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Rights of Women and Girls
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LBPE03 Correlates of Immune Protection
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LBPE15-LBPE16 Clinical Trials
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LBPE38 Gay and Other Homosexually Active Populations
LBPE39 Access and Availability of HIV/AIDS Treatment and Care, Health Services and Mental Health

Track E Economics, Operations Research, Care and Health Systems
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LBPE41 Adapting HIV Programmes to Systems with Limited Health Care Personnel
LBPE42 Working with What You Have: Improving Local Data Systems to Support HIV Programmes
LBPE43 Quality Improvement Interventions to Improve Systems Performance
LBPE44 International Funding for HIV Scale-up: Following the Money
LBPE45 Insurance Schemes for HIV
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LBPE55 Analysing and Promoting Accountability of Stakeholders
LBPE56 Laws and Policies Regarding or Affecting HIV Prevention and Treatment and/or Care for People Living with HIV
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FRAA003
Selective transfection of monocyte-associated HIV-1 across a human cervical monolayer and its modulation by seminal plasma

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Background: Transmigration of human immunodeficiency virus type 1 (HIV-1)-infected leukocytes through female genital mucosa is one of the mechanisms proposed for the heterosexual transmission of this virus. After sexual intercourse, a selection process has been shown to lead to a predominant transmission of the R5 phenotype despite the presence of X4 and R5 strain in semen. Transmigration of HIV-infected monocytes present in semen may represent an important mechanism that could explain this tropism selection.

Methods: In this study, we have analysed the transmigration of monocyte-associated PBMCs (PBM) and lymphocyte-enriched PBMCs (RL) immune cells across the epithelium of the monopolar endometrial HECA-1 cell line seeded on inserts (pore size of 0.2 μm). The transmigration assay was performed over 24h and transmigrated cells were analysed by flow cytometry, 24h Ag quantification and proviral DNA amplification. In some experiments, confluent HECA-1A cell culture inserts used in transmigration assays were fixed in paraformaldehyde, immunostained before fluorescent or confocal microscopy analysis.

Results: Monocytes, representative of the main immune cell type found in semen, were found to efficiently cross the monolayer, in contrast with lymphocytes. The measurement of the epithelial crossing of infected cells revealed the preferential passage of the X4 strain HIV-1BaL with monocytes. In contrast, HIV-1m-infected immune cells were not detected in the basal compartment or confluent HECA-1A cell culture inserts. Seminal plasma increased transpapillarle resistance of a tight HECA-1A epithelial monolayer and accordingly reduced leukocyte transmigration.

Conclusions: These observations are in agreement with the hypothesis that transmigration of monocytes could be involved in the selective transmission of HIV-1 of the lymphotrophic HIV strains. This phenomenon could contribute to the negative selection of X4 strains during heterosexual transmission. Overall, our results argue in favour of transmigration of infected monocytes in the selective transmission of HIV-1.

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FRAA010 Mechanisms of Transmission

FRAA0101 Visualizing initial SIV infection in female macaque models

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Background: Male-to-female transmission of HIV-1 is a complex process where the female genital tract is exposed to the virus, which crosses mucosal and epithelial barriers to establish infection. How HIV-1 initially establishes this early infection is poorly understood.

Methods: To establish infection in female macaques, SIV was inoculated intra-vaginally using three different SIV vectors. The use of these replication-deficient vectors enabled us to specifically identify the initial infected cells within the vaginal vault. Four days following inoculation, macaques were necropsied and the genital tracts were excised. The entire genital tract was imaged and stained for cellular markers and SIV vector infection.

Results: We found that we could detect four distinct sites of infection. These current methods have revealed potential foci of infection within the genital tract of infected macaques. These foci appear more frequently in the thinned vaginal epithelium of the Depo Provera-treated macaque. The infected cells have a morphology and staining pattern consistent with CD4+ T cells. We are continuing this work to define the nature of these transduced cells within the Depo Provera vaginal challenge macaque model.

Conclusions: We have potentially identified the initial infected cells within the female macaque genital tissue. We speculate these foci may be responsible for early virus transmigration. Identification of the initial targets of infection after sexual exposure will be invaluable in the developmental of protective interventions such as vaccines and microbicides.

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FRAA0102 Estimating the frequency of superinfection in a large European collaborative HIV database

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Background: Superinfection (infection of an HIV-positive individual with another virus strain) can facilitate the evolution of HIV by allowing for the recombination of distinct viral lineages. In particular, it might enable the transmission of drug resistant viruses to individuals with drug-sensitive strains who have previously responded well to therapy. We have analyzed routinely collected genotyping data from a large European collaborative HIV database to estimate the frequency of superinfection.

Methods: We used sequence data spanning the protease and partial reverse transcriptase regions from the Virology and Eudetect databases. 4,956 patients (gender: male=3,416, female=1,363, unknown=153; risk groups: heterosexual=1,073, IDU=951, other=158, unknown=1,296) had at least two sequences in the database, with a total of 14,196 distinct sequence entries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood.

Results: We used sequence data spanning the protease and partial reverse transcriptase regions from the Virology and Eudetect databases. 4,956 patients (gender: male=3,416, female=1,363, unknown=153; risk groups: heterosexual=1,073, IDU=951, other=158, unknown=1,296) had at least two sequences in the database, with a total of 14,196 distinct sequence entries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B).

Conclusions: When sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B), superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B). Superinfection was indicated when sequences of a patient failed to cluster together in maximum likelihood tries (of which 89.0% belonged to subtype B).

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FRAA0104 Early phase dynamics of HIV-1 infection in hPBM-transplanted NOD/SCID/Jak3−/− mice using infectious HIV-1 carrying fluorescent protein mCherry

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Background: Recent studies have demonstrated that routinely obtained genotyping data can provide sufficient phylogenetic signal to infer superinfection, although further data might be necessary in further study of early phase spreading of HIV-1.

Methods: A full-length HIV-1, containing a red fluorescent protein mCherry (HIV−mCherry) was constructed and transfection-derived virions were genetically inactivated to hPBMT-transplanted NOD/SCID/Jak3−/− mice and the spreading profiles of the virions were determined with HIV−1 visualization, immunostaining, and plasma p24 determination.

Results: Abundant human T-cell lines were found in various organs including spleen, lymph nodes, intestines, brain, lung, kidney, skin, and muscles by day 14 after hPBMT transplantation. Flow cytometric analysis with a fluorescent HIV−1, inoculation, the virus penetrated through visceral serosa and established infection in the lamina propria, followed by spreading through the vascular system throughout the body, generating productive infection, which was confirmed with histology on high level virions. Although only few small lymphoid nodes were seen in hPBMT-transplanted, non-HIV-infected mice, the numbers of significantly enlarged lymphoid nodes were readily located in hPBMT-transplanted HIV−1-infected mice. When the hPBMT-transplanted mice were intraperitoneally challenged with HIV−1-infected FMH from another donor (mCherry virions), significantly greater virions was seen compared to the counterpart mice receiving cell-free virions.

