23.3% - 89.7%) in this reporting period. The DMF demonstrates the importance of data completeness and routine engagement with data to inform the management of the ART programme in the facility. It also creates an opportunity for facilities to share their best practices; to seek advice or support about how to manage a challenge they are currently experiencing; and facilitates the identification of facilities at risk for drop out.

WEPEP907 Description and evaluation of stage 1 of the ASHM Asia and Pacific regional leadership and mentoring program 2014

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Background: We set out to support regional delegates to attend the AIDS 2014 Conference in Melbourne and through providing a short term period of study and participation in a leadership course, maximise the benefit of these delegates. We also sought to develop an ongoing durable network and mentoring program.
Methods: 15 local civil society groups (CSG) came together to develop the program and ASHM negotiated support from the Australian development agency. Each CSG developed a scholarship program which included the conference and leadership course. The course ran for 2 days before and after the conference. Mentoring was provided during the conference and a mentoring has continued among many groups post the conference. Skills building workshops held after the conference included: Quality, Outcomes Based Management, Mentoring as well as translational skills to assist delegates to share the experiences abstract and manuscript writing, using survey techniques and writing for the web.

Results: 10 agencies submitted 15 application of which 8 agencies ran 10 course. Aus-AID supported full scholarship for 277 delegates (clinicians, government, MSM, TG, SW) from regional lower and middle income countries. A small number of delegates were funded from other sources. The 2 day Leadership course was expose delegates to high level leader, IAS President and President elect, the Hon Michael Kirby, leaders from regional countries and experts in leadership, management. The focus was on engagement of key populations. It evaluated very highly and delegates report taking inspiration from these leaders. Delegates used the mentoring space and mentoring software and report this helped them to navigate the conference. Skills workshops were very highly evaluated delegates indicated that objectives were met and they would apply the skills learned.

Conclusions: The evaluation of part one of the program indicates that it was highly successful. It has also established greater ongoing linkages between the Australian CSGs and their regional counterparts and we will evaluate that over time. As a strategy of combining resources and value adding to a conference it was superb. It also provided delegates with sustained exposure south-south and across interest and professional groups. The IAS should support programs like this at all its meetings.
MOLPBPE01
Low frequency HIV drug resistance in Ugandan patients failing ART with susceptible HIV Sanger genotyping
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Background: We recently described that despite close monitoring and adherence to treatment over 10% patients failed treatment with every first line of treatment regimen (Kyeyune et al 2013 AIDS 27:1899). Only 70% of HIV-infected individuals failing antiretroviral therapy in Kampala, Uganda had a drug resistant HIV-1 genotype based on Sanger sequencing. We suspect that the remaining 30% had low frequency drug resistance mutations, which may impact on treatment outcomes.

Methods: Three patient groups were selected: those that failed treatment and (1) had dominant resistance as controls (N=27), and (2) lacked dominant drug resistant (N=38), and (3) had NRTI and NNRTI resistance but lacked thymidine analog mutations (TAMs) (N=50). We used two novel HIV-1 genotyping assays based on oligonucleotide ligation assay (OLA) and a deep sequencing assay (DEEPGEN™HIV) to quantify minority HIV-1 drug resistant variants. Results: DEEPGEN™HIV and OLA both detected low-level drug resistant mutations as low as 1% in most patients where Sanger failed to detect. Low-level drug resistance mutations were detected by DEEPGEN™HIV in 53% (20/38) of patients with lacking any HIV drug resistant mutations based on standard Sanger sequencing. Mutations associated with resistance to NRTI (e.g., M41L, D67N, M184V) and NNRTI (e.g. K103N, Y181C) were quantified, ranging from 1% to 17.6%. With treatment failures and the absence of TAMs, OLA identified low frequency TAMs in 60% (30/50) of these patients. A subset analyses using DEEPGEN™HIV confirmed the low frequency TAMs detected by OLA. For all 98 patients failing first line treatment but lacking dominant drug resistance, the treatment regimens were not changed and thus, we are currently assessing treatment outcomes following the Sanger drug resistance testing.

Conclusions: These low frequency drug resistant variants detected in antiretroviral-experienced individuals failing treatment, may have significant consequences on current or future outcomes, especially if treatment is not modified based on a susceptible HIV-1 genotype (Sanger) report. Preliminary data suggests that patients with minority drug resistance variants associated with treatment failure did not respond to the continuation of the same treatment regimen.

Natural products are a promising but underevaluated resource for identifying new anti-latency agents that may act via distinct mechanisms.

Methods: We examined 9 extracts from plants used by traditional healers in Sub-Saharan Africa to treat HIV symptoms and 85 pure compounds obtained from the pan-African Natural Product Library (p-ANAPL), which also derive from traditional medicinal plants. Extracts and compounds were screened using the J-Lat 9.2 GFP-reporter T cell line that contains an integrated NL4-3-servative proviral genome. TNFα was used as a control. Natural products that induced GFP expression in >5% cells while retaining <30% cell viability at 5 μg/mL were assessed for 50% activation and cytotoxic concentrations (IC50 and CC50), encephalitotoxic (CC24™) expression, and synergism with histone deacetylase inhibitors (HDACi) panobinostat and romidepsin.

Results: Medicinal plant extract ‘Mokungu’ at 5 μg/mL induced GFP expression in >5% cells and p24™ production, but displayed ~3-fold less cytotoxicity than panobinostat or romidepsin. Pure compound ‘Q6’ at 5 μg/mL also activated GFP expression. Interestingly, both products exhibited synergy with panobinostat and romidepsin, inducing GFP expression in up to 50% of cells when combined with suboptimal doses of HDACi and up to a 38-fold increase in mean GFP intensity vs. untreated cells (i.e. both similar to 50 ng/ml TNFα). We also identified 6 pure compounds that activated nearly 100% of cells but with lower intensity (i.e. 2 to 7-fold increased mean GFP intensity vs. untreated cells) with no evidence of toxicity.

Conclusions: We have identified potential new HIV latency activators of natural origin guided by indigenous medicinal knowledge. These agents display low toxicity and synergy with HDAC inhibitors currently under evaluation, indicating that they may be promising lead compounds for additional study.

TULPBPE03
CD4 mimetics sensitize HIV-1-infected cells to ADCC
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Background: Prevention of HIV-1 transmission and progression likely requires approaches that can specifically eliminate HIV-1-infected cells. There is increasing evidence supporting a role of Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) in controlling HIV-1 transmission and disease progression. Importantly, the interaction of HIV-1 envelope (Env) glycoproteins with the CD4 receptor was recently reported to be required for efficient exposure of ADCC-mediating Env epitopes. In that context, HIV-1-infected cells presenting HIV-1 Env in the CD4-bound conformation on their surface were found to be preferentially targeted by ADCC-mediating antibodies present in sera of HIV-1-infected individuals. However, HIV-1 has evolved a sophisticated mechanism to avoid exposure of ADCC-mediating Env epitopes by downregulating CD4 and by limiting the overall amount of Env at the cell surface.

Methods: Rationally-designed CD4-mimetic compounds (CD4mc) have been shown to induce thermodynamic changes in HIV-1 Env similar to those induced by CD4 and sensitize HIV-1 particles to neutralization by otherwise non-neutralizing CD4-induced antibodies. In this study, we explored the capacity of such compounds to promote the CD4-bound conformation of Env and thereby sensitize HIV-1-infected cells to ADCC mediated by sera, cervico-vaginal lavages and breast milk from HIV-1-infected individuals, using a FACS-based ADCC assay.

Results: We observed that certain CD4mc induce the CD4-bound conformation of Env and thereby sensitize cells infected with primary HIV-1 isolates to ADCC mediated by prevalent and easy-to-elicit antibodies present in sera from early convertors and chronically-infected individuals. Importantly, CD4mc also enhanced recognition and ADCC-mediated elimination of HIV-1-infected cells by antibodies present in breast milk and cervico-vaginal lavages of HIV-1-infected women. Finally, we identified one CD4mc with the capacity to sensitize endogenous CD4mc with the capacity to sensitize endogenous
**TULBPE04**

**Enhancement of microbiota in healthy macaques results in robust beneficial modulation of mucosal and systemic immune function**

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**Background:** With more than thirty million HIV-infected individuals worldwide, developing an effective vaccine to prevent new HIV infections remains a top priority in contemporary biomedical research. Given the critical role of mucosal surfaces in susceptibility of HIV infection, it is imperative that we induce effective mucosal responses.

**Methods:** Modulating the microbiota in the GI tract is a safe and well-tolerated approach to enhance mucosal and overall health, and here we hypothesized that altering TLR signaling via microbiome enhancement may improve mucosal immunity. Thus we treated five macaques (SIV-) with the probiotic (PBio) VSL3 and sampled colon, rectum, blood and LN from prior to PBio treatment, and at days 28 and 80 post-treatment. We assessed cellular and humoral immunity and inflammation.

**Results:** Rearingly, we found that PBio therapy resulted in significantly increased T follicular helper cells (Thf, CDA4+PD-1+CXCR5+), p=0.0065. In addition, immunohistochemistry confirmed that LNs had increased follicles after PBio treatment. Given the ability for Thf to induce B cell responses, we measured surface IgA and IgG expression on B cells, and observed increased frequencies of B cells expressing IgA in the LN (p=0.0151) and colon (p=0.0072). To determine the method for increased Thf, we measured IL-23 production by antigen presenting cells (APCs), and found significantly increased frequencies of IL-23+APCs in the colon (p=0.0173), which correlated with the frequency of LN Thf (p=0.0358).

**Conclusions:** These data have potential implications for using PBio therapy to alter mucosal immunity in the context of vaccination or preventative approaches. In particular, the immunomodulatory properties of probiotic therapy in conjunction with HIV vaccination may provide an opportunity for enhanced mucosal HIV vaccine responses that could improve protection from infection by improving immune defenses at the mucosal portal of entry.

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**WELBPE06**

**CD4 T cell reconstitution following cART is immediate as is CD4+T cell depletion following treatment interruption: coupling the whole-body imaging of the CD4 pool and of the immune system activation**

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**Background:** The number of peripheral blood (PB) CD4+ T cells typically increases within weeks of initiating antiretroviral treatment (cART). Similarly, decreases are observed within the first month following interruption of cART. It remains an open question whether these immediate changes in CD4 cell counts are mainly the result of changes in trafficking between lymphoid tissues (LT) and the PB, or true reconstitution/depletion of the total body pool. In previous work we have demonstrated the feasibility of imaging the whole-body CD4-pool in vivo using a radio-labeled anti-CD4 monoclonal antibody (mAb) and single photon emission computed tomography (SPECT).

The present study was designed to examine changes in the whole-body CD4-pool and immune system activation in the setting of cART using the F(ab’)2 fragment of anti-CD4 labeled with Tc-99m (for SPECT imaging) and FDG (for PET imaging), respectively.

**Methods:** A group of 19 SIV-infected rhesus macaques (PB CD4-counts: 28-1556 cells/µl) started cART, of which 7 were imaged longitudinally. Another group of 9 SIV-infected and treated animals (PB CD4-counts: 176-1661 cells/µl) interrupted cART, of which 1 was imaged longitudinally.

**Results:** At month 1 post-cART initiation, CD4 counts in the PB increased an average of 38% (p<0.01, n=19). No significant changes were noted in CD8 T cell or B cell counts. Whole-body imaging revealed a 15.1 to 19.2% (p<0.05, n=7) increase in the splenic pool of CD4 cells despite decreased FDG-uptake (n=2). Conversely, at month 1 post-cART interruption, CD4 counts in the PB decreased an average of 34% (p<0.05, n=6), again without significant changes observed in CD8 T cell and B cell counts. Whole-body imaging revealed a 30% decrease in the splenic pool of CD4 T cells (n=1).

**Conclusions:** Gains or losses in CD4 count happen rapidly in both the peripheral blood and the spleen. Lymphoid tissues experience increase/decrease up to 30% of the CD4 pool within just 4 weeks from initiation or interruption of cART, respectively. The increases are associated with a decrease in cell activation suggesting that cART has an immediate effect on CD4 T cell survival.
Track B
Monday, 20 July 2015

MOLBPE07
Marked gender differences in mortality on ART in lower- and middle-income countries: a systematic review and meta-analysis
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Background: Across all low- and middle-income countries, men and women comprise similar proportions of people living with HIV who are eligible for antiretroviral therapy (ART). However, men account only 41% of those receiving ART. There has been limited study of men’s experiences and outcomes in ART programs, despite a number of studies suggesting that men have higher mortality rates than women in HIV treatment. The aim of this systematic review (SR) and meta-analysis (MA) was to assess differential mortality between men and women living with HIV and on ART in low- and middle-income countries (LMIC).

Methods: A SR and MA was conducted of published observational studies reporting mortality of adult (>15) men and women in ART treatment programs in LMIC, PubMed, Ovid Global Health, and Embase were searched. Random effects meta-analysis was conducted overall, by geographic region, and by quartiles of time and months on ART (<12, 13-33, 34-60, 61+).

Results: After duplicates were removed, 11,589 records were screened, and 6,726 full text articles were assessed for eligibility. There were 69 included studies reporting 87 hazard ratios (HR), with a total sample size of 249,027 men and 375,807 women, and total follow-up time of 2981 months. The pooled HR (pHR) was 1.37 (1.31-1.43), indicating an overall 37% increased hazard of death for men while on ART. Across Sub-Saharan Africa, the pooled HR was 1.33 (1.28-1.39), and in Asia, it was 1.58 (1.42-1.75). In subgroup analyses by quartiles of time on ART, the pHR increased significantly over time on ART: < 12 months pHR=1.27 (1.18-1.36), 13-33 months pHR=1.35 (1.22-1.49), 34-60 months pHR=1.44 (1.33-1.56); and 61-144 months pHR=1.49 (1.22-1.82) (time trend p<0.055).

Conclusions: These analyses demonstrate that men living with HIV have consistently and significantly greater hazards of mortality compared to women while on ART in LMIC. This effect persisted and increased over time on treatment, suggesting that longer term retention and adherence may be key to improving men’s outcomes. The clinical and prevention benefits of ART will only be realized if programs can improve male engagement, diagnosis, earlier initiation of therapy, clinical outcomes and can support better long-term retention in care and treatment adherence.

MOLBPE08
Elvitegravir (EVG) / cobicistat (COBI) / emtricitabine (FTC)/ tenofovir disoproxil fumarate (TDF) is superior to ritonavir (RTV) boosted atazanavir (ATV) plus FTC/TDF in treatment naive women with HIV-1 infection (WAVES Study)
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Background: Women are under-represented in HIV antiretroviral therapy (ART) studies. The Women AntiretroViral Efficacy and Safety study (WAVES) is the first all-women, international, randomized, double-blind, phase 3 trial designed to evaluate the safety and efficacy of EVG/COBI/FTC/TDF versus ATV+RTV+FTC/TDF.

Methods: HIV infected, ART-naive women were randomized (1:1), in a double-blind, global study (North America, Europe, Africa, Asia). Entry criteria included HIV RNA>500 copies/ml and estimated GFR> 70 mL/min. Women who become pregnant had the option to continue on study. Primary efficacy endpoint was the proportion of women achieving a HIV1 RNA < 50 c/mL at Week 48. Safety was assessed throughout the study.

Results: 575 women were enrolled (EVG/COBI/FTC/TDF, n=289 vs ATV+RTV+FTC/TDF, n=286). Demographic and baseline characteristics were balanced and reflect the global nature of the study (Table 1). The median age was 35 years and 76% had asymptomatic HIV infection. EVG/COBI/FTC/TDF was statistically superior to ATV+RTV+FTC/TDF, with 87.2% and 80.8%, respectively, achieving HIV-1RNA < 50 c/mL at week 48 (adjusted difference 6.5%, 95% CI 0.4% to 12.6%). Mean increases in CD4 cell counts were similar (Table 1). No subject experienced virologic failure with resistance in the EVG/COBI/FTC/TDF arm, compared to 3% (1%) in the ATV+RTV+FTC/TDF arm (M184V/I). Both regimens were generally well tolerated, with most adverse events being mild (grade 1) in severity. Mean decreases in eGFR were small and similar at week 48 (-4.5 vs -2.3 mL/min, p=0.15) with no discontinuations due to renal adverse events (AEs) in the EVG/COBI/FTC/TDF arm. Percent changes in BMI at week 48 were similar at spine (-3.09 vs -3.28, p=0.69) and hip (-3.02 vs -2.55, p=0.37). Of the 24 pregnancies reported, 13 women elected to continue study drug.

Conclusions: EVG/COBI/FTC/TDF was superior to ATV+RTV+FTC/TDF at 48 week, and demonstrated its safety and efficacy for the treatment HIV1 infection in women. Recruitment, enrollment and retention of women in large multinational trials is feasible.

Tuesday, 21 July 2015

TULBPE09
Use of oral DAA-based regimens in HIV-HCV co-infected patients in a real life setting - interim analysis from the ANRS CO13 HEPAVH cohort
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Background: It is widely recommended to treat chronic hepatitis C in HIV co-infected patients, considering its worse evolution and prognosis in these patients. Several new oral direct active agent (DAA)-based regimens can be used, with often quite similar antiviral activity. Methods: HIV-HCV co-infected patients enrolled in the ANRS CO13 HEPAVH cohort who initiated an oral DAA-based regimen were included. We report safety, end of treatment (EOT) response and sustained virologic response (HCV-RNA < 15 Ul/ml) at 12 weeks (SVR12).
**Results:** We included 245 patients, of those, 133 patients reached EOT (54%) and 62 patients SVR12 (25%). Median age was 53 years (IQR: 48-55); 78% were male, 98% were on antiretroviral therapy (ART), 90% had an HIV viral load < 50 copies/mL, and median CD4 was 530/mm³ (IQR: 310-715). Sixty-nine percent of the patients were cirrhotic, and 71% had failed to respond to previous treatment. HCV genotype (Gi) repartition was as follows: G1, 58%; G2, 5%; G3, 13%; Gi, 25%. HCV-RNA was undetectable at the end of treatment (EOT) in 99% of the patients (95% confidence interval (CI): 96-100%) and global SVR12 was 95% (CI: 90-98). Overall, EOT response was 100% in both non-cirrhotic and cirrhotic patients. Two premature stops for safety reasons were observed: EOT and SVR12 according to baseline characteristics and DAA prescribed regimen are presented in Table 1.

Table 1: Proportion of patients with EOT and SVR12 according to baseline characteristics and mostly prescribed anti-HCV treatment regimen

<table>
<thead>
<tr>
<th>Cirrhotic status</th>
<th>Genotype</th>
<th>Most frequent combinations and durations</th>
<th>Undetectable HCV viral load at EOT (%)</th>
<th>SVR12 (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>non cirrhotics</td>
<td>1</td>
<td>SOF + DCV 12W</td>
<td>100% (77%)</td>
<td>100% (97-100)</td>
</tr>
<tr>
<td>non cirrhotics</td>
<td>1</td>
<td>SOF + LDV 12W</td>
<td>100% (22%)</td>
<td>100% (95-100)</td>
</tr>
<tr>
<td>non cirrhotics</td>
<td>1</td>
<td>SOF + DCV 24W</td>
<td>100% (44%)</td>
<td>100% (93-100)</td>
</tr>
<tr>
<td>non cirrhotics</td>
<td>3</td>
<td>SOF + PR 12W</td>
<td>100% (22%)</td>
<td>100% (11-23)</td>
</tr>
<tr>
<td>cirrhotics</td>
<td>4</td>
<td>SOF + DCV 12W</td>
<td>100% (33%)</td>
<td>100% (77-100)</td>
</tr>
<tr>
<td>cirrhotics</td>
<td>3</td>
<td>SOF + DCV 24W</td>
<td>100% (60%)</td>
<td>100% (56-100)</td>
</tr>
<tr>
<td>cirrhotics</td>
<td>4</td>
<td>SOF + LDV 12W</td>
<td>100% (88%)</td>
<td>100% (83-100)</td>
</tr>
</tbody>
</table>

**DCV: Daclatasvir; LDV: Ledipasvir; PR: Pegylated interferon-ribavirin; SOF: Sofosbuvir; W: Weeks.**

**Table 1**

**Conclusion:** In this real-life prospective french national cohort, oral-DAA based regimens showed high efficacy and excellent tolerability in HIV-HCV co-infected patients in a large variety of clinical settings.

**TULBPE10 Efficacy and safety of 12 and 8 weeks of simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naive and -experienced patients with chronic HCV genotype 1 infection without cirrhosis: OPTIMIST-1**

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**Background:** In a Phase II study (COSMOS), oral, once-daily (QD) combination SMV (Hepatitis C virus [HCV] NS3/4A protease inhibitor)+SOF (HCV nucleotide-analogue NS5B polymerase inhibitor)orsubviro for 12 or 24 weeks (wks) achieved high sustained virologic response (SVR) rates and was well tolerated in treatment-naive and prior null responder patients (pts), including METAVIR F4-F3 pts. This Phase II, randomised, open-label study (OPTIMIST-1; NCT02114177) evaluated efficacy and safety of 8 and 12 wks of SMV+SOF, in treatment-naive or -experienced HCV genotype (GT)-infected pts without cirrhosis.

**Methods** Randomisation (1:1, stratified by HCV GT1 subtypexQ80K, IL28B GT, treatment history) to 12 or 8 wks of SMV 150mg QD+SOF 400mg QD. Severity of each treatment arm vs a historical control (HC, from published data), was assessed. Primary endpoint was SVR 12 wks after end of treatment (SVR12).

**Results:** In total, 310 pts received treatment (male, 55%; median age, 56 years. Black/African American, 18%; IL28B CC, 27%; GT1a/b 75/25%; treatment-naive [n=218], treatment-experienced [n=92, 30%]). SVR12 with 12 wks of SMV+SOF (97% [95% confidence interval (CI), 94-100%]) was superior to HC (87%). SVR12 with 8 wks of SMV+SOF (83% [95% confidence interval (CI), 76-89%]) did not achieve superiority vs HC (83%). AEs of interest, increased bilirubin and rash, occurred in 1 (1%) and 10 (7%) pts in the 12-wk arm vs 1 (1%) and 12 (8%) pts in the 8-wk arm, respectively. No pts discontinued treatment due to an AE. Serious AEs were infrequent (12-wk arm, 1 pt [1%], 8-wk arm, 3 pts [2%]). No deaths occurred. PI-reported outcomes significantly improved from baseline to SVR12 in both treatment arms (Table).

**Conclusions:** SMV+SOF for 12 wks was superior to HC and SMV+SOF for 8 wks did not achieve superiority vs HC in treatment-naïve and -experienced HCV GT1-infected pts without cirrhosis. SMV+SOF was well tolerated.

**TULBPE11 Efficacy and safety of 12 weeks of simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naive or-experienced patients with chronic HCV genotype 1 infection and cirrhosis: OPTIMIST-2**

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**Background:** Hepatitis C virus (HCV)-infected patients (pts) with cirrhosis are historically a difficult-to-treat pt population. In a Phase II study (COSMOS), high sustained virologic response 12 weeks (wks) after end of treatment (EOT; SVR12) rates were achieved in META- VIR F4 treatment-naïve and prior null responder pts treated with an all oral, once-daily (QD) combination of SMV (HCV NS3A/4A protease inhibitor)+SOF (HCV nucleotide-analogue NS5B polymerase inhibitor) for 12 or 24 wks, regardless of the presence or absence of ribavirin. The OPTIMIST-2 (NCT02114151) study aimed to demonstrate superiority of 12 wks of SMV+SOF, in treatment-naive or -experienced (including interferon (IFN)-intolerant) HCV genotype (GT)-infected pts with cirrhosis compared with a historical control (composite of the SVR12 rates of approved direct-acting antiviral/IFN+ribavirin regimens).

**Methods** Treatment-naive or -experienced pts with chronic HCV GT1 infection and documented presence of cirrhosis received SMV 150 QD+SOF 400 mg QD for 12 wks. The primary endpoint was SVR12 in the overall population. Safety and pt-reported outcomes were assessed.
Results: 103 pts received treatment (male, 81%; median age, 58 years; Black/African American, 18%; IL28B CC, 28%; GT1a/1b, 70/30%; treatment-naïve [n=50, 49%]; treatment-experienced [n=53, 52%]). SRV2 with SMV+3TC (84% [95% confidence interval: 76, 91]) met the primary endpoint of superiority to the historical control (70%). Other endpoints are summarised (Table). Adverse events (AEs) were observed in 72 (70%) pts; these were mainly Grade 1/2 (84%). Most frequent AEs: fatigue (20%), headache (20%) and nausea (11%). AEs of interest, increased bilirubin and rash, occurred in 2 (2%) and 16 (16%) pts, respectively. Three (3%) pts discontinued at least 1 drug due to an AE. Serious AEs were infrequent (5 pts [5%]). One pt died in a motor vehicle accident. Pt-reported outcomes improved from baseline to follow-up w/12 with clinically important improvements in quality of life for pts who achieved SRV2 (Table).

Conclusions: SMV+3TC for 12 wks achieved superiority in SRV2 rates vs the historical control in treatment-naïve and -experienced HCV GT1-infected pts with cirrhosis and was generally well tolerated.

Tuesday 21 July

Wednesday 22 July
Methods: Virologically suppressed adults (HIV-1 RNA < 50 c/ml; 26 mos) with chronic HBV infection, no cirrhosis, and eGFR<50 ml/min switched to E/C/F/TAF. Week (W) 24 viral suppression rates for HIV (HIV-1 RNA < 50 c/ml, FDA snapshot algorithm) and HBV (HBV DNA < 2000 IU/ml, Misferring/Failure Analysis), biochemical (ALT normalization), serological (HBeAg, HBsAg loss), and seroconversion endpoints are reported.

Results: Participants were older (median age 51), predominantly male (92%), 70% white, 18% black, and 10% Asian. Prior to enrollment, most (69/72 (96%)) patients were on a TDF-containing regimen and the majority were on a regimen containing 2 c pills. At baseline, 71/72 (99%) had HIV-1 RNA < 50 c/ml, and 67/72 (93%) had normal ALT, including 5 with baseline abnormal ALT. No patients met pre-specified ALT flare criteria (confirmed serum ALT > 2×Day 1 value and >10×ULN); the patient who lost HBsAg and gained HBV DNA had a grade 3 ALT abnormality. One of 71 HBsAg-positive patients had HBsAg loss with seroconversion; another individual (100% HBsAg-positive patients) experienced HBsAg loss with seroconversion. There was no change in eGFR (±1.2, p=0.038). Renal tubular proteinuria decreased with switch to E/C/F/TAF: urinary median RBP/Cr ratio decreased from 98.8±9.1 to 91.9±9.5 (p=0.001). Urinary median beta-2MC ratio decreased from 138.8±9.9 to 92.5±10.0 (p=0.001). Most AEs were mild/moderate; one patient had an AE (increased weight/appetite) leading to study discontinuation. Three treatment-emergent SAEs (acute myocardial infarction and two pneumonias) unrelated to study drug occurred.

Conclusions: Through W24, simplifying to single tablet E/C/F/TAF effectively maintained HIV and HBV viremic suppression while improving liver and renal safety endpoints. E/C/F/TAF shows promise for treating HIV/HBV co-infection.

## WELBPE1
### Telomere length shortening and DNA methylation disruptions occur early following HIV serocconversion

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Background: Persons living with human immunodeficiency virus (HIV) have demonstrated a higher risk of accelerated aging. Whether this occurs immediately following HIV serocconversion or throughout the chronic infection period is unknown. To address this knowledge gap, we measured telomere length and DNA methylation changes longitudinally following documented HIV serocconversion in injection drug users within the Vancouver Injection Drug Users Study.

Methods: We measured peripheral leukocyte telomere length (TLT) and performed peripheral blood DNA methylation in 31 HIV-negative participants who subsequently contracted HIV. These were analyzed at three time points: pre-HIV (T0, early post-HIV (T2, mean 2.0 years after T1), and late post-HIV (T3, mean 2.2 years after T2). T1 and T2 samples were available for all subjects with 19 subjects also providing a T3 sample. TLT was measured using quantitative polymerase chain reaction methods. DNA methylation profiles were obtained using the Illumina Infinium 450K DNA methylation platform. CGG sites differentially methylated between T1, T2, and T3 were identified using paired tma analysis after correction for CD4 cell counts, with a Benjamini-Hochberg false discovery rate (FDR)-adjusted p-value <0.05 considered significant.

Results: TLT decreased significantly between T1 and T2 (mean±standard deviation 227±64 vs. 218±52 kb/gpm, paired t-test p=0.005), but there was no significant difference between T2 and T3 (218±52 vs. 186±52 kb/gpm, paired t-test p=0.244). 36 CGG sites corresponded to 33 unique genes differentially methylated between T1 and T2, while there were no significant CGG sites distinguishing T3 from T2. Six CGG sites with both a beta methylation difference >0.1 and an FDR-adjusted p-value <0.05 between T1 and T2 were identified; five of these corresponded to three genes (CRSPNP1, tumor suppression, TNF-pro-inflammatory cytokine, and OBFC1) telomere protection) with the remaining CGG site corresponding to an unknown gene (Figure). The 33 genes differentially methylated between T1 and T2 were highly enriched for apoptotic pathways.

Conclusions: HIV-positive individuals with multiple malignancies have elevated serum free light chains as early as 2 to 5 years prior to their cancer diagnosis. sFLC should be considered as a biomarker for assessing risk for HIV-1-associated non-Hodgkin and Hodgkin lymphomas.
WELBP16
The HIV continuum of care for adolescents and young adults (12-24 years) attending 13 urban US centers of the NICHD-ATN-CDC-HRSA SMILE collaborative

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Background: The HIV Continuum of Care (CoC) is a major focus of US HIV prevention and care efforts. Approximately one-quarter of all new infections occur among youth ages 13-24 years. Adolescent HIV providers and youth face numerous challenges across the HIV CoC, but few empirical youth-specific data are available.