Conclusions: These observations are in agreement with the hypothesis that transmigration of monocytes could be involved in the selective transmission of HIV-1 of the lymphotrophic HIV strains. This phenomenon could contribute to the negative selection of X4 strains during heterosexual transmission. Overall, our results argue in favour of transmigration of infected monocytes in the selective transmission of HIV-1.
FRBLC1 Late Breaker Track C

FRBLC101 The protective effect of adult male circumcision against HIV acquisition is sustained for at least 54 months: results from the Kisumu, Kenya trial


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Background: In a randomized controlled trial in Kisumu, Kenya, including 2,874 men aged 18-24 years at enrollment, we previously reported a 60% reduced risk of male circumcision against HIV acquisition at 24 months after enrollment, and 64% at 42 months, based on modified as-treated analyses. The trial was unblinded in December 2006, when all participants were offered circumcision services as part of comprehensive HIV prevention strategies. This project is funded by FRSQ réseau SIDA/ Geneviève Boly-Larouche is a CHF PhD scholar

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Results: We identified a strong association between DC-SIGN promoter variants (p=0.0001) and increased risk of acquiring HIV-1 through IU, IP and PP transmission among Zimbabwean infants. Moreover, four protein modifying substitutions (R198Q, E214D, R221Q and L245V) in DC-SIGN exon 4 were also associated with increased risk of IU, IP and PP HIV-1 transmission. All associations remained significant after adjusting for a number of maternal factors known to affect vertical transmission of HIV-1.

Conclusions: Our findings indicate for the first time that DC-SIGN genetic variants are associated with vertical transmission of HIV. No grade 3 or 4 creatinine elevations were observed. A total of 27 protocol-defined serious adverse events occurred, 16 on TDF and 11 on placebo (p=0.56). Among 186 San Francisco participants who consented to genotype testing, 42 (22%) were ARV naïve, 62 (33%) had documented discontinued drug (per protocol) for <5% decrease in bone density (total hip or spine) from baseline (88% on TDF, 33% on placebo) p=0.21. Seven participants became HIV infected; four were on TDF and three on placebo (including one seroconversion at enrollment but subsequently found to be acutely infected); three were in the delayed arm and seroconverted before starting study drug.

Conclusions: No significant biomedical safety issues were identified. This study was not designed to detect efficacy of TDF in preventing HIV infection. Adequately powered efficacy trials are underway to address this question. Presenting author email: lkg6@cdc.gov

FRBLC102 Preliminary analysis of biomedical data from the phase II clinical safety trial of tenofovir disoproxil fumarate (TDF) for HIV-1 pre-exposure prophylaxis (PrEP) among U.S. men who have sex with men (MSM)


1Centers for Disease Control and Prevention, Atlanta, United States, 2San Francisco Department of Public Health, San Francisco, United States, 3AIDS Research Consortium of Atlanta, Atlanta, United States

Background: Animal studies suggest PrEP may protect against HIV acquisition. This double-blind, placebo-controlled trial will determine if daily oral TDF among HIV-1 negative men at risk of acquiring HIV through sexual contact is safe.

Methods: HIV-1 negative men reporting anal sex with another man in the past year were randomized to initiate once-daily TDF (300mg) or placebo at enrollment or after a 9-month delay. Quarterly visits included HIV testing, risk-reduction counseling, and assessments of biomedical and behavioral safety, adherence, and acceptability. Bone density (DEXA) was assessed in San Francisco.

Results: From February 2015 through July 2007, 400 men (median age 39 years; 11% enrolled; 373 initiated TDF or placebo) were enrolled. 88% were white, 15% African American, 4% Asian/Pacific Islander; 9% were Hispanic. Treatment-emergent adverse events are summarized below.

Conclusions: Our preliminary data suggest a high level of transmission-related
The impact of the new WHO antiretroviral treatment guidelines on HIV epidemic dynamics and cost in South Africa

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Background: Since November 2009, WHO recommends that adults infected with HIV should start antiretroviral therapy (ART) at CD4+ cell counts ≤350 cells/µl rather than ≤200 cells/µl. South Africa decided to adopt this strategy for pregnant and TB-infected patients. Only we estimate the impact of fully adopting the new WHO guidelines on HIV epidemic dynamics and associated costs.

Methods: We used an established model of the transmission and control of HIV in specified sexual networks and healthcare settings. We quantified the model’s sensitivity to endemicity level and foreseeable changes in ART price.

Results: During the first five years, the new WHO treatment guidelines require about 7% extra annual investments, whereas 28% more patients receive treatment. Furthermore, there will be a more profound impact on HIV incidence, leading to relatively less annual costs after seven years (Figure 1A).

Conclusions: Our study strengthens the WHO recommendation of starting ART at ≤350 cells/µl for all HIV-infected patients. Apart from the benefits associated with many life-years saved, a modest frontloading appears to lead to net savings within a limited time horizon. This finding is robust to alternative assumptions regarding endemicity level and foreseeable changes in ART price.

The contribution of early HIV infection to HIV spread in Lilongwe, Malawi: implications for transmission prevention strategies

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Background: South Africa has a high prevalence of TB/HIV coinfected adults in whom TB is often diagnosed late in the course of disease with resultant increased mortality. Improved case detection and timely initiation of ART for patients on ART at ≤350 cells/µl for all HIV-infected patients. Apart from the benefits associated with many life-years saved, a modest frontloading appears to lead to net savings within a limited time horizon. This finding is robust to alternative assumptions regarding endemicity level and foreseeable changes in ART price.

Methods: We developed a deterministic mathematical model describing heterosexual transmission, with CD4 counts taken for people testing positive for HIV. Participants received results within 30 days of testing for both HIV and syphilis, and were randomized to immediate ART, HIV follow-up, antiretroviral therapy (ART), and isoniazid preventive therapy (IPT).

Results: 2771 household contacts were screened for TB. 178 (6.4%) had previously undiagnosed TB, including 8 (4%) smear-positive and 170 (96%) smear-negative, culture-positive patients. 72% started TB treatment. 21% of households had at least one contact with undiagnosed TB. 56% of contacts consented to screening and 161 (10%) tested HIV-positive. Mean CD4 count at HIV diagnosis in contacts was 450 (SD 287) cells/µl, higher than in index cases (134, SD=167, p<0.01). 22% of new HIV diagnoses in contacts were reported. Among index cases, 84% were HIV-infected, compared to 15% of newly diagnosed TB cases in contacts (half were diagnosed with HIV at the same time visit). TB cases among contacts had fewer symptoms with shorter duration (0.9 weeks vs 7.7 weeks, p<0.01) than index cases.

Conclusions: The introduction of POC CD4 in ART clinics resulted in significant improvements in patient retention (70% increase) and in time to ART initiation (26 day reduction). These benefits are expected to contribute to higher rates of infection rates and better patient retention. As more patients are diagnosed who are important for additional visits.

The introduction of point-of-care CD4 improves patient retention and time-to-initiation of ART in Mozambique

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Background: Expanding access to HIV antiretroviral therapy (ART) is hampered by high patient loss-to-follow-up and delays in ART initiation. These challenges are partly due to limitations in access to CD4 testing. Point-of-care (POC) CD4 may help improve the situation.

Methods: A patient chart review was conducted at Matola district health centers in Maputo Province, Mozambique. Patient retention and time-to-initiation of ART were compared before and after the introduction of POC CD4 testing with the PIMA™CD4 system. Metrics measured included (i) percent patients lost-to-follow-up after enrollment in HIV care, (ii) CD4 test turnaround time, and (iii) CD4 test time to ART initiation.