Methods: The Strategic Multisite Initiative for the Identification, Linkage and Engagement in Care of HIV-infected youth (SMILE) collaborative between the NICHD-NNRH-sponsored Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN), CDC and HRSA, forged local collaborations between health departments and ATN sites to help HIV-infected youth link to youth-friendly care, and evaluated each milestone of the HIV CoC for adolescents. Numbers of HIV-infected youth referred, linked (342 days after referral), engaged (21 additional visits within ≤16 weeks after linkage) and retained (≥1 additional visits within ≤52 weeks of engagement) in care were recorded, along with socio-demographics. Viral suppression was defined as a participant having achieved a plasma HIV viral load (VL) below the assay’s limit of detection (BLD) during the study period. VL suppression was examined by socio-demographics, risk behaviors, antiretroviral therapy (ART) and healthcare utilization, and ATN site using Cox Proportional Hazards models.

Results: 1543 HIV-infected youth ages 12-24 years were identified through SMILE between 10/2012 and 09/2014. Among 733 subjects (47.4%) with biomedical data at baseline, the mean age was 20.6±2.3 years, most were males (81%) and non-Hispanic black (72%). Seventy percent had detectable VL, 43% had ≥16 weeks after linkage and 57% retained (≥1 additional visits within ≤52 weeks of engagement) in care were recorded, along with socio-demographics. Viral suppression was defined as a participant having achieved a plasma HIV viral load (VL) below the assay’s limit of detection (BLD) during the study period. VL suppression was examined by socio-demographics, risk behaviors, antiretroviral therapy (ART) and healthcare utilization, and ATN site using Cox Proportional Hazards models.

Conclusions: Prior studies have suggested that HIV-infected US youth are less likely to know their status than adults. The SMILE collaborative has demonstrated that youth with HIV had high levels of plasma viremia and advanced infection at diagnosis. While they linked to care at similar rates as adults, youth achieved disproportionately low rates of virologic suppression. Interventions are urgently needed to improve knowledge of undiagnosed HIV-infection, access to care, medication adherence and long-term VL outcomes in youth.

WELBP17
Efavirenz-based therapy could simplify LPV-based therapy initiated before the age of 2 in HIV-infected children not exposed to single dose NVP to prevent mother-to-child transmission (PMTCT) in West-Africa

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Background: An early antiretroviral therapy (ERT) therapy of years age in HIV-infected children virologically suppressed after 12-15 months of a lopinavir (LPV)-based therapy could be simplified with an efavirenz-based therapy (EFV).

Methods: The MONOD-ANRS-12026 study is an international, randomized, phase 2-3 non-inferiority trial conducted in Abidjan, Côte d’Ivoire and Ouagadougou, Burkina Faso (ClinicalTrial.gov registry number: NCT01172204). All HIV-infected children, tuberculosis-free, receiving <2 years, a 12-15 month suppressive twice-daily LPV-based therapy (undetectable viral load [VL]<500 copies/mL) were randomised in two arms: once-daily ABC-3TC-LPV/r (EFV) therapy versus continuation of the twice-daily LPV therapy (AZT or ABC-3TC-LPV/r).

Table 1. Likelihood of Viral Suppression with Covariates

<table>
<thead>
<tr>
<th>Study interval window (REF = Linked to care)</th>
<th>Unadjusted HR (95% CI)</th>
<th>p-value</th>
<th>Adjusted HR (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engaged in care</td>
<td>2.16 (0.29 - 16.00)</td>
<td>0.4621</td>
<td>2.30 (0.17 - 17.16)</td>
<td>0.4175</td>
</tr>
<tr>
<td>Retained in care</td>
<td>1.46 (0.19 - 10.24)</td>
<td>0.7407</td>
<td>1.53 (0.21 - 11.37)</td>
<td>0.6757</td>
</tr>
<tr>
<td>Long10 HIV VL at linkage (continuous)</td>
<td>0.75 (0.64 - 0.87)</td>
<td>&lt;0.001</td>
<td>0.64 (0.53 - 0.76)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Most current ART (REF = No)</td>
<td>2.84 (1.59 - 4.05)</td>
<td>&lt;0.001</td>
<td>3.10 (1.36 - 5.18)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Data sharing plan (REF = Formal data sharing)</td>
<td>3.21 (1.80 - 5.61)</td>
<td>&lt;0.001</td>
<td>2.33 (1.22 - 4.47)</td>
<td>0.0106</td>
</tr>
<tr>
<td>Time from HIV testing to referral (REF = x3 months)</td>
<td>1.49 (1.08 - 2.46)</td>
<td>0.0263</td>
<td>1.64 (1.03 - 2.61)</td>
<td>0.0883</td>
</tr>
</tbody>
</table>

Table 1. Likelihood of Viral Suppression with Covariates

<table>
<thead>
<tr>
<th>Time from HIV testing to referral (REF = x3 months)</th>
<th>0-7 days</th>
<th>7-12 days</th>
<th>&gt;12 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time from HIV testing to referral (REF = x3 months)</td>
<td>11.17 (0.69 - 1.99)</td>
<td>0.5695</td>
<td>1.64 (0.93 - 2.91)</td>
</tr>
<tr>
<td>7-12 days</td>
<td>1.64 (1.00 - 2.69)</td>
<td>0.0485</td>
<td>2.32 (1.50 - 4.23)</td>
</tr>
<tr>
<td>&gt;12 days</td>
<td>1.49 (0.81 - 2.75)</td>
<td>0.1960</td>
<td>2.08 (1.08 - 4.04)</td>
</tr>
</tbody>
</table>

[Figure 1. HIV continuum of care for 1,546 adolescents and young adults (12-24 yrs) attending 13 urban US centers of the NICHD-ATN-CDC-HRSA SMILE Collaborative - Oct 2012 - Sept 2014]

[Figure 2. HIV continuum of care for 1,546 adolescents and young adults (12-24 yrs) attending 13 urban US centers of the NICHD-ATN-CDC-HRSA SMILE Collaborative - Oct 2012 - Sept 2014]
Monday, 20 July 2015

MOLBPE19

HPTN 071 (PopART): Uptake of first year of a combination HIV prevention intervention including universal HIV testing and treatment across 4 communities in Zambia.

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Background: HPTN 071 (PopART) is a 3-arm community-randomised trial in 21 communities in Zambia and South Africa, with adult HIV prevalence of approximately 15% and an adult population of 350,000 across 14 intervention communities. It will test the impact of a combination prevention intervention in Arms A and B, compared with a control arm providing standard-of-care (Arm C), on HIV incidence within a randomly selected population cohort. In arms A and B, the intervention comprises annual rounds of home-based voluntary HIV counselling and testing (HCT) by Community HIV Care Providers (CHiPs), who support referral to, and retention in, HIV care. ART is provided at local clinics, and is offered irrespective of CD4 count in Arm A and according to national guidelines in Arm B.

Methods: The first annual round of intervention occurred between December 2013 and March 2015. Here we summarise data for the four Arm A communities in Zambia. CHiPs record data electronically during household visits, including consent to participate, acceptance of HCT among adults who do not self-report HIV-positive, the HIV test result, and referral to HIV care. CHiPs document clinic linkage to care and ART initiation for all HIV-positive adults. Results: 46,676 households (~100%) in Arm A communities were visited by CHiPs during the first round. Enumeration of household members was completed in 96% of households. 75% of men and 89% of women consented to participate (Figure). 15% of men and 4% of women were not contacted, and 8% of men and 5% of women refused. Of those enumerated, 81% of men and 85% of women accepted HCT, reported they were HIV-positive, or had tested for HIV in the previous 3 months and were HIV-negative. Among HIV-positive individuals who had never previously registered for HIV care, 99% were accepted and started ART. Of all those referred, 81% of men and 85% of women consented to participate (Figure), 15% of men and 4% of women were virally suppressed (3 samples rejected/lost by laboratory). Pregnancy and postnatal HIV exposure and transmission risk was evident as 38% of FSW engaged in sex work during their prior pregnancy (on average for 5 months), and 48% returned to sex work before 6 months postpartum.

Conclusions: These data suggest that MTCT risk is likely not evenly distributed among women in South Africa and FSW represent an underserved and at-risk population for this preventable outcome. Health assessments and family-focused interventions for pregnant FSW and their children are critically needed to reduce MTCT risk and promote early infant HIV diagnosis.

Tuesday, 21 July 2015

TULBPE21

PrEP, sex, and the paradoxes of prevention: qualitative data from New York city participants in HPTN 067

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Background: Daily oral FTC/TDF is effective in preventing HIV infection. HPTN 067 evaluated the feasibility of intermittent dosing strategies for FTC/TDF-based pre-exposure prophylaxis (PrEP). 179 men who have sex with men (MSM) and transgender women enrolled in New York City (NYC) were randomly assigned 1:1:1 to three PrEP dosing regimens over 24 weeks: daily, time-driven (taken twice weekly plus a post-sex dose), or event-driven (pre- and post-sex). Qualitative data was collected to explore PrEP-users experiences and beliefs about HIV prevention.

Methods: Focus groups (FG) and in-depth interviews (ID) were conducted with a subset of participants within three months of study completion. Stratified convenience sampling was used to enroll two FG and two ID per PrEP dosing arm (total six FG and six ID). Semi-structured guides were used to explore experiences and changes in HIV prevention-related attitudes and behavior while taking PrEP. Transcripts were coded and analyzed using the constant comparative method. Critical dimensions of participants’ HIV prevention strategies emerged as themes within coded data.
Results: 37 MSM participated in FG and IDI. Participants were 68% Black, 11% White, 8% Asian; 27% Hispanic. Median age was 34 years; 68% were unemployed. Analysis identified critical dimensions of prevention strategies and PrEP adherence, including HIV risk conceptualization; endorsement of combination prevention; HIV-related stigma; and difficulty with sex-dependent doses (Table). These dimensions affected adherence to PrEP in distinct ways. Participants associated HIV risk with partner characteristics and linked motivation to use PrEP with partner risk. Many participants reported adopting additional HIV prevention strategies while on PrEP, including discussing HIV status with partners, reducing partners, and increasing condom use. Participants described HIV-related stigma that made disclosing PrEP use difficult, affecting their ability to adhere to intermittent regimens. Similarly, value placed on sexual spontaneity made adhering to sex-dependent doses in non-daily intermittent regimens challenging.

TULBPE22
Baseline characteristics of a rectal phase 2 extended safety and acceptability microbiocide study of tenofovir reduced-glycerin 1% gel: MTN-017
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Abstract Author: ncid27@pitt.edu

Background: Men who have sex with men (MSM), and transgender women (TGW), are disproportionately affected by human immunodeficiency virus (HIV) infection worldwide. MTN-007 previously demonstrated that the reduced-glycerin formulation of 1% tenofovir gel is safe and acceptable when applied rectally for up to 7 consecutive days. MTN-017 is a Phase-2, 3-period, randomized sequence, open label, expanded safety and acceptability crossover study evaluating RGT when used either daily or before and after receptive anal intercourse (RAI), compared to daily oral emtricitabine/tenofovir disoproxil fumarate (FTC/TDF). Baseline study participant (ppt) characteristics are presented here.

Methods: MTN-017 recruited ppts through social media, online advertising, flyers, community events and engagement, and word of mouth. Healthy HIV-1 uninfected MSM and TGW ≥18 years of age were enrolled at 8 clinical research sites in the United States (4), Peru (1), South Africa (1) and Thailand (2).

Results: Between September 2013 and November 2014, 347 ppts were screened and 195 enrolled. Reasons for screen outs were mostly for laboratory criteria (including sexually transmitted infections) and investigator discretion, with 7 individuals diagnosed as HIV-infected. The mean ppt age was 31.1 years (range 18-64). The race/ethnic composition was predominantly white: 64 (33%), Thai: 54 (28%), or mixed race: 29 (15%). Thirty three ppts (17.1%) considered themselves at some risk for HIV infection, and nearly half (49%) had condomless RAI in the past 8 weeks. Most ppts (67%) self-identified as TGW/women, and 156 (80%) had a college education. At enrollment 29 (15%) and 32 (16%) had a perianal or rectal mucosal abnormality detected, respectively. Of those who reported having RAI in the past 8 weeks, 95% reported some lubricant use. Most ppts (67%) considered themselves at some risk for HIV infection, and nearly half (43%) had condomless RAI within the previous 8 weeks. Only a few ppts said they would be unlikely to use the daily gel (7%) or oral medication (6%), with fewer (3%) unlikely to use gel before and after RAI to prevent HIV were it available and effective.

Conclusions: An international cohort of MSM and TGW at risk for HIV infection who may potentially benefit from rectal microbicides, if shown to be effective, was successfully engaged into research and enrolled into a Phase 2 rectal microbiocide study.
**Wednesday, 22 July 2015**

**WELBPE24**

Role of condyloma acuminata in incident HIV infection: a population-based cohort study in Taiwan 2000-2010

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**Background:** The role of Condyloma Acuminata (CA) in incident HIV infection has not been well documented. We aimed to elucidate this relationship by analyzing a large national cohort.

**Methods:** Medical claim records 2000-2010 of 1 million individuals randomly selected from the Taiwan National Health Insurance Research Database (NHIRD, approximately 23 million individuals in total) were retrieved. We included all patients with definite CA diagnosis (those with clinical diagnosis and specific clinical treatment for CA, PDCs) and patients with possible CA diagnosis (those with clinical diagnosis but no specific clinical treatment for CA, PPCs). We matched five patients never clinically diagnosed with CA (PNCs) for every one PDC by year of first CA treatment (PDCs)/first clinical visit (PNCs), gender and age. PDCs, PPCs and PNCs were followed from the date of first CA treatment, first CA screening and first clinical visit, respectively. Endpoint was incident HIV infection. Chi-square test was used to compare socio-demographic characteristics among patients. Characteristics with a P value of < 0.1 using univariate Cox regression were entered into a multivariate Cox regression model to calculate adjusted hazard ratio (aHR) of incident HIV infection.

**Results:** We included 1539 PDCs, 1106 PPCs and 7895 PNCs. HIV incidence among PDCs, PPCs and PNCs was 284.0 (95% confidence interval (CI): 164.9-489.1), 110.6 (95% CI: 41.5-294.7) and 3.8 (95% CI: 5.5-27.2) per 100,000 person-years, respectively. After adjusting for potential confounders, PDCs were more likely to develop incident HIV infection compared to PNCs (adjusted Hazard Ratio (aHR)=23.1, 95% CI: 2.7-195.1). Other variables associated with incident HIV infection were being a male (aHR=14.0, 95% CI: 3.1-63.4), being under 30 years of age (aHR=2.5, 95% CI: 1.07-5.7), having tested HIV once during the year of observation commencement (aHR=9.8, 95% CI: 2.9-33.8) and having tested HIV multiple times during the year of observation commencement (aHR=24.7, 95% CI: 5.7-106.4).

**Conclusions:** CA seemed to be associated with elevated incident HIV infection. HIV risk reduction interventions and routine HIV screening among patients with CA are warranted.

**WELBPE25**

Epidemiology of HIV among men who have sex with men: respondent driven survey in Dodoma Tanzania

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**Background:** Tanzania’s HIV epidemic has been characterized as a generalized epidemic though there are sub groups in society with high HIV and STIs prevalence. This study aimed at determining the prevalence of HIV, other sexually transmitted infections and risk related behaviors amongst MSM in Dodoma, Tanzania

**Methods:** Respondent-driven sampling was used to recruit self identified MSM aged 18+ years living in Dodoma who reported to had anal or oral sex with another man in the last 6 months. Socio-demographic characteristics, HIV/STI knowledge and behavioural profile were collected. Blood samples were tested for HIV, HSV2, Syphilis, Hepatitis B and Hepatitis C.

**Results:** From June to August 2014 409 MSM were recruited. Their median age was 27 (range 18 - 50). The median age at first anal sex was 15 and the majority (80.4%) were single. While 8.1% were married/cohabiting a woman. 37.5% had had receptive anal sex. 47.6% insertive and 15.0% both an insertive and receptive sex during last anal sex. Perceived risk for HIV infection was fairly low in this population and was associated with lower condom use during the last sex. The prevalence of HIV, HSV2, Syphilis and Hepatitis B infections were 17.4%, 38.5%, 0.2%, and 3.4%, respectively. HIV infection was associated with HIVSTGple (Adjusted Odds Ratio (AOR) 5.0, 95%CI: 3.01-11.21) and having lived outside Dodoma (AOR, 1.70 95% CI: 1.05, 6.73). Other predictors of HIV infection included ; young age (18-24) (AOR, 2.1, 95% CI: 1.7-3.65), sexual relationship with a woman (AOR, 5.6, 95% CI: 3.99, 12.8), receptive anal intercourse (AOR, 7.11 95% CI: 4.87, 17.41) and both a receptive and insertive intercourse (AOR, 4.5, 95%CI: 1.3, 14.9) during last anal sex, engaging in group sex (AOR, 3.10, 95% CI: 1.21, 7.64), and use of drugs (AOR, 3.97, 95% CI: 1.11, 13.5).

**Conclusions:** HIV prevalence (17.4%) among MSM is five times higher than that of men in the general population in Dodoma. These findings cement the plans to mount intensified HIV prevention programs that address key populations in Tanzania.
a risk contact a median of 1 times (IQR: 1). 78% of risk contacts named by persons with HIV infection tested HIV positive during DIS investigation.

Conclusions: HIV-infected persons in this outbreak had a large number of risk contacts, reflecting a very dense network through which HIV could spread rapidly. A large majority of ties in the risk network were between injection partners, suggesting that HIV infection spread primarily via parenteral transmission due to shared injection equipment. A network-informed analysis of this outbreak investigation provided a method to characterize the outbreak and inform contact tracing efforts.

Track D

Monday, 20 July 2015

MOLBPE27
Interpreting the UNAIDS 90-90-90 targets in the context of the HIV care continuum in Vancouver, Canada

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Background: UNAIDS predicts that reaching its 90-90-90 targets by 2020 will substantially reduce the HIV epidemic by 2030. Using an HIV transmission model of the care continuum in Vancouver, we determined HIV incidence in 2030 for various operational strategies for implementing the targets, with or without optimizing allocation of healthcare resources.

Methods: We used our previously developed model which incorporates details of Vancouver’s HIV care continuum, including delays associated with progressing through the healthcare system (doi:10.1007/s10729-014-9312-0). We simulated service-delivery expansion for men who have sex with men (MSM), injection drug users (IDU) and the general population (GP) such that by 2020, 90% of HIV-positive individuals in each population were diagnosed, 90% of them were on antiretroviral therapy, and 90% of those treated were virologically suppressed; these targets were achieved: (1) without optimizing resource allocation; (2) by simultaneously minimizing 2030 HIV incidence through optimized allocation of resources among targeted and routine testing programs (each with its unique combination of per-test cost and diagnostic efficiency), or (3) with optimized testing resource allocation that minimized the cost of reaching 2020 targets.

Results: Total HIV incidence in 2030 varied minimally among strategies (95-97 cases). However, the unoptimized strategy (1) required 7 times more resources than the minimum-cost strategy (3). For MSM, IDU and GP respectively, strategy (1) reduced incidence from 2010 baselines of 122, 41 and 20 cases to 66, 23 and 7 cases (reductions of 46%, 43% and 65%). Applying 95-95-95 targets, incidence was reduced by 76%, 75% and 82% for MSM, IDU and GP, respectively.

Conclusions: All operational paths reduced HIV incidence to comparable levels by 2030. However, costs required to achieve these same outcomes varied widely among strategies. Thus, operational guidance accompanying UNAIDS targets will be critical for ensuring appropriate use of scarce resources. Additionally optimizing allocation of care and treatment service resources promises further benefits. More specific outcome definitions—possibly emphasizing absolute rather than relative incidence reductions—may help better adapt the 90-90-90 strategy to local conditions, which can vary widely in baseline service levels. This will facilitate interpretation of the targets within local contexts and the meaningful evaluation of progress toward ending the HIV epidemic.

MOLBPE28
Economic analysis of HIV self versus facility testing and counselling in the context of a cluster-randomized trial in Blantyre, Malawi

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Background: Rates of HIV testing and counseling (HTC) in sub-Saharan Africa remain suboptimal and substantially below target. HIV self-testing (HIVST) is safe, accurate, and can reach high coverage levels among otherwise hard-to-reach groups such as adolescents and men. However, design of affordable and scalable implementation strategies requires the economic impact of HIVST for health providers and users to be known.

Methods: A cross-section of adult (aged≥18 years) participants was recruited from residents of 28 neighborhoods in Blantyre, Malawi, demarcated for a cluster-randomized trial (ISRCTN02004005) investigating health impacts of semi-supervised semi-restricted HIVST. Specifically, a random sample of HIV self-testers was recruited from the trial’s quality assurance cohort, along with all cluster residents testing at health facilities (Clinic A, Clinic B) serving the study population. Participants were questioned about direct health care, direct non-medical and indirect costs incurred in accessing either modality of HTC, and their health-related quality of life (HRQoL) measured using EuroQoL EQ-5D. The costs of HTC were estimated from health provider and societal perspectives to estimate costs per individual tested and costs per
HIV positive individual identified. All costs were adjusted to 2014 US and International Dollars.

Results: 1,241 participants underwent either HIVST (n=775) or facility-based HTC (n=466) and completed study questionnaires. Participants receiving HIVST reported better HRQoL, with those testing positive receiving higher mean EQ-SD utility scores (0.84, 95%CI:0.81-0.87) than those testing positive at health facilities (0.803, 95%CI:0.784-0.822). The mean health provider cost per individual tested through HIVST was comparable (US$87.78) to routine facility-based HTC (US$70.50 & US$103.53), although the mean cost per HIV positive individual identified through HIVST was higher (US$97.50) than for the two health facilities (US$67.07 & US$726.14). Facility testing was associated with higher direct non-medical and indirect costs, and consequently the mean societal cost of HTC was lower for the HIVST group.

Conclusions: Optimizing community-based HTC is essential to achieving high testing coverage among at-risk populations. Enhanced linkage to care is critical to the success of community HTC.

**MOLBPE30**

Performance characteristics and cost benefit of the SD Bioline Duo HIV/Syphilis in clinics in Zimbabwe


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Background: Clinics are having to provide a range of rapid tests because of the increased need at a point-of-care. One such test that can simultaneously detect both HIV and syphilis using a single specimen and a single cartridge is the SD Bioline HIV/Syphilis Duo rapid test kit. Mother-to-child transmission of syphilis and HIV can result in severe adverse pregnancy outcomes and serious illness in infants, including miscarriage, stillbirth, preterm delivery, congenital syphilis, and pediatric HIV infection, hence the need to assess the performance characteristics of this kit.

Methods: Specimens were collected from 321 mothers attending 3 clinics in Harare where the rapid test was carried out by the nurses at sites. Specimens were then tested in the laboratory using EIA assays with the gold standards for HIV being Anlabas (Labsystems Diagnostics Oy, Finland), Vironostika HIV ag/ab (Biomerieux, France) confirming with HIV Blot 2.2 western blot kit (IMM Diagnostic, Singapore). The reference tests for syphilis were the RPR kit (Labor 21 Health Care Ltd, UK) TPHA kit (AMS, UK). For the other 5 clinics that were far from the testing lab, in the Northern part of the country inter-reader variability of the SD color scale was assessed for positive tests from 241 pregnant mothers by 2 nurses reading results independently of each other. The cost benefit of using this single test as compared to using 2 separate tests was also assessed.

Results: For HIV the sensitivity and specificity were 100% (37/37 and 284/284) respectively. For syphilis the sensitivity and specificity were also 100% (4/4 and 290/290) respectively. Concerning the inter-reader variability assessment, 63(26%) were HIV positive and 30(12.4%) were syphilis positive. According to the SD Bioline grading scale there was no reader variability as no results among all readers overlapped to the next category of the 3 grades. The cost of using the SD duo ($1.50/test) compared to the cost of 2 separate kits (HIV $1.00, syphilis $0.75) was cheaper by 14%. Distribution and storage costs were also reduced by half.

Conclusions: Simultaneous testing of two diseases using a single cartridge is cost effective in resource constraint environments as results are also comparable to laboratory results.

**MOLBPE29**

Community-based approaches address gaps in HIV testing and linkage: a systematic review and meta-analysis

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Background: HIV testing and counseling (HTC) is the critical first step for linking to life-saving ART and reducing further transmission. Despite high HIV burden in sub-Saharan Africa, only 50% of HIV-positive persons are aware of their status, with youth and men least likely to be tested. HTC scale-up is urgently needed to reach the UNAIDS’ target of 90% of persons knowing their HIV status. Community-based HTC testing (not based in health facilities) has the potential to achieve widespread coverage, but whether community testing modalities address gaps in population coverage has not been reviewed.

Methods: Following Cochrane Guidelines, we searched PubMed, EMBASE, Cochrane Library, Global Health Database, African Index Medicus, and conference abstracts using MeSH terms including “HIV Infections/diagnosis” AND “testing/screening/diagnosis” published from 2000 to 2014. We identified and screened 1,428 abstracts; 122 studies met eligibility criteria for inclusion. We characterized facility and community (home, mobile, index, key populations, workplace and self-testing) testing modalities by population reached, e.g. coverage, first-time testers, men, youth and high-risk groups, as well as HIV positivity rate, CD4 count at diagnosis, and cost per person tested when available.

Results: Facility HTC achieves limited population coverage, 14% (95% CI: 9-20%), compared with home HTC which achieved 66% coverage (95% CI: 56-74%). Facility HTC also identifies HIV-positive persons later in the course of their disease: 61% of newly diagnosed HIV-positives had a CD4 count < 350 (95% CI: 51-71%), compared to 42% (95% CI: 34-51%) in mobile and 38% (95% CI: 36-41%) in home HTC. Mobile testing reached more men (51%, 95% CI: 48-55%) than facility HTC (42%, 95% CI: 38-45%). Among youth, self-testing had the highest uptake (66%, 95% CI 65-67%) compared to all other modalities. Summary facility and community-based HTC costs were comparable (US$17.35 and 23.92 per person tested, respectively). Community HTC with enhanced linkage to care has the potential to achieve high rates of linkage to care (Figure) similar to rates for facility HTC (68% linkage 95% CI: 57-77%).
MOLBPE31
PEPFAR allocation priorities: an assessment of PEPFAR COP allocations across strategic are and country

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Background: Since PEPFAR’s inception, the country operational plans (COPs) have been the primary medium through which spending priorities and proposed activities are documented. Increasing pressure on both domestic and international financial resources for HIV requires an increased focus on ensuring priorities are appropriately documented. amfAR’s COP database enables users to view PEPFAR’s evolving process of priority setting and decision making within broad strategic areas. We analyze how COP allocations by strategic area have been changing over time and examine country level variability across these areas for the most recent year.

Methods: Utilizing standard open source tools, amfAR created a navigable database of all allocation data contained in published COPs from 2007 through 2014. Data were entered by host country, year, and strategic area (among other categories). Total allocations to each strategic area (Care, Treatment, Prevention, Governance and Systems, and Management and Operations) were tallied by country and year and graphed proportionally.

Results: PEPFAR allocations to Care reached their highest levels in 2014 (21.35% of all COPs allocations) from a low of 19.02% in 2012. Likewise, allocations for Treatment increased from 2014 to 37.16% from 26.20% in 2011 - though below its highest level of 38.21% in 2007. After peaking at 28.29% in 2012, Prevention spending declined to 22.17% in 2014. Governance and Systems also decreased in 2014 to 13.13%, from 19.72% in 2012. With the growth of the PEPFAR program, management and operations costs increased from 4.57% in 2007 to 8.82% in 2013. At the country level within 2014, significant variability is apparent. For countries with funded Care programming, allocations ranged from a low of 7.56% (Guyana) to a high of 38.57% (DRC, 2014); Treatment: 0.79% (Caribbean Region) to 47.04% (Uganda); Prevention: 9.86% (Botswana) to 34.40% (Cambodia). Management and Operations: 0.6% (Burundi) to 34.40% (Cambodia).

Conclusions: Although PEPFAR COP allocations have varied widely by strategic area depending on the country and context, a strong commitment to Treatment and Care is evident. Civil society groups and PEPFAR should engage each other to identify priorities and needs on the ground.

All data is available at http://copsdata.amfar.org

MOLBPE32
Systematic literature review and network meta-analysis of tenofovir/emtricitabine and abacavir/lamivudine backbone regimens for HIV-1

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Background: Recommended treatment regimens for HIV-1-infected patients combine antiretroviral from different therapeutic classes, usually a two-drug NRTI (TDF/FTC) backbone (tenofovir/emtricitabine) with a third agent from another therapeutic class. We sought to understand the clinical evidence differentiating these backbone.

Methods: A systematic literature review (SLR) identified randomised and non-randomised prospective studies of TDF/FTC or ABC/3TC in HIV-1 infection. MEDLINE, EMBASE, and the Cochrane Library were searched in March 2014. Bayesian network meta-analyses (NMA) of randomised controlled trials (RCTs) in treatment-naive patients were run in WinBUGS for virologic response (VR, viral load < 50 copies/mL) and all-cause discontinuation at 48 and 96 weeks. The treatments evaluated included a backbone plus a third agent, and regimens were grouped by third agent class (protease inhibitors [PI], non-nucleoside reverse transcriptase inhibitors [NNRTI] and integrate strand transfer inhibitors [INSTI]). Inconsistency was assessed using an unrelated mean-effects model. The effects of baseline characteristics (gender, age, viral load, CD4 count and race/ethnicity) were gauged by network meta-regression.

Results: Of 1,093 citations retrieved, 243 citations were included in the SLR, reporting 18 RCTs that were included in at least one network. In the NMA, fixed-effects models represented a better fit for VR data, whereas random-effects models fitted the all-cause discontinuation data best. No significant differences were found between TDF/FTC and ABC/3TC with PIs. With NNRTIs, TDF/FTC was associated with significantly higher odds of VR than ABC/3TC at 48 and 96 weeks (Table, Figure). In combination with INSTIs, TDF/FTC had a significantly higher odds of VR at 96 weeks compared with ABC/3TC (Table, Figure). No statistically significant differences in all-cause discontinuation at 48 and 96 weeks were observed between the backbones when these were combined with the same class of third agent (Table, Figure). Networks showed little inconsistency, and baseline characteristics did not have any significant effect on results.