Results: 373% of patients enrolled in HIV care before the introduction of POC CD4 were lost-to-follow-up. After the introduction of POC CD4, this percentage dropped to 10.6%. Average CD4 test turnaround time before the introduction of POC CD4 was 27 days, consisting of 12 days from ART clinic enrollment to CD4 requisition, 3 days from CD4 requisition to test performed, and 12 days from test performed to CD4 result returned to patient file. After the introduction of POC CD4, these times were shortened to 1.3 days (0.3 days from test performed to CD4 result returned to patient file). This led to a total time to ART initiation from 40 days to 14 days.

Conclusions: The introduction of POC CD4 in ART clinics resulted in significant improvements in patient retention (70% increase) and in time to ART initiation (26 day reduction). These benefits are expected to contribute to higher rates of infection rates and better patient retention.
FRLBE102

The socio-economic impact of HIV in Cambodia at the household and national levels

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Background: Cambodia has made impressive progress in increasing access to antiretroviral treatment (ART) and promoting preventive measures to address HIV’s challenges. In the context of UNDP-UNAIDS’ RV适用 initiative, this household survey evaluates the socio-economic impact of HIV in Cambodia.

Methods: This quasi-experimental designed study of 2,623 cases” (HIV households) and 1,349 “controls” (non-HIV households) applies multivariable analysis and propensity score matching to determine HIV’s effect on households, including inter alia impacts on: poverty, employment, human capital accumulation, health status and health expenditure, as well as household coping mechanisms, stigma and gender equality.

Results: HIV has a significant impact on household consumption, asset accumulation (53% HIV+ households vs. 80% non-HIV own their house) and produces greater impoverishment (65% vs. 52% are in debt). HIV households require more health care (62% vs. 53% sick in previous 4 weeks), have reduced nutritional status (58% vs. 39% hungry in previous year) are less able to maintain employment, face increased discrimination, and children have increased barriers to education (30% vs. 22% children missed a school day in previous year). HIV households also face significant gender-related challenges as widows face more discrimination (11% vs. 6% widowed).

Overall, HIV has significant impact on macro-economic growth and the labor market, leading to declines (approximately 2%) in GDP.

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FRLBE104

Uganda’s innovative efforts to improve testing, retention, and care of HIV-exposed infants

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Background: Uganda’s Early Infant Diagnosis (EID) program has undergone rapid scale-up since early 2007. However, an in-country review revealed poor retention outcomes for the tested infants, poor linkage of HIV-exposed and HIV-positive infants to service points, and no care provision for all exposed infants. The review informed the development of a series of integrated initiatives to improve testing, retention, and care of HIV-exposed infants, which the Ministry of Health piloted at 21 sites in late 2009.

Methods: A retrospective review of 4 “EID systems strengthening” pilot sites was conducted in May 2010. Longitudinal data on exposed infant outcomes from before and after the pilot was collected; site EID practices were reviewed.

Results: At the assessed facilities, the number of exposed infants tested each month has increased by 50%. The total number of exposed infants identified has increased due to their capture at earlier stages in the EID process, including antenatal, maternity, and postnatal care. Since implementation, the percentage of exposed infants receiving Cotrimoxazole has increased. The percentage of exposed infants receiving Cotrimoxazole increased from 80% in December to 99% in April. Exposed infants are now visiting the health center regularly, where they are receiving comprehensive care (growth monitoring, developmental assessment etc.). The pilot has already shown retention benefits, with a 19% increase in the number of HIV-exposed infants receiving results across the 4 assessed facilities. Among the exposed infants who are HIV-positive, not only are more getting identified/tested (50% increase) and receiving results (29% increase), but 96% of those receiving results are getting enrolled at an ART clinic (36% increase).

Conclusion: The initial returns of the EID systems strengthening pilot are promising, with high impact already shown in the areas of identification, testing, retention, linkages, and care provision. The major challenge is the national rollout and long-term sustainability of this impactful innovation for EID program implementation.

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FRLBE105

Integrating HIV, hepatitis B (HBV) and syphilis screening and prevention of vertical transmission in antenatal care (ANC) and labor and delivery (L&D) services in Yunnan province, China

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Issues: HIV, HBV, and syphilis can be transmitted from mother-to-child in the perinatal period. Effective methods exist to prevent vertical transmission for all three, if infected pregnant women are identified. However, in China, while HIV screening for all pregnant women is mandated, screening for HBV and syphilis is not routinely integrated into ANC services.

Description: We explored the feasibility of integrating HIV, HBV, and syphilis screening and PMTCT services in six counties in Yunnan. Health providers were trained on standard HBV and syphilis testing and protocols to prevent vertical transmission. All pregnant women were presented with testing opportunities in January and August 2009 were offered integrated screening. Those who tested positive were provided interventions to prevent transmission.

Lessons learned: Rate of uptake was high. Eighty-four percent (84%, 13,418) of women delivering in the catchment area received all three tests. The majority of pregnant women were between the course of ANC (83% in ANC, 18% during L&D). HBV prevalence rate (2.46%) was significantly higher than HIV prevalence rate (0.7%). Syphilis prevalence rate was 0.28%. Interventions to reduce MTCT were delivered to almost all positive women and exposed infants. Ninety-six percent (96%) of HBV-exposed babies received an HBIG injection along with the first shot of HBV vaccination on the day of birth. Ninety-four percent (94%) of syphilis-infected women completed penicillin treatment. Ninety-seven percent (97%) of HIV-infected women and infants received ARV prophylaxis.

Next steps: Given the overall low prevalence of HIV in China, packaging HBV and syphilis services for pregnant women strengthens the public health...
system, improves the cost-effectiveness of MCH care, and reduces the stigma of testing for HIV alone. We plan to expand this integrated service model across Yunnan, and to provide technical support at the national level to adapt this model nationwide.

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FRAX0102 High prevalence of symptomatic acute HIV infection in an outpatient ward in Southern Mozambique: identification and follow up
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Background: HIV-infected individuals are considered hyperinfectious from the onset of acute HIV infection (AHI) up to 6 weeks thereafter. It has been suggested that this phase may be crucial in fuelling the HIV pandemic. Approximately half of patients with AHI develop non-specific fever and flu symptoms. In Southern Mozambique, although approximately 30% of fevers are due to malaria, most of the remaining fevers have unknown aetiology. The objective of this study was to determine the prevalence of AHI within the HIV-seropositive adult population presenting with reported fever in a district hospital in southern Mozambique and evaluate clinical, immunological and virological parameters of AHI.

Methods: Three hundred and forty-six adults presenting with reported fever to a public hospital in southern Mozambique were screened for AHI by serology testing, followed by HIV-RNA testing in HIV-seropositive individuals. Plasma from HIV-seropositive patients was pooled 1 : 5 for HIV-RNA testing. Whole blood was used for Plasmodium falciparum rapid-test determination at screening visit. Follow-up visits at days 7, 4 and 2 months included clinical examination, HIV serostaining, assessment of HIV-RNA, CD4 cell counts and percentage of activated CD8 T cells.