Conclusions: TDF/FTC was associated with VR benefits compared with ABC/3TC with NNRTIs as the third agent at both 48 and 96 weeks and with INSTIs at 96 weeks, and no statistically significant effect was seen with respect to all-cause discontinuation.

MOLBPE33
Artificial Intelligence (AI) accurately predicts HIV treatment response in the setting of treatment failure without resistance testing

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Background: To date, individualised therapy remains the Standard of Care in high-income countries, with resistance testing used to guide selection of the optimum drug combination following treatment failure. In contrast, a public health approach is mostly used in low-middle income countries (LMIC) where genotyping is not available, using treatment guidelines based on the probability of cross-resistance between regimens. Unfortunately high rates of treatment failure are being reported. We evaluated a novel AI approach to predicting virological response to enable individualised therapy in LMIC without a genotype, and compare it to previous models, whose accuracy had plateaued at 75%.

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Methods: We trained ‘standard’ random forest (RF) models to predict virological response (plasma viral load < 50 copies) to a change of therapy using data from 31,274 treatment change episodes including viral load and CD4 count prior to treatment change, drugs in prior and the new regimen and virological response. A novel algorithm was developed to divide these data into similar clusters and new RF models were developed from each cluster. For independent test cases, a prediction of treatment response from the standard models was used, together with their historical data, to allocate them to the appropriate ‘cluster model’ and a refined final prediction obtained from that model.

Results: The new models predicted virological response with accuracy of 91% overall and 93% for 222 test cases from South Africa (vs 73% for standard models). The area under the ROC curve was 0.97 and 0.98 (vs 0.82). Sensitivity and specificity was 91-92% (vs 68-77%). They identified alternative, available regimens that were predicted to be more effective than those used in the clinic for all but one of the South African cases and, for up to 74% of the cases that failed their new regimen in the clinic, alternatives were identified that were predicted to give a full response.

Conclusions: This novel AI approach predicted treatment response highly accurately within the setting of treatment failure, in the absence of resistance testing. This makes it possible to individualise HIV therapy in LMC and greatly reduce treatment failure, supporting the roll out of ART and the proposed UN 90-90-90 Target implementation.
randomized groups on each of the three outcomes. Compared to the control group, no condition had an effect on each outcome that was decipherable from chance alone.

**Conclusions:** We found no effect of cash transfers on mortality, adherence or CD4 cell count change. Although there were few events on which to build a model, sample adherence and mortality do not suggest that the non-significant results are due to low power.

**WELBPE37**

**Cost-effectiveness of the National Mobile Antiretroviral Therapy Services in Zambia: an evaluation study on decentralizing treatment and care program**

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**Background:** In resource-limited settings with high prevalence of human immunodeficiency virus (HIV) infection such as Zambia, the decentralization of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) treatment and care services with effective use of these resources serves as a cornerstone for implementing universal treatment and care. Free anti-retroviral therapy (ART) services were introduced at the hospital level in 2005, and further expanded to selected rural health centers (RHCs) in 2007 through the unique national “Mobile ART Services” program in Zambia. Although this program has contributed to decentralizing the ART services to the primary health care level in order to maximize the efficient use of the extremely limited resources, no economic evaluation has been conducted. This research aims to analyse the cost-effectiveness of the program as a means of decentralizing ART services.

**Methods:** Cost-effectiveness analysis was performed using decision analytic model and simple Markov model to compare the original ART program, “Hospital-based ART”, with the intervention program, Hospital-based plus “Mobile ART” services, from the perspective of district government health office in Zambia. Total cost of ART services including capital, recurrent and operational costs, quality-adjusted life year (QALY) and incremental cost-effectiveness ratio (ICER) were examined.

**Results:** The mean annual per-patient costs were 1,259.16 USD for the original program and 2,601.02 USD for the intervention program, while the mean numbers of QALY’s were 6.81 for the original and 7.27 for the intervention programs. Although the cost-effectiveness ratio was higher for the intervention program (357.93 USD/QALY) than for the original program (184.78 USD/QALY), the ICER of the intervention program relative to the original program was 2965.17 USD/QALY which was much below the willingness-to-pay (WTP), or three times the GDP per capita (4,224 USD). Even in the sensitivity analysis, the cost-effectiveness of the intervention program was not much affected.

**Conclusions:** The National Mobile ART Services Program in Zambia could be a cost-effective approach for decentralizing ART services into rural areas in Zambia. It should be expanded to more districts where the program has not yet been introduced in order to improve access to ART services and the health of people living with HIV in rural areas.
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Track A

PUB001

HIV-induced abnormalities of the B-cell compartment persist in patients on long-term ART and may reflect a state of terminal B-cell exhaustion

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Background: HIV infection induces B-cell activation, which causes abnormalities of circulating B-cell subpopulations and serum immunoglobulin levels. This leads to B-cell exhaustion, characterised by increased proportions of CD21low B-cells. Persistent B-cell activation and/or exhaustion in HIV patients receiving antiretroviral therapy (ART) may contribute to poor pneumococcal vaccine responses and increased risk of invasive pneumococcal disease.

Methods: The effects of long-term ART on B-cell activation and exhaustion were examined in ART-treated (n=30, median years on ART=9.25) and ART-ununtreated (n=20) HIV patients and non-HIV subjects (n=20). B-cell activation was determined by enumerating naive, early transitional, late transitional, activated mature differentiated, resting memory and exhausted tissue-like B-cell subpopulations. B-cell activation was assessed by expression of TNF-related apoptosis-inducing ligand (TRAIL), B and T lymphocyte attenuator (BTLA) and IL-21 receptor (IL-21R). B-cell exhaustion was assessed by CD21 expression. We also assessed B-cell differentiation and activation by assaying serum levels of IgG subclasses and kappa and lambda immunoglobulin light chains (FLCs), respectively.

Results: ART-treated patients exhibited increased proportions of TRAIL+ B-cells and CD21low B-cells compared to non-HIV subjects (p<0.03 and p<0.01, respectively). The proportion of CD21low B-cells negatively correlated with CD4 T-cell counts (R=−0.68; p<0.001) but not with TRAIL+ B-cells. Proportions of BTLA and IL-21R B-cells did not differ from non-HIV subjects. When ART-treated patients were compared with ART-ununtreated patients, proportions of CD21low B-cells were lower (p<0.001) but there was no difference in the proportion of TRAIL+ B-cells. Interestingly, in ART-ununtreated patients, BTLA-expression on all B-cell subpopulations correlated negatively with CD21low B-cells (R=-0.38, p<0.01). Serum FLC levels correlated with proportions of CD21low B-cells in ART-ununtreated patients (r=0.65; p<0.002 and lambda: R=0.59; p<0.008) and were substantially lower in ART-treated patients (p<0.001 for kappa and lambda). In ART-ununtreated patients, serum FLC levels also correlated with IgG1 (kappa: R=0.75; p<0.001 and lambda: R=0.74; p<0.0002) but IgG2.

Conclusions: Although markers of HIV-induced B-cell activation and exhaustion improve on ART, they persist in HIV patients receiving long-term ART. B-cell exhaustion in ART-treated patients is associated with low CD4 T-cell counts and BTLA expression on B-cells, and may have a common immunological cause.

PUB002

Flow-based differentiation between latently HIV-1-infected single cells expressing Gag mRNA alone or in conjunction with Gag protein following latency reversal

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Background: Current antiretroviral treatments cannot eradicate HIV-1 infection due to a pool of persisting latently infected cells. Reactivation of the latently infected cells, using for example HDAC inhibitor, has been suggested as an approach to reduce the HIV-1 reservoir. However, it remains unclear in how many latently infected cells reactivation occurs, and whether reactivation leads to production of viral RNA alone versus production of viral proteins or viruses. We aimed to develop an approach to evaluate the molecular kinetics of HIV-1 latency reactivation on the single cell level to distinguish cells in which only viral mRNA is expressed from cells in which viral proteins or novel viruses are produced.

Methods: J96 cells were used as a HIV-1 latency reactivation model, and treated with different concentrations of hTNFα cytokine for defined time periods ranging from 1 hr to 24 hrs. Combined intracellular staining for p24 Gag protein and Gag mRNA was performed, using a newly established technique that allows for simultaneous detection of mRNA targets and intracellular proteins. HIV-1 p24 Gag protein production and p24 Gag mRNA synthesis was quantified simultaneously on the single cell level using multiparameter flow cytometry.

Results: Following stimulation of J87 cells with 1 nM of hTNFα for 6h, moderate HIV-1 Gag mRNA expression was detected, accompanied with almost no intracellular Gag protein detection. Higher concentrations of hTNFα (10ng/ml) resulted in elevated expression of HIV-1 Gag mRNA as well as intracellular Gag protein synthesis. After 24h stimulation with 10ng/ml of hTNFα, three distinct populations were identifiable by flow cytometry: only HIV-1 Gag mRNA positive cells, HIV-1 Gag mRNA and Gag protein double-positive cells, and cells only expressing Gag protein, but no HIV-1 Gag mRNA anymore.

Conclusions: We here describe a novel method allowing for the first time to simultaneously quantify the kinetics of HIV-1 mRNA and HIV-1 protein synthesis upon latency reactivation. This approach will enable the phenotypic characterization of latently infected cells at different stages of latency reversal and the identification of surface markers that render these cells as targets for innate and adaptive immune responses.

PUB003

Improved assays to measure the inducible latent HIV reservoir

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Background: Precise and practical assays that can reliably measure the impact of a candidate treatment strategy are essential. We improved the standard quantitative viral outgrowth assay (QVOA) and developed a new assay, which promises to be faster, more sensitive, and higher throughput than the standard QVOA.

Methods: Freshly isolated CD4 T cells from 7 ART-suppressed subjects treated during chronic infection were analyzed for total HIV DNA by droplet digital PCR (dPCR, gag) and our newly developed assays for the inducible HIV reservoir - modified QVOA (mQVOA) and inducible cell-associated RNA expression in dilution (iCARED). For mQVOA, CD4 T-cells in limiting dilution were activated with anti-CD3/CD28 antibodies. After 2 days of culture, MOLT-4/CRCS cells were added to the culture and cell-free (cf)-DNA was quantified by real-time PCR (Pu) at day 7. Similarly, we used CDV/DC02 co-stimulation for the iCARED assay in the presence of raltegravir. After 3 days of culture, cell-associated (ca) RNA was quantified by dPCR (gag and tat-rev). In both cases, we used a magnetic-bead based RNA extraction system (Holoclip™) to specifically extract HIV RNA molecules, making it more sensitive than conventional methods and allowing the testing of large volumes of both cells and culture supernatant.

Results: The median fold for total HIV DNA was 168 [105-332] copies/10^6 PBMCs and for mQVOA was 5 [1.7-7.3] infectious units/10^6 CD4 T cells. There was only a 42-fold difference between the two measures; substantially less than what has been reported previously. In the iCARED assay, the median frequency of cells with inducible ca-RNA was 45 [20-61] cells/10^6 CD4 T cells, which was 10 times more than the median frequency measured by mQVOA and 4 times less than the median frequency given by total HIV DNA. The latently infected cells detected by iCARED assay had highly correlated with quantification by mQVOA (R=0.89, p<0.007) and HIV DNA (R=0.95, p<0.01).

Conclusions: iCARED is a simple method to quantitatively classify latent HIV reservoir. Our results suggest that CARED, which is more rapid (4 days), less expensive, less cell-consuming and hands on time than QVOA, could prove to be a useful tool for clinical investigations.

PUB004

The tip of the iceberg: impact of asymptomatic STI's on immune cells in the male foreskin

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Background: C-Medical Male Circumcision (MMCM) reduces the risk of HIV acquisition by up to 60%, confirmed in a number of large clinical trials throughout Africa. MMCM has also been shown to reduce the prevalence of other sexually transmitted infections (STIs), which in turn may impact HIV acquisition. We hypothesized that the underlying mechanisms for this protection may be removal of potential target cells for HIV infection and altered levels of keratinisation in men after MMC.

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Methods: In a longitudinal study involving 2 clinical sites and 150 participants within South Africa, we have characterised Langerhans cells, proliferating and CD4+ T cell densities by immunofluorescent imaging in a subset of 30 HIV negative boys and men (14 - 24 years) undergoing elective MMC at Edendale Hospital in Kwa-Zulu Natal and at the Perinatal HIV Research Unit in Soweto, Johannesburg. CCR5 expression was also investigated in foreskin tissues. In addition we have compared the levels of keratinisation between the inner and outer foreskin and assessed the impact of STIs (C. trachomatis, N. gonorrhoea, M. genitalium, T. vaginalis, HSV-1 & 2) on HIV target cell density in foreskin tissues. Testosterone levels were measured in all men included in the study.

Results: Immunofluorescent staining for CD4, CD8 and CD207 to identify proliferating immune cells showed elevated numbers of both CD4+ and CD207+ Langerhans cells in the foreskin of men with STIs compared to those without an STI. There was a slight yet significant increase in keratin thickness of the stratum corneum of outer compared to inner foreskins.

Conclusions: STI-induced inflammation and recruitment of immune cells to the foreskin, may be elevating the risk of HIV acquisition in uncircumcised men. We conclude that MMC may reduce the risk of HIV infection in this highly susceptible age group of men by removing the potential CD4+ HIV target cells present in foreskins of young uncircumcised men in South Africa.

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Characterization of HCW TB service utilization found that only 10% of HCWs provided a date for their last TB screening, with a median time elapsed of 2.3 years (interquartile range 0.6-5.1). 51% expressed concern that the facility layout might increase their chances of contracting TB; 21% were currently on TB treatment.

**Conclusions:** Implementation and knowledge regarding IPC guidelines is suboptimal. HCW-infected patients are not routinely screened for TB and knowledge deficits among HCWs may further limit screening effectiveness. Especially given significant well-documented occupational risk in this setting, HCWs are not sufficiently screened for TB. Future work will address effective strategies to implement IPC measures and facilitate HCW access to care.

**PUB007**

The prevalence of anorectal STI in HIV-positive and negative MSM in Guangzhou, China

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**Background:** There is an increased prevalence of sexually transmitted infections (STIs) in men who have anal sex with men (MSM). The study hypothesis is to compare the rates of anorectal STIs in HIV positive versus HIV negative MSM. We tested the Neisseria gonorrhoea, Chlamydia trachomatis, Mycoplasma genitalium, and Human papillomavirus of the anorectal mucosal in MSM.

**Methods:** The study conducted in the STD counseling clinic of Lingnan Fellows Health Support Center in Guangzhou, China from January 1 to October 31, 2014. We recruited 164 participants who had a history of receptive or had both insertive and receptive anal sex with men by phone. We excluded men who did not receive anal sex. Seventy-nine participants were HIV positive and 85 were HIV negative. Using nucleic acid detection methods, we tested for Neisseria gonorrhoea, Chlamydia trachomatis, Mycoplasma genitalium, and Human papillomavirus infection by using anorectal swabs. Participants also completed a demographic and sexual history questionnaire.