Results: Twenty-one HIV-seropositive adults had both AHI and a positive HIV-RNA testing. Median HIV-1 RNA levels at diagnosis of AHI were 6.21 log10 copies/ml (IQR 5.92-6.41) and significantly higher than at 4 months. At day 7, 4 and 2 months after screening, patients showed a median decrease in CD4 cell count of 384 cells/ml (IQR 239-441) and a median percentage of activated CD8 T cells of 6.84% (IQR 5.56-8.79).

Conclusions: High prevalence of AHI in southern African populations may play a significant role in the transmission of HIV in rural populations for a screening as a novel way to address HIV prevention.

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FRAX0103 Association between genital tract inflammation during acute HIV-1 infection and HIV disease progression
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Background: Early immune responses in the female genital tract have been shown to influence systemic spread of SIV in primate models. We have previously shown in humans that inflammation in the genital tract during acute HIV-1 infection is associated with lower CD4 counts in blood, suggesting that local mucosal factors may influence clinical HIV disease progression. The aim of this study was to investigate the relationship between genital tract cytokine levels during acute HIV infection and the subsequent rate of disease progression.

Methods: The concentrations of 32 cytokines in cervicovaginal lavage (CVL) samples from women with acute HIV-1 infection (n=37) from the CAPRISA 02 acute HIV infection cohort in Durban, South Africa were measured using Lumex and ELISA. Cytokine concentrations during acute infection were compared to matched pre-infection samples (n=18). Associations between cytokine concentrations and markers of HIV disease progression (CD4 count and viral load set-points at 12 months post-infection) were determined by regression analysis.

Results: Cytokine concentrations in CVL from acutely HIV-infected women who did not differ significantly from concentrations measured in their pre-infection CVLs. However, 12/32 cytokines measured were found to be significantly correlated pre- and post-infection. Elevated IL-1α, IL-8, IL-12(p70), IL-15, GM-CSF, TNF-α and IL-10, were each associated with higher viral load set-point 12 months post-infection, while high levels of IL-6 and RANTES were associated with lower CD4 counts. Higher concentrations of IFN-γ and TNF-α were also associated with lower CD4 counts. Following adjustment for multiple comparisons, significantly associated with CD4 counts 12 months post-infection. The profile of the inflammatory cytokine cluster (IL-1α, IL-1β, IL-6, IL-12(p70), TNF-α), determined by factor analysis, was significantly associated with both higher viral load and lower CD4 count set-points.

Conclusions: Genital tract inflammatory cytokine responses during acute HIV-1 infection were associated with more rapid HIV disease progression, while IFN-γ was associated with better disease progression.

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FRAX0104

Acute retroviral syndrome and high baseline viral load are predictors of rapid HIV progression among untreated patients diagnosed during primary HIV infection in Argentina

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Background: Diagnosis of Primary HIV Infection (PHI) is challenging and has important clinical and public health implications. PHI treatment is controversial.

Objective: To describe clinical and immunological outcomes and identify potential predictors of progression during the first year of infection among Argentinean seroconverters.

Methods: Multicenter registry of PHI-patients (negative/indeterminate WB + positive virologic test or positive WB with negative HIV-test within the previous 6 months). Cox regression was used to analyze potential predictors of progression (LT-CD4< 350 cells/µL, B or C events) at 12 months among untreated PHI-patients diagnosed between 1997-2008. Time until event was studied with Kaplan-Meier survival analysis.

Results: n=134 (males=109), 53% MSM, 37% heterosexuals. At baseline: median age 32 (IQR 25-39), median VL: 74,275 copies/mL (IQR 12,738-326,005), median LT-CD4: 479 cells/µL (IQR 341-682). Acute retroviral syndrome (ARS): 74%. Seven OIs (1 death), 9 B events and 10 non-AIDS defining serious events were observed. Forty-two patients started HAART (< 90 days of infection). Among the 92 untreated patients, 24 (26%) progressed at 12 months (1 died) versus 3 (7%) in the treated group (p=0.01). Estimates of rates of progression at 12 months among untreated patients with ARS were 34% (95%CI 22.5-46.3%) versus 13% (95%CI 1.1-24.7%) in asymptomatic patients (p=0.04). In univariate analysis, high baseline and six-month VL and lower baseline LT-CD4 were associated with progression. No association was found with age, gender, mode of HIV acquisition and calendar-year of infection. In multivariate analysis, only ARS (p=0.034) and baseline VL>100,000 copies/mL (p=0.015) remained as independent predictors of progression; HR 9.23 (95%CI 1.2-72.4) and 16.4 (95%CI 1.74-154.6), respectively.

Conclusions: In Argentina, PHI is associated with significant morbidity. One quarter of patients would require HAART during the first year according to current guidelines. HAART should be considered in PHI-patients with ARS and high baseline VL to prevent disease progression. Partially granted by Fogarty/NIH AITRP Grant#D43TW0010137.

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Virus-specific cellular immunity

**LBPE01**

Control of M184V HIV-1 mutants by CD8 T cell responses


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**Background:** Highly active antiretroviral treatment (HAART) is most effective, yet limited among others by the development of drug resistance mutations. Our hypothesis was that CD8 T cells targeting drug resistant viral mutants exist and are able to inhibit viral replication in the setting of a failing HAART regimen.

**Methods:** HIV-1 infected individuals (treatment-naïve or experiencing HAART failure) were studied. CD8 T cell responses towards overlapping peptides or optimal epitope/truncations were evaluated by interferon-gamma ELispot and intracellular cytokine staining. Autologous virus was sequenced by RT-PCR. Epitope-specific CD8 T cell lines/clones were tested for recognition of wild-type and M184V-mutated viruses in-vitro.

**Results:** CD8 T cell responses towards the regions of viral drug resistance mutations in Pol are frequently detectable in both groups of study subjects. Focusing on the M184V lamivudine resistance, we found that individuals with HAART failure who had a CD8 T cell response recognizing the M184V region had a significantly lower viral load after the emergence of the M184V mutation than those without a CD8 T cell response towards this region (p=0.01).

So far, we have defined two new CD8 T cell epitopes within this region: A0201-VYYQVDDLYV and A0201-VYYQVDDLYV. Preliminary data also suggest that M184V viruses are recognized by CD8 T cell lines/clones specific for the new epitopes in-vitro. Finally, we analyzed subject TR42 in detail. TR42 took her HAART regimen again and her viral load decreased significantly. This demonstrates that M184V viruses are recognized by CD8 T cells and that these cells are associated with a lower viral load.

**Conclusions:** We provide several lines of evidence that control of M184V HIV-1 mutants by CD8 T cells is probable. This makes a new way of prophylactic therapy feasible, namely the vaccination against drug resistance mutations.

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**Immune responses in resistant cohorts: elite controllers and uninfected**

**LBPE02**

Low levels of immune activation in viremic non-progressors HIV-infected individuals


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**Background:** In contrast to the majority of HIV-infected individuals, long-term non-progressors (LTNPs) maintain healthy CD4+ T-cell counts and do not progress to AIDS. These individuals typically have low or undetectable viremia, however, a small subset of LTNPs, hence-to-forth referred to as viremic non-progressors (VNP), present with viremia comparable to normal progressors. VNP are a largely uncharacterized patient population presenting a unique opportunity to study how progression to AIDS may be avoided despite robust virus replication. Given the role of chronic immune activation as a risk factor for progressive HIV infection, we hypothesized that the VNP phenotype is associated with low levels of T-cell activation.

**Methods:** Archived cells from 7 VNP, 10 normal progressors, and 11 uninfected individuals were analyzed by flow cytometry for markers of T-cell activation. All normal progressors and VNP had viral loads in excess of 30,000 RNA copies/ml, but VNP were defined by having little to no CD4+ T-cell loss over time.

**Results:** VNPs and progressors, respectively, had a mean viral load of 53,517 and 74,133 RNA copies/ml, and a mean CD4+ T-cell loss of 0.65 and 1.48 cells/year with respect to baseline, as calculated by linear regression. Multi-color flow cytometric analysis revealed that, in VNP, the fraction of CD4+ and CD8+ T-cells expressing markers of activation and proliferation, including HLA-DR, CD38, and Ki67, were lower than those from normal progressors.

**Conclusions:** The preliminary results of this study indicate that VNPs have lower levels of T-cell activation in comparison to normal progressors, despite similarly high viremia. Overall these data are consistent with the hypothesis that low levels of T-cell activation are a feature, and possibly a determinant, of the VNP phenotype during HIV infection. The results of this study encourage further investigation into the immunological and virological signatures of HIV-infected individuals with the VNP phenotype.

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**Viral persistence and latency**

**LBPE04-LBPE06**

Identification of Tat-responsive pre-initiation complexes (PICHs) at the HIV-1 core promoter

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**Background:** The goal of eradicating HIV from infected patients remains out of reach in large part due to the persistence of latent viral reservoirs. Latently infected cells that harbour HIV proviruses are incorporated into their genomes and are established early during infection. Active HIV replication can be reactivated from these reservoirs that are unaffected by currently available HIV therapies. HIV latency is controlled primarily at the level of transcription by the host cell trans-activating protein Tat. Signals that are essential for Tat-mediated trans-activation converge upon the HIV core promoter region that recruits the Pol II machinery. The HIV core promoter is uniquely responsive to the viral Tat protein but the molecular basis for this specificity is unknown.
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Methods: Electrophoretic mobility shift assays were employed to analyse cellular proteins that bind to the HIV core promoter. Transient transfection of reporter plasmids and single-protein assay systems with poly(A)-negativ virus were used to monitor the effect of core promoter mutations on HIV transcription.

Results: We have characterized pre-initiation complexes that bind specifically to the HIV core promoter to confer Tat responsiveness. Supershift experiments reveal that the complexes contain basal transcription factors such as TBP, TFIIA and RNA Pol II, but are biochemically distinct from those that bind to the HIV enhancer or those that do not bind to the accessory protein Tat or the cellular hpn70 gene. Furthermore, our data show that CTGC DNA sequence motifs flanking the HIV TATA box are essential for the formation of these complexes in vitro as well as for Tat trans-activation in PMBCs.

Conclusions: Our studies reveal the existence of functionally distinct pre-initiation complexes (PICs) that are necessary for Tat-activated transcription. These complexes represent potential therapeutic targets to eliminate latent reservoirs.

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Keywords: HIV, Tat, RNA polymerase, chromatin

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Antibody based vaccines

LBPE09

Induction of neutralizing antibodies by HIV-1 Env trimers fused to costimulatory molecules targeting B cells

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Background: Subunit protein or DNA vaccines are often poorly immunogenic compared to live-attenuated and whole-inactivated virus vaccines. One reason is that subunit vaccines lack co-stimulatory signals provided by various components of the more complex vaccines. We hypothesized that the immunogenicity of HIV-1 envelope glycoprotein (Env) subunit vaccines could be improved by directly fusing them to molecules targeting and activating dendritic cells or B cells.

Methods: We fused stabilized, soluble and trimeric HIV-1 Env (SOSIP.R6 gp140) to the globular domain of the costimulatory molecules CD40L, APRIL or BAFF. APRIL/BAFF constructs were expressed in insect cells, isolated and purified to homogeneity. APRIL/BAFF/CD40L fusion constructs, in particular Env-APRIL induced higher secreted IL-6, IL-10 and IL-12 in response to stimulation by Env-CD40L and through CD40 and induce maturation of human dendritic cells. Dendritic cells infected with Env-CD40L or Env-BAFF induced proliferation of autologous and allogeneic T cells (medians) and had still moderate but detectable proliferative responses to Env-APRIL. The rationale was to target the Env antigen directly to dendritic cells and B cells (CD40L) or to B cells (BAFF/APRIL), while at the same time activating these cells. CD40L, BAFF and APRIL are all trimeric TNF superfamily members with similar structures, facilitating fusion to trimeric Env. Since we had several functional assays available for measuring CD40L activity, we optimized our construct with Env-CD40L.

Results: The Env component of the Env-CD40L fusion construct bound to CD4 and neutralizing antibodies, while the CD40L moiety interacted with CD40. Furthermore, the chimeric molecule was able to signal efficiently through CD40 and induce maturation of human dendritic cells. Dendritic cells secreted IL-6, IL-10 and IL-12 in response to stimulation by Env-CD40L and were able to activate naïve T cells. When rabbits were immunized with Env-APRIL/BAFF/CD40L fusion constructs, in particular Env-APRIL, induced higher gp120-specific antibody responses and improved memory responses compared to Env alone. Furthermore, virus neutralizing antibody responses were improved and the neutralization capacity correlated with a high proportion of Env-specific antibody responses and improved memory responses compared to Env alone. Since we had several functional assays available for measuring CD40L activity, we optimized our construct with Env-CD40L.

Conclusions: Targeting antigens to B cells using APRIL or other cis-adjuvants should improve the induction of neutralizing antibodies by HIV-1 Env vaccines. Presenting author email: r.w.sanders@amc.uva.nl

Cellular immunity based vaccines

LBPE10

Longterm proliferative CD4+ and CD8+ T cell memory detected 7 years after intradermal immunizations against short HIV Gag p24-like peptides targeting dendritic cells

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Background: Raising cell-mediated responses to short peptides has been considered challenging. Vacc-4x, a mixture of 4 p24-like peptides (20-27 aa in length) were initially injected intradernally in conjunction with local small dose GM-CSF in patients on effective ART. Immunizations started late 2002 and were able to activate naïve T cells. When rabbits were immunized with Env-APRIL/BAFF/CD40L fusion constructs, in particular Env-APRIL, induced higher gp120-specific antibody responses and improved memory responses compared to Env alone. Furthermore, virus neutralizing antibody responses were improved and the neutralization capacity correlated with a high proportion of antibodies recognizing trimeric Env.

Methods: The Env component of the Env-CD40L fusion construct bound to CD4 and neutralizing antibodies, while the CD40L moiety interacted with CD40. Furthermore, the chimeric molecule was able to signal efficiently through CD40 and induce maturation of human dendritic cells. Dendritic cells secreted IL-6, IL-10 and IL-12 in response to stimulation by Env-CD40L and were able to activate naïve T cells. When rabbits were immunized with Env-APRIL/BAFF/CD40L fusion constructs, in particular Env-APRIL, induced higher gp120-specific antibody responses and improved memory responses compared to Env alone. Furthermore, virus neutralizing antibody responses were improved and the neutralization capacity correlated with a high proportion of antibodies recognizing trimeric Env.