**Results:** Compared the demographic and sexual history questionnaire, HIV-positive participants had more homosexual sexual partners (P<0.05) and less knowledge about the regular sexual partner’s STIs status (P<0.05) than HIV-negative participants. The infection rates for Neisseria gonorrhoea, Chlamydia trachomatis, Mycoplasma genitalium and HPV were 10.4%, 32.3%, 15.2, and 64.0%, respectively. Except for gonococcal infection (P=0.92), the prevalence of STIs in HIV-positive participants was higher than in HIV-negative participants (P<0.05).

**Conclusions:** There were high STI infection rates in anorectal sites among this sample of MSM, and a large number of participants were infected with more than one pathogen. Infection rates among HIV-positive individuals were significantly higher than among HIV-negative individuals. Our findings suggest a need to strengthen anorectal mucosal STI screening among MSM populations in order to increase early detection and treatment.

**PUB008**

Is depression a serious psychosocial problem among men who have sex with men? Evidence from India

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**Background:** Mental health has been a largely neglected issue among men who have sex with men (MSM) across the world and was not given proper attention particularly in developing nations including India. This study examines the prevalence and correlates of mental depression among MSM.

**Methods:** Data for this study are used from a cross-sectionalBehavioural Tracking Survey (BTS-2012) conducted among 1176 MSM from southern state of India. Besides collecting information on MSMs’s typology, experience of physical and sexual violence, STI symptoms, self-reported HIV status, mobility, poverty, discrimination and condom use, the mental health status of MSM was assessed using Patient Health Questionnaire-2 depression scale. Descriptive statistics, frequency, bivariate and multivaricade logistique regression techniques were used for analysis.

**Results:** More than one-third of MSMs (35%) in the survey reported to have mental depression. The likelihood of experiencing depression was 5 times higher among MSM who were mobile for sex work outside their place of residence (55% vs 17%, AOR: 5.2, 95% CI: 3.7-7.3) and had experienced physical or sexual violence in past 6 months (52% vs 33%, AOR: 6.0, 95% CI: 2.1-17.4) than their respective counterparts. The probability of reporting mental depression was significantly higher among MSM who had experienced STI symptoms in past 6 months (59%, AOR: 3.1, 95% CI: 1.9-5.0), whose know their HIV positive status (51%, AOR: 2.4, 95% CI: 1.2-4.7), who did not use condoms during anal sex with any clients/partners in past one year (82%, AOR: 2.0, 95% CI: 1.5-2.7), those who used alcohol in past one month (50%, AOR: 2.3, 95% CI: 1.7-3.2) and were under financial debt at the time of survey (41%, AOR: 2.0, 95% CI: 1.4-2.6) than others. Those who were associated with any community groups have 50% less chances of reporting depression.

**Conclusions:** The study certainly highlighted that the HIV prevention efforts with MSM in India require an integrated approach on addressing the mental health issues. To support this, programs and research based evidence will be highly needed to ensure that mental health issues are properly addressed among MSM and other high risk groups.

**PUB009**

Early treated HIV-infected children seronegative by ELISA in Cameroon: frequency, factors associated and evolution

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**Background:** Recent studies have shown that initiation of early antiretroviral therapy (ART) in HIV-infected children may lead to seronegative HIV tests. This could have implications in treatment adherence especially in resource limited settings (RLS) where presumptive diagnostic followed by ART and serological confirmation at 18 months is recommended. We aimed to identify factors associated with the seronegative status in early treated HIV-infected children and describe evolution of serological test results during follow-up.

**Methods:** The ANRS-Pediacam is an ongoing prospective cohort which enrolled HIV-infected children identified during the first week of life or not but diagnosed later and before 7 months of age in three urban referral hospitals in Yaounde and Douala. Systematic ART was offered at inclusion and visits planned every 3 months till 2 years of age, and every 6 months thereafter. Frequency and factors associated with seronegative status defined as any negative HIV ELISA test result during follow-up were studied using uni and multivariables logistic regression.

**Results:** From 2007 to 2011, 210 HIV-infected children were included. Among them, 147 that initiated ART at 4.2 months (IQR: 3.2-5.7) were serologically tested at a median age of 20.2 months (IQR: 18.2-22.5), 28 (19.1%) of them were negative. HIV seronegative status was associated with initiation of ART at age ≤3 months (aOR: 2.9, 95%CI[1.6-7.8]), female gender (aOR:3.2, 95%CI[1.2-8.2]) and WHO clinical stage 1 or 2 at ART initiation (aOR:2.9, 95%CI[1.0-8.6]). No association was found with ART protocol between lopinavir/ritonavir and nevirapine based regimens. Almost all seronegative treated HIV-infected infants were virally suppressed (VL< 1000 copies/ml) around the serological test period (96.4% vs 65.6%, p<0.001). Of the 28 seronegative infants, 24 did at least two serological tests in a median follow-up period of 33 months (IQR:18.2-38.1), sixteen remained negative, five became positive and three indeterminate due to viral load rebound.

**Conclusions:** Early initiation of ART in HIV-infected children with clinically satisfactory health conditions may lead to seronegative HIV test results. The evolution of this seronegative status is variable depending on the efficacy of ART. Health care personnel especially in RLS need to be trained on the interpretation and relevance of such serological tests.

**PUB010**

Drug resistance mutations 2 years after delivery in HIV+ pregnant women who have discontinued antiretroviral drugs 6 months postpartum

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**Background:** One of the possible drawbacks associated to the Option B strategy for the prevention of HIV mother-to-child transmission (the administration of triple combination therapy until the risk of transmission has ceased) is the emergence of drug resistance as a consequence of drug interruption. In this study we aimed to determine 2 years after delivery the rate of drug resistance in HIV-infected pregnant women who have discontinued drugs 6 months ago.
postpartum and to assess a possible correlation with baseline resistance. Since in the absence of drug pressure mutations may quickly be no longer detectable in plasma, we evaluated the presence of resistance in HIV-DNA.

Methods: Study population included treatment-naive (with the exception of single-dose nevirapine) HIV-infected Malawian pregnant women receiving a nevirapine-based triple antiretroviral regimen from week 25 of gestational age until six months of breastfeeding. Drug resistance was assessed in HIV-DNA extracted by whole blood samples 24 months postpartum. In patients with resistance the presence of mutations was also evaluated in HIV-DNA at baseline.

Results: A total of 42 women were studied. Their baseline CD4+ count was 503/mm^3 and their baseline HIV-RNA level was 3.4 log_10 copies/ml. Six months postpartum 79% of them had HIV-RNA <50 copies/ml. At month 24 their CD4+ count was 603/mm^3 and their HIV-RNA level was 3.5 log_10 copies/ml. Seven out of 42 women (16.6%) had archived drug resistance at Month 24 (in 6 cases there were non-nucleoside reverse transcriptase inhibitors (NNRTI) associated mutations and in 2 cases the M184I mutation was present). In 4 cases resistances mutations were already present at baseline (all NNRTI mutations). In 3 cases there was emergence of "new" resistance (1 K103N mutation and 2 M184I mutations).

Conclusions: Among women who had discontinued drugs 6 months postpartum only 3/42 (7.1%) had accumulated 2 years after delivery, new resistances mutations in HIV-DNA possibly affecting response to treatment re-initiation. This is re-assuring in terms of the safety of the Option B strategy for the prevention of HIV mother-to-child transmission.

**PUBO11**

Routine cryptococcal antigen screening before ART initiation: a study from an ART center of Eastern India

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Background: Cryptococcal disease, particularly meningitis, is a major cause of morbidity and mortality among HIV-infected subjects. The WHO advocates the routine screening of cryptococcal antigen in serum/plasma in ART-naive patients with low CD4 count (< 100 cells/mm^3) in settings where the burden of cryptococcal disease is high. Retrospective analysis of the Program data from 114 ART centers across India, the prevalence of cryptococcal meningitis (CM) was found to be about 3% in PLHIV with CD4 < 100 cells/mm^3. We conducted a prospective study on prevalence of cryptococcal infection in ART-naive patients from an ART Center of eastern India.

Methods: Approved by the Clinical Research Ethics Committee of Calcutta School of Tropical Medicine, India, this was conducted at the ART Center of the Institute during 18th December 2013 - 4th December 2014. Following written & informed consent, 200 consecutive ART-naive subjects were screened for serum cryptococcal antigen (CRAG) by Latex Agglutination test, irrespective of their symptomatic status. Patients, already diagnosed as CM, were excluded from enrollment.

Results: The median age of the 200 enrolled participants (male - 160, female - 40) was 38 (32-45) years. The cases were distributed in WHO Clinical stage of 1 (41), 2 (20), 3 (91) and 4 (45) respectively. The median CD4 count was 78 cells/mm^3 (range 2 -198, IQR 41 - 121). Overall serum CRAG positivity was 11.5% (23/200) while in subjects with CD4 < 100 cells/mm^3 the prevalence was 14.06% (18/128). CRAG titer varied from 1:32 to 1:1024 with a median titer of 2013 - 4

Conclusions: Among women who had discontinued drugs 6 months postpartum only 3/42 (7.1%) had accumulated 2 years after delivery, new resistances mutations in HIV-DNA possibly affecting response to treatment re-initiation. This is re-assuring in terms of the safety of the Option B strategy for the prevention of HIV mother-to-child transmission.

**PUBO12**

Utility of mobile communication devices as a tool to improve adherence to antiretroviral treatment in HIV-infected children and adolescents in Argentina

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Background: Optimal adherence is critical to achieve the benefits of the antiretroviral (ARV) treatment and minimize the risk of ARV resistance. Multiple aspects are involved in adherence in children and adolescents. Although, published evidence about strategies to improve it is scarce in our setting.

The aim of this study is to evaluate the effects on adherence to ARV treatment using mobile devices as a communication strategy to improve it.

Methods: A prospective study was conducted in a cohort of HIV+ patients less than 25 years old. Patients taking ARV were evaluated to establish suboptimal adherence (SOA). Inclusion criteria: HIV-infected, taking ARV, viral load (VL)>1000 copies/ml, SOA, use of mobile device. The intervention was based on mobile generic contact twice a month through any of the applications the patient chose (WhatsApp, Facebook, text message etc.) during an 8 month period. If the patient or parent required additional information a feedback phone call was generated. VL was performed before and after the intervention as an outcome measure of adherence.

Results: 25/47 patients identified as SOA were able to be contacted. One refused to participate and 2 have no mobile. 22 patients were enrolled. Median age was 17.2 years old (range: 6-25); 15 (68%) were female; median baseline VL was 25,100copies/ml (range: 500,000-1,020,000copies/ml); median log was 4.3 log (Range: 3.5-7.07); 22/section were contactd through their parents. 10 (43%) preferred to be contacted by WhatsApp; 8 (32%) by text message; 4 (18%) by Facebook and others. Each participant received a total of 15 contacts, 84% (296) were answered by the patient, 65% (189) of the contacts generated additional requests (about medications, appointments or symptoms). After eight month of strategy implementation 20/22 VL results were available. 13/20 (65%) were undetectable, 14/20 (70%) had VL <10,000 copies/ml. 6/20 (30%) VL had no changes.

Conclusions: The use of mobile technology improved adherence to treatment evaluated through VL measurement. The strategy is feasible in our setting. The reminder messages trigger additional contacts between patients and provider and may lead to better engagement with HIV care. Longer follow up time is needed to evaluate the effects of this intervention in the long term.

**PUBO13**

Factors associated with depression among adolescents living with HIV in Malawi: a strong association with bullying victimization

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Background: There is a high estimated prevalence of depression amongst HIV-infected youth with data suggesting a detrimental impact on treatment outcomes. Associated risk factors and correlates of depression amongst HIV-infected youth in sub-Saharan Africa have been poorly examined.

This study aimed to identify contributory/protective factors associated with depression in Malawian adolescents living with HIV.

Methods: This was a cross-sectional study assessing factors associated with depression amongst a convenience sample of HIV-infected Malawian 12-18 years old. Depression was measured by a Chichewa version of the Beck Depression Inventory version II (BDI-II) and the Children’s Depression Rating Scale-Revised (CDRS-R). Data on >70 variables were collected including: socio-demographics, past traumatic events/stressors, behavioural factors/ social support and bio-clinical parameters. Chi-square test or two sample t-test was used to explore associations between factors and depression. A second round of screening utilized linear/logistic regression, adjusting for age and sex and identified 18 candidate variables (p< 0.05).

Final regression models included variables with significant main effects and interactions.

Results: Of the 562 participants enrolled (mean age 14.5 years (SD 2.0), and 56.1% female) the prevalence of depression as measured by the CDRS-R was 18.9% (106/562). In multivariate linear regression (Table 1) the variables significantly associated with higher BDI-II score were female gender, fewer years of schooling, death in the family/household, failing a school exam全球最大, not disclosed or not having shared one’s HIV status with someone else, low level of immunosuppression, and being bullied for taking medications. Bullying victimization was reported by 11.6% of respondents. We found significant interactions: older participants with
lower height-for-age z-scores and disattributed with their physical appearance had higher BDI-II scores (Table 1). In multivariate logistic regression: older age OR 1.23 [95% CI 1.07-1.42], fewer years of schooling OR 3.30 [95% CI 1.54-7.05], and being bullied for taking medications OR 4.20 [95% CI 2.29-7.68] were significantly associated with depression.

### Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Beta Coefficient [95% CI]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>2.13 [0.82, 3.43]</td>
<td>0.0015</td>
</tr>
<tr>
<td>Grade- Not in school/Primary School</td>
<td>3.64 [1.71, 5.58]</td>
<td>0.0005</td>
</tr>
<tr>
<td>Nobody in my family has died</td>
<td>-1.77 [-3.15, -0.39]</td>
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<tr>
<td>Did not fail school term/class</td>
<td>1.46 [-2.78, -0.17]</td>
<td>0.0268</td>
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<tr>
<td>Bullied for taking medication</td>
<td>5.31 [3.19, 7.43]</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Disclosed HIV status and have shared with someone</td>
<td>-1.89 [-3.79, -0.03]</td>
<td>0.0168</td>
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<tr>
<td>Level of Immunosuppression (None or not significant)</td>
<td>-2.59 [-4.29, -0.87]</td>
<td>0.0009</td>
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<tr>
<td>Age+ satisfaction with physical appearance interaction</td>
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</tr>
<tr>
<td>Age+ Height for age 2-score interaction</td>
<td>-0.39 [-0.68, -0.11]</td>
<td>0.0072</td>
</tr>
</tbody>
</table>

### Track C

#### PUB015

**Understanding behavioural and psychosocial factors influencing use of female condoms among female out-of-school adolescents in urban Cameroon**

E.E. Tarkang

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**Background:** The female condom is a proven effective female controlled HIV prevention device in Cameroon, which is relatively new, compared to the male condom. A major challenge facing HIV prevention efforts among out-of-school adolescents aged 15-24 in Cameroon is inadequate research on factors influencing use of female condoms. This study aimed at understanding the psychological and psychosocial factors influencing use of female condoms among female out-of-school adolescents aged 15-24 years in an urban area of Cameroon, using the Health Belief Model (HBM) as the behavioural change model.