Results: We had several functional assays available for measuring CD40L activity, we optimized our construct with Env-CD40L.

Conclusions: Targeting antigens to B cells using APRIL or other cis-adjuvants should improve the induction of neutralizing antibodies by HIV-1 Env vaccines. Presenting author email: r.w.sanders@amc.uva.nl
Prophylaxis of HIV associated infections; vaccines e.g. pneumococcal, hepatitis and HPV, co-trimoxazole prophylaxis and IPT

**LBPE13**

**Immunogenicity of the 2009 influenza A (H1N1) vaccine in HIV-infected compared to HIV-uninfected adults**

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**Background:** A novel influenza virus (2009 H1N1) recently caused a worldwide pandemic. HIV-infected persons may be at risk for influenza-related complications. However, little data exists on the immunogenicity of the 2009 influenza A (H1N1) vaccine among HIV-infected adults.

**Objective:** We conducted a clinical trial on the immunogenicity and tolerability of a single dose of an injectable monovalent 2009 influenza A (H1N1) vaccine among HIV-infected and HIV-uninfected adults (18-50 years). The primary endpoint was an antibody titer of >1:10 measured by hemagglutination-inhibition assay. Geometric mean titers (GMT), influenza-like illnesses (ILI), and tolerability were evaluated.

**Results:** We evaluated 131 participants (65 HIV-infected and 66 HIV-uninfected) with a median age of 35 (interquartile range, IQR, 27-42) years. HIV-infected persons had a median CD4 count of 811 (IQR 764-814) cells/mm³ and 82% were receiving HAART. At baseline, 35 subjects (27%) had an antibody titer >1:10. HIV-infected (29/52, 56%) compared to HIV-uninfected (35/44, 82%) were receiving HAART. At baseline, 35 subjects (27%) had an antibody titer >1:10. HIV-infected (29/52, 56%) compared to HIV-uninfected (35/44, 80%) persons were less likely to generate an antibody response post-vaccination (OR 0.26, p=0.008). Changes in the median GMT from baseline to day 28 were also significantly lower among HIV-infected versus HIV-uninfected persons (75 vs. 153, p=0.001). Five ILI occurred (two among HIV-infected persons), but none was due to the 2009 H1N1 virus. The vaccine was well tolerated in both groups.

**Conclusions:** HIV-infected adults generated significantly poorer antibody responses to the 2009 influenza A (H1N1) vaccine compared to HIV-uninfected persons. Future studies evaluating a two-dose series or more immunogenic influenza A (H1N1) vaccines among HIV-infected adults are needed.

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regimen (OBR), presence of primary PI mutations and PI RAMs or M184V/V mutation at baseline, and adherence (based on patient questionnaire). A multivariate logistic regression analysis was conducted to investigate factors predictive of virological response.

**Results:** Differences in virologic responses between DRV/r qd and bid arms were consistent across subgroups (Table).

In the multivariate model baseline CD4 cell count, number of prior PI, number of active NRTIs in the OBR, the presence of primary PI mutations and PI RAMs were not significantly associated with response. Baseline HIV-1 RNA (P=0.0014), M184V/V at baseline (P=0.0001) and adherence (P<0.0001) were significantly associated with response.

**Conclusions:** Week 48 virologic responses were comparable between DRV/r qd and bid for all subgroups. Baseline HIV-1 RNA, presence of M184V/V and adherence were independently associated with virologic response, but other factors examined (including study arm and prior PI mutations) were not.

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**LBPE16**

**Boosted protease inhibitor monotherapy as maintenance second-line anti-retroviral therapy in Africa: a randomised controlled trial (SARA)**

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**Background:** Switch to boosted protease inhibitor (BPI)-based second-line therapy usually occurs following immunological or clinical failure under the public health approach to ART. Use of BPI monotherapy as a second-line maintenance could maintain effectiveness whilst improving tolerability and decreasing costs.

**Methods:** Participants in the DART trial who had received 24 weeks of lopinavir/ritonavir-containing second-line combination therapy (CT), or move to BPI monotherapy maintenance (BPI mono) within a nested pilot trial (SARA). Participants were assessed 4-weekly by nurses and 12-weekly by doctors. The primary endpoint was change in CD4 to 24 weeks after randomisation (non-inferiority). All analyses are intention-to-treat.

**Results:** 192 participants (61% female, median 41 years) were randomised to CT(n=93) or BPI mono(n=98), a median 4.4 years after starting first-line therapy. Participants were assessed 4-weekly by nurses and 12-weekly by doctors. The primary endpoint was change in CD4 to 24 weeks after randomisation (non-inferiority). All analyses are intention-to-treat.

**Conclusions:** Week 48 virologic responses were comparable between DRV/r qd and bid for all subgroups. Baseline HIV-1 RNA, presence of M184V/V and adherence were independently associated with virologic response, but other factors examined (including study arm and prior PI mutations) were not.

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**Mean (CV%) PK Parameter**

<table>
<thead>
<tr>
<th></th>
<th>FTC/RFV/TDF FDR Tablet</th>
<th>FTC + RPV + TDF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RPV</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cmax</td>
<td>116 (20.6)</td>
<td>99.8 (30.5)</td>
</tr>
<tr>
<td>AUClast</td>
<td>3010 (34.4)</td>
<td>2600 (32.5)</td>
</tr>
<tr>
<td>AUCint</td>
<td>3410 (39.8)</td>
<td>2900 (33.8)</td>
</tr>
<tr>
<td><strong>FTC</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cmax</td>
<td>1750 (23.6)</td>
<td>1650 (21.9)</td>
</tr>
<tr>
<td>AUClast</td>
<td>9420 (14.3)</td>
<td>9420 (13.9)</td>
</tr>
<tr>
<td>AUCint</td>
<td>9560 (14.1)</td>
<td>9600 (13.5)</td>
</tr>
<tr>
<td><strong>TFV</strong></td>
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<tr>
<td>Cmax</td>
<td>325 (26)</td>
<td>291 (26.4)</td>
</tr>
<tr>
<td>AUClast</td>
<td>3110 (21.1)</td>
<td>3040 (21.3)</td>
</tr>
<tr>
<td>AUCint</td>
<td>3310 (18.7)</td>
<td>3240 (18.7)</td>
</tr>
</tbody>
</table>

**Conclusions:** The FTC/RFV/TDF fixed dose regimen tablet is bioequivalent to its individual components. This tablet is a next-generation, once-daily single-tablet antiretroviral regimen for the treatment of HIV-1 infection and may offer an attractive alternative to efavirenz-containing regimens due to tolerability concerns and potential reproductive risks.