**Methods:** A cross-sectional design was adopted and carried out in the month of November 2014, on a multi-stage probability sample of 340 consenting female out-of-school adolescents aged 15-24 years in Kumba, the Southwest region of Cameroon, collecting data through self-administered, pretested questionnaires in English. Data were analysed using Statistical Package for Social Sciences (SPSS) version 20 software program. Binomial logistic regressions analyses were conducted at the 0.05 significance level.

**Results:** 241 (70.9%) were sexually experienced, of whom only 53 (22.0%) reported ever using the female condom. Up to 94 (39.0%) reported having multiple concurrent sexual partners during the period of this study. Perceived susceptibility, severity, benefit, self-efficacy and perception of HIV risk were low, while perceived barrier was high. Behavioural and modifying factors significantly influenced the use of female condoms: respondents who had multiple concurrent sexual partners were 2.07 (95% CI 1.12-3.84, p=0.021) times more likely to use the female condom during sex; increasing age was associated with a reduction in the likelihood of using the female condom, OR=0.46 (95% CI 0.21-1.01, p=0.05); lack of HIV/AIDS knowledge was associated with a reduced likelihood of using the female condom, OR=0.50 (95% CI 0.26-0.97, p=0.039). None of the perception components of the HBM was statistically associated with use of female condom.

**Conclusions:** Interventions to increase the perception of risk of contracting HIV, and the knowledge level regarding HIV/AIDS among female out-of-school adolescents aged 15-24 years in urban Cameroon, and strategies to empower them with female condom negotiation skills and to overcome tangible and psychosocial barriers to female condom use are highly recommended.

#### PUB016

**Modeling cost-effectiveness of HIV counseling and testing modalities in Tanzania**

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**Background:** HIV counseling and testing (HCT) is a key HIV/AIDS control intervention. Several modalities have been developed for expanding HCT coverage in developing countries. Thus the objective of the study was to compare per client tested cost across four modalities which existed in Tanzania’s HCT services.

**Methods:** A retrospective study was conducted in four districts in two regions. The modalities assessed were Co-located or Integrated Client-Initiated HCT (CoICT/VCT), Mobile or Outreach HCT (Mobile CICT), Facility-based Provider-Initiated HCT (PITC), Home-based HCT (door-to-door and client index approaches) (HBCT). Client’s demographics and program costs incurred from January to December 2012 were collected. Client characteristics were extracted from National AIDS Control Program (NACP) monitoring systems register. Costing data was abstracted from site specific programme accounts, supply and inventories. Moreover, Cost and effectiveness were measured and compared across HCT modalities by taking a ratio of total cost per modality per clients tested. PITC modality was a baseline modality on cost effectiveness analysis.

**Results:** Overall, 16,561 records were extracted from the HCT registers. The majority of the clients were aged between 25 and 34 (36.3%), mean (SD) age of clients was 31 (8.11) years. More female accessed HCT services 51.23% and had a higher HIV prevalence of 8.89% compared to male (48.77% and 5.49%). Voluntary Counselling Testing (VCT) was found to be a leading modality in detecting HIV positive clients with a HIV prevalence of 9.1% and the least was Door-to-door reported 2.7%. PITC modality reached the largest proportion of previously untreated individuals 92.9%. Costs per client (for 2012 in USD) were $17.45 for PITC, $19.92 for VCT, $25.88 for mobile and $21.59 for door-to-door.
When compared to baseline, incremental cost across all modalities increased by 1.5 folds for mobile, 1.1 times for VCT and 1.2 folds for door-to-door. PITC was having least unit cost across HCT modalities.

**Conclusions:** PITC was most cost effective modality across HCT modalities in Tanzania however multiple HCT modalities is an important components for HCT coverage expansion.

## PUB017

**Level of adherence to antiretroviral therapy and its determinants among people living with HIV/AIDS in SNP Region, Ethiopia**

M. Belaneh

**Abstract:** Recently more than 9.7 million people living with HIV were receiving antiretroviral therapy (ART) in low- and middle-income countries. However, the information related to adherence has been documented only in limited studies which are based in hospitals and there is a need to have regional estimates of these major indicators in Ethiopia.

**Methods:** Facility based cross-sectional study design using quantitative methods supplemented with qualitative methods was conducted from June to July, 2014. For quantitative part, questionnaire was used to collect the data from a total of 1320 population from twenty different public health institution (12 hospitals and 8 health centers). The data was analyzed using SPSS version 16.0 for windows. Univariate and multivariate logistic regression with 95% confidence interval was carried out.

**Results:** According to this study, the level of complete adherence as of patient report over four days was found to be 87.2%. Being away from home (11.9%), simply forget (8.1%), busy with other things (6.3%) and ran out of pills (5.4%) were major reasons among others for missing ART dose. Factors associated with non-adherence after multivariate analyses were educational level, religion, distance to clinic, drinking alcohol, attitude towards HIV/AIDS treatment and other predictor variables. According to ART supporters interviewed, though there is adherence counseling and defaulter tracing mechanism (phone call and/or home visit), the tracking mechanism was highly challenged by shortage of financial support, incomplete and fake patients address and name during intake registration.

**Conclusions:** Adherence level was still below the recommended WHO early warning indicators for HIV drug resistance. Clinicians and adherence supporters should reinforce counseling and defaulter tracing mechanism (phone call and/or home visit), the educational level, religion, distance to clinic, drinking alcohol, attitude towards HIV/AIDS treatment and other predictor variables during intake registration.

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## PUB018

**Impact of Option B+ implementation in HIV-positive pregnant/breastfeeding women in Bafoussam: a cross-sectional study**

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**Background:** More than 90% of HIV infection in children is as a result of mother to child transmission. Elimination of mother-to-child transmission aims at reducing the transmission rate to <5%. To attain this objective, in 2013, WHO recommended placing every HIV positive pregnant/breastfeeding woman on long term antiretroviral therapy (ART) no matter their CD4 count- Option B+. Does associated with increased contraceptive use (87.0%) compared to inappropriate attitude (3.3%),

**Methods:** A cross-sectional study was carried out from January to October 2014 involving HIV positive pregnant and breastfeeding women newly placed on option B+ at the Bafoussam Regional Hospital. Anthropometric, clinical and immunologic (CD4 count) parameters were collected. Descriptive statistics were performed to analyse data.

**Results:** A total of 47 HIV positive pregnant/breastfeeding (39B) women newly placed on treatment were recruited with an average age of 28.3 years; 27.7% were single, 28.8% were cohabiting, 25.4% and 14.9% in monogamous and polygamous marriages respectively. As a whole, 26 (53.5%) of subjects received treatment <3months after knowing their status, 44 (93.6%) were classified stage 1 according to the WHO classification, 2(4.3%) stage 2 and 1(2.1%) stage 3. The average CD4 count at start of treatment was 463 (19 - 1,390) cells/mm3. Using the 2010 WHO recommendations (using CD4 count<350 and clinical staging), only 18/47 (38.3%) would have been on ART. Using just the CD4 count <500, and the clinical classifications for eligibility to ART in the 2013 WHO recommendations, 30/47 (63.8%) would have been on treatment. But with option B+ an additional 30.2% received ART.

**Conclusions:** Option B+ increases considerably the percentage of HIV positive pregnant/breastfeedingwomen benefit from ART as we struggle to attain elimination of mother to child transmission at the Bafoussam Regional Hospital.

Further research should be carried out to verify the impact in mother of Option B+ in preventing new infections in children at the Bafoussam Regional Hospital.

## PUB019

**Factors affecting contraceptive uptake among female sex workers (FSWs) in Sex Workers Outreach Program (SWOP) in Nairobi, Kenya**

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**Background:** Female sex workers (FSWs) are often targeted by public health interventions designed to prevent sexually transmitted infections including HIV. However, such targeted programs sometimes overlook the broader reproductive health needs of these women. This study was conducted to determine contraceptive prevalence among FSWs in SWOP.

**Methods:** This was a descriptive cross-sectional study which utilized both quantitative and qualitative approaches. Systematic random sampling was used to select 385 participants to whom questionnaires were administered. 36 were randomly selected from the 385 for the 3 FGDs. Quantitative data was analyzed using SPSS with qualitative data being manually analyzed according to thematic areas of study.

**Results:** Most of the respondents were aged between 25-34 years (49.1%), with the highest proportion having been in the program 25 months or more. Almost all the respondents (93.8%) had attained some formal education. Majority were divorced/widowed/separated/or unhaving (68.8%) with a small proportion (7.0%) being married. Majority (75.9%) indicated having a regular sexual partner with (82.3%) reporting having had multiple pregnancies. 73.8% were currently using a contraceptive method with the most reported methods being; condom (61.3%) and injection (21.3%). The main source of the contraceptives was SWOP (50.9%), followed by other hospitals/clinics (30.4%). Having been in the program for 13-24 months or more was significantly associated with increased contraceptive use (74.7%) compared to being in the program for 12 months or less (54%), (OR=4.25; 95% CI: 1.27 - 4.72; p<0.001). Assessment of attitude towards contraceptive use revealed that appropriate attitude was significantly associated with increased contraceptive use (87.0%) compared to inappropriate attitude (3.3%), (OR=198.07; 95% CI: 46.65-841.03;p< 0.001). In one of the FGDs, asked what an FSW would have done to prevent an unplanned pregnancy, one said: “She should have used family planning or consistently used condom.”

**Conclusions:** The level of contraceptive use was generally high. However, condom was the most utilized contraceptive method. A lot has to be put to ensure increased use of modern contraceptives in combination with condoms to enhance dual protection.

## PUB020

**Mixed method approach for determining the factors associated with late presentation to HIV/AIDS care in Southern India**

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**Background:** Early diagnosis and treatment of Human Immunodeficiency virus (HIV) is not only beneficial for the people living with HIV/AIDS (PLHA) but for the public and society as well. Delays in HIV care are common and the factors that contribute to delay in seeking treatment are not fully understood. The aim of the study present study was to identify factors associated with late presentation to HIV/AIDS care.

**Methods:** A facility-based unmatched case-control (1:1) study along with in-depth qualitative assessment was conducted at the ART Plus center in Udupi district, Southern India. A sample of 320 HIV patients (160 cases and 160 controls) was selected randomly between February and July, 2014. Information was collected using interviewer administered semi-structured questionnaire. The qualitative component was assessed by in-depth interviews of four health professionals and 12 HIV positive patients who were late for HIV care. The quantitative data was analyzed using SPSS version 15.0. Thematic analysis was adopted for analysis of qualitative data. Ethical approval was obtained from the Institutional Ethics Committee (IEC: 75/2014), of a tertiary care hospital.

**Results:** HIV positive individuals who lived with families (OR=5.11, 95% CI: 1.90-13.77), were found to have non-AIDS co-morbidities (OR= 2.19, 95% CI: 1.09-4.40), who perceived fear of losing family (OR= 5.11, 95% CI: 1.90-13.77), had low CD4 count (OR= 4.3, 95% CI: 2.65-11.33), who perceived fear of being stigmatized in the community (OR= 2.00, 95% CI: 1.01-3.97), who perceived fear with side effects of ART (OR= 198.07; 95% CI: 46.65-841.03;p<0.001). In one of the FGDs, asked what an FSW would have done to prevent an unplanned pregnancy, one said: “She should have used family planning or consistently used condom.”

**Conclusions:** The level of contraceptive use was generally high. However, condom was the most utilized contraceptive method. A lot has to be put to ensure increased use of modern contraceptives in combination with condoms to enhance dual protection.
Background: Many HIV positive children and adolescents on ART are developing into adults. This paradigm requires that their caregivers understand social requirements of such individuals. One of the decisive development tasks for adolescents and young adults is to expose and establish relationship with the opposite sex. Recent literature has documented sexual behaviors, and unplanned pregnancies among HIV positive adolescents. However their challenges in establishing healthy sexual relationships and disclosure of their HIV status to their partners before they are not yet known. The study objective was to assess the key sexual and status disclosure challenges faced by HIV positive adolescents.

Methods: Well thought out interviews were carried out with 30 adolescents during the facility’s HIV positive adolescent clinic. Most respondents were females (n=19, 63%), and males were 11 (37%). The mean age was 17.5 (range 15-20 years). The focus of the interview was on their viewpoint on having a sexual partner(s), sexual activity, Status disclosure, as well as contraceptive use. Quantitative and qualitative analysis of findings was done.

Results: Findings showed that majority of the respondents (22, 73%) are sexually active and find it easier to relate with individuals who are not of the same status. 18 (60%) of these had never disclosed their HIV status to their current dating partners. The major reported barrier to disclosure was fear of relationship cessation (n=16, 53%), and social discrimination. A few respondents (n=3) reported a positive outcome with supported disclosure. 21 (95%) of sexually active participants reported ever use of condoms but only 10 (45%) reported consistent condom use. None of the respondents had ever used any other type of contraceptive methods.

Conclusions: Status disclosure is a crucial and pertinent factor in prevention with positives among HIV positive adolescents. HIV counseling information to adolescents should centre on how to instigate a healthy sexual relationship, prevention with positives and contraceptive use.

Background: The links between gender-based violence (GBV) and HIV are well documented; however, there is still a pressing need to identify effective strategies for addressing this dual epidemic. Drawing from a systematic review of evaluated gender-integrated health programs in low- and middle-income countries, undertaken by the USAID-funded Health Policy Project, in collaboration with MEASURE Evaluation, Public Health Foundation of India, and the International Center for Research on Women, New Delhi, India, a systematic review of evaluated gender-integrated programs in low- and middle-income countries was conducted. The National AIDS Support Organization, Medical Department, Kampala, Uganda

Methods: The study was carried out in late 2012. We used Respondent Driven Sampling (RDS) to recruit the sample groups of PWUD. A person who had used any illicit drug, as defined by the Cambodia Drug Control Law, by any route of administration in the past 12 months was invited to participate in the study. After receiving consent, the research team ‘tagged’ study participants by giving the token. The same recruitment method was used to recruit PWUD from the same geographic location at the recapture stage. The protocol was approved by the National Ethics Committee for Health Research.

Results: Of the total sample (n=1,626), 82.2% were male, and 17.8% were female with a mean age of 25 years. Approximately, 52% were single at the time of the survey, while 31% were married. About 50% of them reported currently living with their parents. A total of 1,252 PWUD were tagged at the capture stage, and 314 of the previously tagged PWUD were recaptured. The calculation of the numbers of PWUD was the product of the number of PWUD met in the capture divided by the % of the tagged PWUD who were re-contacted at the recapture stage. Based on this method, the estimated size of PWUD population in the nine provinces was 9,221 (low estimate of 8,666 and high estimate of 9,777). Proportion of PWUD from the nine provinces contributed to the total of 75% of the total number of PWUD in the whole country. Thus, the average number of PWUD for all 24 provinces of the country was 12,296 (low estimate of 11,555 and high estimate of 13,037).

Conclusions: Capture-recapture seems to be a feasible and robust method among the most direct techniques, which can be applied to estimate PWUD population using RDS, where reliable size estimation of PWUD population is lacking.
**Results:** Providers reported ambivalence about supporting childbearing among their clients with HIV. They raised concerns about HIV-infected individuals having children, and in certain cases expressed judgment that people with HIV should not have children because of these concerns. Providers lack specific knowledge about safer conception strategies and have little level of reproductive knowledge, the efficacy of PMTCT, and the risks of pregnancy for HIV-infected women.