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**Author Index**

Background: The patients were 81% male and 85% Caucasian, with median age 36 years, baseline CD4 count 302 cells/μL and HIV RNA 4.8 log copies/mL, well balanced between the arms. In the Intent to Treat analysis, Grade 1-4 drug-related neuropsychiatric adverse events (AEs) were reported in 13/79 patients (16.5%) in the ETR arm versus 36/78 (46.2%) in the EFV arm (p = 0.001). Consistent results were seen for the Per Protocol analysis. Using the Human-Patient Symptoms Profile questionnaire, patients in the ETR arm also reported better neuropsychiatric tolerability than patients in the EFV arm. The reduction in HIV RNA to Week 12 was +2.9 log10 in both treatment arms. The median rise in CD4 count was +146 cells/μL in the ETR arm and +121 cells/μL in the EFV arm. Eighteen patients discontinued the trial by Week 12 (10 in ETR arm, 8 in EFV arm). There were fewer Grade 2-4 elevations in total cholesterol and LDL-cholesterol in the ETR arm (3 and 6 patients) versus the EFV arm (18 and 13 patients).

Results: More rapidly in the MVC compared to the CT treatment group [MVC: 190/mL (-1.53/+0.73); CT group: -0.23(-1.05/+0.88); p=0.352]. CD4+ cells increased both in groups [median change per week (slope) in the MVC group: -0.70(-2.43/+1.02); in the CT group: -0.60(-2.17/+1.37); p=0.440]. DBP: p=0.307; IL-6: p=0.260; hsCRP: p=0.378]. sEPCR values decrease in both groups [median change per week (slope) in the MVC group: -0.70(-1.53/+0.73); CT group: -0.23(-1.05/+0.88); p=0.352]. CD4+ cells increased more rapidly in the MVC compared to the CT treatment group [MVC: 190/mL (100-261); CT: 133/mL (40-194); p=0.025]. Overall, changes at week 24 in sEPCR were correlated with baseline levels of CD4 + cell counts (r = 0.38, p = 0.005) [MVC group: r = -0.613, p < 0.0001; CT group: r = 0.044, p = 0.781].

Conclusions: There were no differences in the CVF PK parameters of these patients who did participate in one of three Mono Trials (Indinavir/ r, ATARITMO (Atazanavir/r), MOST (Lopinavir/r)), and remained successfully suppressed (< 50 cp/ml) in CSF and/or plasma during the entire trial, were offered the possibility to continue on long-term mono-maintenance. While on rt-MT, patients were asked to provide CSF samples in yearly / two-yearly intervals. All patients fully suppressed in CSF and plasma for at least 12 month, were included in the analysis. Patients demonstrating HIV-RNA > 100 copies/ml in CSF discontinued rt-MT and resumed triple therapy.

Results: To date, at our centre, 27 patients (15 women, 12 men) 20 years of age have started rt-MT, which has been maintained for at least one year. Until now there is a medium follow up time of 4.8 (1.1-8.4) years. 23/27 (85%) patients consented to a spinal tap for HIV-RNA detection in the CSF with a total of 63 examinations (average: 2.3 per patient). 6/27 (21.4%) patients (2 women, 7 men) developed virologic failure: 4/9 both in plasma and CSF, 2/9 in plasma only, 3/9 in CSF only. Failure in plasma occurred after a median follow up time of 2.1 years (range: 1.1 - 2.9) and in CSF after a median follow up time of 2.3 years (range: 1.1 - 5.6).

Conclusions: Even after 12 months of fully HIV-RNA suppression, 1/3 of patients may still develop failure in plasma or CSF (median follow up time of 5 years). Thus, regular lumbar punctures for therapy monitoring are recommended.
Epidemiology of HIV in male and female sex workers LBPE25

A study of AIDS/STIs-related knowledge, attitudes, beliefs, and practices among establishment-based money boys in Shenzhen, China

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Background: Money boys (MBs) who typically sell sex to gay men may also have sex with women and can be a bridge to the heterosexual population.

Methods: In Shenzhen, China, 28 establishment-based MBs were interviewed in-depth and 418 MBs were surveyed using computer-assisted self-interview. Blood samples were collected for HIV, syphilis, HCV, and HSV-2 antibody testing.

Results: MBs self-identified as homosexual, heterosexual, or bisexual. They sold sex to both men and women, and sex from male and/or female partners, and also had male and/or female casual and/or stable partners. Consistent condom use was lower with non-commercial female partners (58.6% with female casual partners, and 43.9% with girlfriends) than with commercial male partners (82.4% with male partners, and 77.2% with paid and MBs). They changed establishments frequently. One fifth (20.8%) reported ever using drugs, such as ketamine and methamphetamine. HIV/STI prevalences were: HIV 3.3%, syphilis 10.5%, HCV 21.1%, and HSV 1.4%. Overall prevalence of any HIV/STI was 21.8%; 58.3% for minorities, 21.1% for Hans (the largest ethnic group); and 28.1% for those who had only male partners, but 16.7% for the rest. Odds for HIV infection was significantly higher for MBs with only male partners, OR=8.01 (95% CI: 1.77, 36.26).

Conclusion: MBs, especially homosexual and minority MBs, are at high risk of HIV/STI infections and have a potential to spread HIV/STIs to both homosexual and heterosexual groups. Targeted appropriate interventions emphasizing safer sexual activities with all types of partners need to be implemented.

Epidemiology of HIV in people who use drugs LBPE24

Does initiation of HIV antiretroviral therapy influence patterns of syringe lending among injection drug users?

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Background: The delivery of antiretroviral therapy (ART) to injection drug users (IDU) may be influenced by provider concerns regarding the potential for increased HIV-related risk behaviour following the initiation of HIV treatment.

Methods: We evaluated whether ART initiation was associated with changes in syringe lending patterns among a long-term prospective cohort of HIV-positive IDU in Vancouver, Canada. The date of ART initiation was determined through a validated linkage to a centralized provincial pharmacy database. We used generalized linear mixed-effects models to examine whether syringe lending was more common during the 12 months following ART initiation.

Results: Among 380 ART-naïve individuals eligible for this analysis, the median age was 34 (interquartile range [IQR]: 28 - 41), 171 (45.0%) were female, 148 (38.9%) were of Aboriginal ancestry, and 92 (24.2%) reported lending syringes at baseline. Between May 1996 and April 2008, 260 (68.4%) initiatedART. Syringe lending was not significantly associated with ART initiation in unadjusted (odds ratio = 0.72, 95% CI: 0.38 - 1.36) or adjusted (odds ratio = 0.78, 95% CI: 0.42 - 1.45) analyses.

Conclusion: Concerns regarding increased injection risk behaviours following the initiation of ART were not observed in this setting. These findings should be helpful in addressing the concerns among ART prescribers that IDU may engage in more injection-related risk behaviours after initiating HIV treatment. In light of these findings, in addition to the known impact of ART on morbidity and mortality, ART delivery to IDU should be immediately scaled up to meet the needs of this marginalized and underserved population.

Epidemiology of HIV in male and female sex workers LBPE26

SIALON Project (2008-2010): HIV prevalence and undiagnosed HIV infections among MSM attending gay venues in six European cities (Barcelona, Bratislava, Bucharest, Ljubljana, Prague and Verona) - project co-funded by the European Commission under the Public Health Programme 2003-2008

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Background: HIV prevalence among MSM has risen in recent years in Western Europe. The objective was to obtain reliable information on HIV prevalence and undiagnosed HIV infections.

Methods: Cross-sectional study on MSM who have had sex with another man during the last year. 2,407 subjects were enrolled (circa 400 per country).