**Conclusions:** Providers in our setting have complex attitudes about HIV-infected clients having children and lack knowledge to appropriately counsel clients about reproductive health and contraception. Further need for research in this area as well as the need for provider training in reproductive health and safer conception.

**PUB025**

**Examining health and health service utilization of heterosexual men with HIV: a scoping review**

N. Koy, J. Bertrand Ngome Djimelo, A. Agha, A.-M. Tyan, T. Antoniou
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**Background:** The prevalence of HIV infection among heterosexual men has increased over the past two decades. Consequently, the need for health and support services for this group is likely to increase. The purpose of this scoping review is to provide an overview of the evidence related to the health and health service use of heterosexual men with HIV related to domains of interest identified by the community.

**Methods:** We searched 6 databases from inception to August 2014. We included all English-language qualitative and quantitative studies examining the health and health service use of heterosexual men with HIV. Two reviewers independently screened titles and abstracts for inclusion in the review, and disagreements were settled by a third reviewer. We extracted data regarding study characteristics (i.e. country of study, design, participant demographics, comparison groups, main findings, and limitations), and used content and thematic analysis to summarize the findings.

**Results:** Our search strategy yielded 2344 references, of which 87 were included in the scoping review. We summarized the research into the following domains: treatment of HIV and its complications (n = 7), health and social support services utilization (n = 20), social determinants of health (n = 8), prevention (n = 17), family planning (n = 8), and psychosocial research (n = 29). Key findings include difficulties accessing care, poor mental health-related well-being and self-reported functional health, over-representation of younger patients’ carers, greater fear of disclosure relative to gay men, being recast as violent and monstrous by mainstream media, and a lack of support regarding family planning and fatherhood.

**Conclusions:** This is the first comprehensive review of the literature regarding heterosexual men with HIV. The review supports the need for multi-sector collaboration (medical and community) to develop programming and support for these patients.

**PUB026**

**Effects of a cognitive-behavioral intervention on condom use and serostatus disclosure in Mexicans living with HIV**

N.P. Caballero Sugrue, E. Rodriguez Estrada,1 M.C. Iglesias Chiesa,1 J.M. Menez Diaz,2 A. Riveros Rosal3, G. Reyes Gerlein1,2
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**Background:** Serostatus disclosure to sexual partners and condom use are relevant variables for prevention of HIV transmission. Few studies assess interventions promoting disclosure, and fewer still assess both disclosure and condom use. We designed and evaluated an evidence-based, modular, cognitive-behavioral intervention aimed at improving consistent and correct condom use and facilitate serostatus disclosure in people living with HIV (PLWHV).

**Methods:** In a single case experimental design (n=1), outpatient PLWHV of the Center for Research in Infectious Diseases in Mexico City, who were under antiretroviral treatment and had moderate to severe levels of anxiety and/or depression were invited to participate between June 2013 and March 2014. Participants received 10 individual weekly cognitive-behavioral sessions, consisting of 6 modules: emotional regulation, serostatus disclosure, quality of sexual life/couple life, triggers of sexual risk behavior, correct and consistent condom use and sex negotiation. Depression and Anxiety were measured weekly using Beck Inventories; basal, end of intervention and 3-month follow-up measures also included questionnaires on pattern of sexual behaviors, quality of sexual life/couple life, and antiretroviral treatment adherence. Data were analyzed using Wilcoxon or Friedman tests, effect size was obtained through Cohen’s d index, and the Jacobson-Truax method was used for clinical significance.

**Results:** Our search strategy yielded 2344 references, of which 87 were included in the scoping review. We summarized the research into the following domains: treatment of HIV and its complications (n = 7), health and social support services utilization (n = 20), social determinants of health (n = 8), prevention (n = 17), family planning (n = 8), and psychosocial research (n = 29). Key findings include difficulties accessing care, poor mental health-related well-being and self-reported functional health, over-representation of younger patients’ carers, greater fear of disclosure relative to gay men, being recast as violent and monstrous by mainstream media, and a lack of support regarding family planning and fatherhood.

**Conclusions:** This is the first comprehensive review of the literature regarding heterosexual men with HIV. The review supports the need for multi-sector collaboration (medical and community) to develop programming and support for these patients.

**PUB027**

**Delay in early infant diagnosis and high risk to follow-up among infant born to HIV-infected women**

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**Background:** Many HIV-infected infants and children die from HIV related causes without their HIV status being known or receiving HIV care. All HIV exposed infants should be tested by Dried Blood Spots (DBS)-PCR before or at 6 weeks of age. In order to facilitate ART or prophylaxis initiation as soon as possible, the WHO recommends HIV diagnostic testing for all HIV-exposed infants at 4 - 6 weeks of age and to initiate therapy soon thereafter. Testing is a crucial step to facilitate early access to antiretroviral treatment (ART) and then functional cure. However, studies that assess the level of use and implementation of HIV DNA testing in Ethiopia are lacking.

**Methods:** A multicentre cohort study was conducted in three public hospitals and three health centers. Mother-infant pairs were followed from delivery until the time of the infant HIV diagnostic test. Data were captured using standardized forms. The time-to-diagnostic test was estimated using Kaplan-Meier estimators. Factors associated with Early Infant Diagnosis (EID) were evaluated using logistic regression.

**Results:** Of the 266 HIV-exposed infants, 59% had no early infant diagnostic DNA-PCR test. The median age at the time of HIV diagnostic testing was 60 days (95% CI: 47 - 73 days), and the median turnaround time between blood draw for DNA-PCR testing to delivery of a test result to the respective health facility was 36 days (95% CI: 33 - 40 days). A total of 35 (13.2%) infants were diagnosed with HIV infection. The predictors of EID were the mother having prenatal care, maternal receipt of ART during pregnancy and place of birth.

**Conclusions:** Three out of five infants born to HIV-infected women in Ethiopia tested positive for HIV. This shows an urgent need for provider training in reproductive health and safer conception. Our findings highlight need for further research in this area as well as the need for provider training in reproductive health and safer conception.
Progress made to enhance understanding of clinical trials by the media: following inaccurate reporting of clinical trials in Zimbabwe in 2011

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Background: Following the inaccurate reporting that 127 HIV negative women had tested HIV positive after the VOICE trial in November 2011 in Zimbabwe, Zimbabwean stakeholders in health research have realised the need to actively engage the media and improve their research literacy to guard against potentially harming misconceptions being relayed to the public. The main objectives of this paper are to note the progress made so far in engaging and enhancing comprehension of the media and to determine whether these efforts have resulted in changes in the nature of reporting.

Methods: The project being reported was conducted between November 2011 and December 2014. The project activities included making use of observations of the magnitude of media engagement and level of media coverage of clinical trials since the publishing of an inaccurate report in November 2011. Efforts to engage the media by various stakeholders in the conduct of clinical trials were reported.

Results: There has been an increase in the engagement of the media throughout the process of clinical trials research. “ASPIRE” study researchers in Zimbabwe now engage the media in radio shows where listeners also phone to ask questions. Throughout the project duration, a number of newspaper articles were written updating readers of the ASPIRE Dapoxetine vaginal ring study. There is now better coverage of events like Research and Intellectual Expos, Annual Health Research Ethics Forum and Research Symposiums hosted by regulators and research institutions. Medical Research Council of Zimbabwe has written articles published in local magazines explaining its role in medical research.

Conclusions: There is growing engagement between the media and clinical trials conduct stakeholders. Researchers in particular now go the extra mile to engage the media so that accurate information is relayed to the public. Regulators and universities have also been making efforts to reach out to the media. However, more could be done to enhance clinical trials literacy among media personnel as some articles they write still have some minor mistakes which could be rectified by better understanding. There is thus need to hold seminars for media practitioners for them to better understand HIV prevention and treatment trials.

Need for improved testing: HIV testing patterns among female sex workers in Ukraine

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Background: Ukraine has been experiencing one of the fastest growing HIV epidemics in Europe, with current estimates of HIV prevalence in the general population at 0.78%. Since 2008, as a primary mode of HIV transmission evolved from concentrated within networks of people who inject drugs (PWID) to spread through unprotected heterosexual contact. Expansion of high-risk sexual networks, in combination with continued spread in networks of PWID, currently fuels the HIV epidemic.

Beginning in 2007, as a part of comprehensive response, rapid HIV testing was introduced across Ukraine. By 2013, 13,763 female sex workers (FSWs) were reached, however this represents only 17% of the estimated number of FSWs. This paper explores the HIV testing patterns and risk factors among FSWs in Ukraine.

Methods: Integrated biological and behavioural surveys (IBBS) were conducted among FSWs in all regions of Ukraine in 2013 (n=4,908) using time location sampling (TLS) and respondent driven sampling (RDS). FSWs were defined as those providing sexual services for remuneration (money or goods or other services) within the last 6 month. Logistic regression analysis was performed to define factors associated with willingness to undertake HIV testing.

Results: FSWs aged 18 years old or less reported higher willingness to undergo HIV testing (OR=7.4 (2.17-24.21), Still more women working on the streets (OR=1.82 (1.54-2.16), and working in brothels (OR=5.32 (3.59-7.76)) were more likely to get tested for HIV. The negative perception towards HIV testing and the fear to be stigmatised were the most common reasons for not testing. The women who tested HIV positive after engagement in commercial sexual acts were significantly more likely to undergo HIV testing in comparison with their counterparts (OR=11.30 (4.59-29.21)).

Conclusions: FSWs, including those who are street based, victims of violence, and inject drugs have significantly greater risk of HIV infection, yet are less likely to undertake HIV testing. This has important programmatic implications. HIV testing approaches targeting the most vulnerable FSWs should be introduced, with comprehensive prevention interventions to address their prevention and care needs.
Results: Age ranged from 20-62 years. Male were majority and only 9% of them were female. About half (47%) of them had primary education or below. Among the study participants, 40% (53) are still on ART, 36 % (49) died, 23% (31) were stopped treatment, only 1 was lost, 1 transfer out to another center. Significant proportion of them (71%) had history of taking Co-trimoxazole (CTX) Prophylaxis. Among the death cases, about 70% (34) had co-infection. It was observed that more than 80% of both death cases along with interrupted treatment cases had history of not taking ART. Usually they came late under treatment and care.

Conclusions: It is assumed that treatment with ART could retain the patients in the program. Their physical and social well-being were dependent on it. For that HIV case detection and linked to continuum of care is vital to revert morbidity & mortality. Early diagnosis and eligibility for ART, efficiently medico-social management can motivate patients to receive treatment and followed up. Smooth distribution of ART from Government authority need to be ensured.

### PUB034

**Highlighting the burden of data capture and reporting associated with provision of HIV/AIDS health services in Uganda**

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**Background:** Access to quality data is important for the successful implementation of HIV/AIDS programs. Nonetheless, the burden of data capture and reporting associated with the provision of HIV services is not known. We present the total number of tools, indicators, and data sources for the HIV/AIDS program in Uganda and their implications.

**Methods:** We conducted a desk review of the National Management Information System in April 2015 to establish the total number of registers used to capture routine data for HIV/AIDS programs and counted the reports, frequency of reporting, indicators and data sources for HIV related data.

**Results:** In total there are 26 registers/tools used to collect routine data at health facilities for different HIV/AIDS programs, as follows; HIV counselling and testing: 4 (HCT client card, HCT register, HIV test kits, Daily consumption log and triplicate referral booklet), Pre-ART and ART: 5 (HIV care/ART card, Pre-ART register, ART register, Appointment book and the integrated Nutrition register), Safe male circumcision: 3 (safe male circumcision client form and safe male circumcision register). Early infant diagnosis: 2 (Exposed infant card and register), Medicines and supplies: 2 (ARV dispensing log and stock card) and laboratory monitoring: 2 (laboratory test register and EID dispatch booklet).

**Conclusions:** There are many data collection tools, variables, reports, indicators and data sources that health workers have to work with. This increases workload for health workers with implications not only on quality of data but also services provided. The MOH should reduce the number of tools and indicators reported through merging and getting some data through evaluations.

### Methods

This was a retrospective cohort study with routinely collected medical data of HIV (+) people who inject drugs from an exclusive ART center based in Dhaka, Bangladesh. The register had data of about 200 cases from December, 2008 to December, 2013. Paramedic and counselors extracted data. But consistent outcome data were found for 135 case which was analyzed here using established MS Excel based database.

**Results:**

- Age ranged from 20-62 years.
- Male were majority and only 9% of them were female.
- About half (47%) of them had primary education or below.
- Among the study participants, 40% (53) are still on ART, 36 % (49) died, 23% (31) were stopped treatment, only 1 was lost, 1 transfer out to another center.
- Significant proportion of them (71%) had history of taking Co-trimoxazole (CTX) Prophylaxis.
- Among the death cases, about 70% (34) had co-infection.

**Conclusions:**

- It is assumed that treatment with ART could retain the patients in the program.
- Their physical and social well-being were dependent on it.
- For that HIV case detection and linked to continuum of care is vital to revert morbidity & mortality.
- Early diagnosis and eligibility for ART, efficiently medico-social management can motivate patients to receive treatment and followed up.
- Smooth distribution of ART from Government authority need to be ensured.

### PUB033

**Estimating district-level adult unmet need for ART in Mozambique 2012-2014**

J. Lara1,2,3, A. Couto1, V. Macome1, I. Wanyeki1, N. do Nascimento4

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**Background:**

In 2013 Mozambique launched its Acceleration Plan for Combating HIV, which aimed to increase the percentage of ART eligible persons in treatment to 80% by 2015. To support the strategic allocation of resources and maximize intervention impact at a district level, a methodology leveraging demographic and epidemiologic inputs was developed by the Ministry of Health and CDC to identify priority districts based on estimated unmet need for adult ART. From January 2013 to June 2014 prioritized districts with more than 1,000 adults in need of ART received enhanced support for HIV service scale-up and quality improvement. Absolute unmet need for adult ART decreased between 2013 and 2014, suggesting that district prioritization and strategic resource allocation may be an effective approach to continued ART scale-up. More research and policy analysis are required to determine what factors contributed to the reduction in unmet need in the districts not prioritized in the follow-up analysis. Finally, the identification of eight new priority districts in the follow-up analysis highlights the need for a better understanding of prioritization effects in non-priority districts.

**Methods:**

This was a retrospective cohort study with routinely collected medical data of HIV (+) people who inject drugs from an exclusive ART center based in Dhaka, Bangladesh. The register had data of about 200 cases from December, 2008 to December, 2013. Paramedic and counselors extracted data. But consistent outcome data were found for 135 case which was analyzed here using established MS Excel based database.

**Results:**

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- Among the death cases, about 70% (34) had co-infection.

**Conclusions:**

- It is assumed that treatment with ART could retain the patients in the program.
- Their physical and social well-being were dependent on it.
- For that HIV case detection and linked to continuum of care is vital to revert morbidity & mortality.
- Early diagnosis and eligibility for ART, efficiently medico-social management can motivate patients to receive treatment and followed up.
- Smooth distribution of ART from Government authority need to be ensured.
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