Results: Valid oral fluid samples were 2,287. Average age of respondents was higher in Barcelona and Verona (38.2 and 35.8 years respectively) than in the other cities. Overall HIV prevalence was 3.3%.

Conclusions: Concerns regarding increased injection risk behaviours following the initiation of ART were not observed in this setting. These findings should be helpful in addressing the concerns among ART prescribers that IDU may engage in more injection-related risk behaviours after initiating HIV treatment. In light of these findings, in addition to the known impact of ART on morbidity and mortality, ART delivery to IDU should be immediately scaled up to meet the needs of this marginalized and underserved population.

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Track C > Epidemiology and Prevention Sciences

Risk factors for acquisition of HIV LBPE23

The risk factors of HIV infection among young women in Sub-Saharan Africa: evidence from the Demographic and Health Surveys (DHS)

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1City University London, Department of Sociology, London, United Kingdom

Background: Women in sub-Saharan Africa (SSA) bear a disproportionate burden of HIV infections, accounting for 60 percent of HIV infections. The gender disparity is particularly striking among young people, which has been partly attributed to women having older sexual partners, especially in societies where social norms dictate marriage at an early age for women. The specific objectives of this paper are to: (i) determine the risk factors of HIV infection among young women in SSA; and (ii) establish the role of early marriage and other sexual behaviour factors in the risk of HIV infection.

Methods: We use existing data from the international DHS programme conducted during 2003-2008 in 20 countries across SSA, focusing on the sample of young respondents aged 15-24 years in households sampled for HIV testing. The analysis is based on multilevel logistic regression models, placing particular emphasis on country/community level variations in the risk of HIV infection among young women, and on gender disparities.

Results: Across countries in SSA, young women aged 15-24 years have on average about triple the odds of HIV infection as their male counterparts of similar age, and the gender disparity remains high after socio-economic and sexual behaviour characteristics are controlled for. Socio-economic factors are more important predictors of the risk of HIV infection among young women than among men. As might be expected, earlier sexual debut, premarital sex, multiple sex partners and non-condom use with non-spousal partner are all associated with an increased risk of HIV infection among young women, but there is no evidence that early marriage is associated with a higher risk.

Conclusions: Interventions on safer sexual practices targeting less empowered young women such as those with no/low education or living in female-headed households are likely to have a considerable impact in reducing the risk of HIV infection among young women in SSA.

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Epidemiology of HIV in people who use drugs LBPE24

Methods:

- Collection of oral fluid samples from ART-naive IDU
- Detection of HIV-1 antibodies using an EIA test
- Confirmatory testing using Western Blot
- Determination of ART initiation date

Results:

- Among 380 ART-naive IDU, HIV prevalence was 3.3%.
- Syringe sharing was not significantly associated with ART initiation.

Conclusion:

- Articulate strategies are needed to reduce injection risk behaviors among ART-naive IDU.
- Further research is needed on the socio-economic factors associated with HIV infection among IDU.

Epidemiology of HIV in men having sex with men LBPE26

Methods:

- Collection of oral fluid samples from MSM
- Detection of HIV-1 antibodies using an EIA test
- Confirmatory testing using Western Blot
- Determination of ART initiation date

Results:

- Among 380 MSM, HIV prevalence was 3.3%
- Syringe sharing was not significantly associated with ART initiation.

Conclusion:

- Articulate strategies are needed to reduce injection risk behaviors among ART-naive MSM.
- Further research is needed on the socio-economic factors associated with HIV infection among MSM.
Methods: The stepwise approach was used in the scaling up PMTCT services, coupled with the regionalization of PEPFAR-PMTCT implementing partners and the use of district approach. The sites started with hospitals at regional and districts and later on scaled down to the health centres and dispensaries. Regionalization process involved allocations of regions to each implementing partner. This helped in the distribution of resources and equity of health services. The district approach included building capacity at the current level, ensuring financial sustainability of the programme activities and creating mechanisms for on-going supportive supervision and monitoring.

In addition, adherence to the UNAIDS strategy of Jones, facilitated the rapid expansion of the services.

Results: Results showed that, between 2000 and 2009, the number of sites offering PMTCT services have increased from five to 3,628, pregnant women tested for HIV increased from 8,489,15,472(55%) to 1,194,172(2,223,964(98%)) and those HIV infected pregnant women who received ARV prophylaxis increased from 351,98,000(0.3%) to 8,832,86,000(0.8%) respectively.

Conclusions: More expansion of PMTCT services is needed to achieve universal access. In addition, quality of services along the continuum of care needs to be improved so as to avert Paediatric HIV infection, identify and link those who need HIV care and treatment services.

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Population-based surveys with HIV testing

**LBPE28**

**Prevalence of undiagnosed HIV-infection in the general population in Madrid, Spain: evidence for the need of effective testing programs**

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Background: Cost-effectiveness studies have shown that routine voluntary HIV testing should be considered in populations with HIV prevalence 20.1%. Knowledge of the prevalence of both diagnosed and, especially, undiagnosed HIV-infection in a given population is key to adopting decisions on testing programs. We aim to estimate prevalence of undiagnosed HIV infection in Madrid.

Methods: Population-based cross-sectional study conducted in 2008-2009 among a representative sample of the population ≥15 years in Madrid. A blinded serosurvey was carried out in blood samples of people who attended a primary care center for any reason. The sample was weighted according to health area, age, sex, and immigration status. Persons previously diagnosed with HIV infection were excluded from testing. Overall, 70% of the selected population agreed to participate in the study.

Results: A total of 3,683 persons were included in the study. Eight patients who self-reported as being HIV-infected were not tested. Among the remaining 3,675 participants, HIV-infection was diagnosed in 12 patients (pondered prevalence 0.32%;95%CI 0.13-0.57). The prevalence of undiagnosed HIV infection was greater in men (0.51%;95%CI 0.12-0.89%) than in women (0.20%;95%CI 0.00-0.44), in participants from other countries (0.51%;95%CI 0.23-1.18) than those born in Spain (0.30%;95%CI 0.06-0.53), and those aged 21-30 years (0.65%;95%CI 0.01-1.29) or 31-40 years (0.71%;95%CI 0.02-1.41). Eleven out of the 12 patients were aged between 20 and 45 years. Of note, 10 of the 12 participants with undiagnosed HIV-infection had been at least once to see their physicians in the last month for reasons unrelated to HIV-infection.

Conclusions: We have found a high prevalence of undiagnosed HIV infection among persons seen at primary care centers in Madrid among a representative sample of the population ≥15 years in Spain. These findings support the need to implement more effective testing programs among persons seeking medical care, including routine voluntary HIV testing.

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Prevention of mother-to-child transmission

**LBPE29-LBPE30**

**LBPE29**

Scale up of PMTCT services in Tanzania

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Background: The Ministry of Health and Social Welfare (MoHSW) in collaboration with UNICEF established the initial five PMTCT pilot sites in the year 2000 located in four referrals and one regional hospital of Tanzania mainland. In response to the international goals and commitments, ( UNGASS and MDGs 2000 located in four referrals and one regional hospital of Tanzania mainland.

In Central-Eastern European cities.

HIV prevalence: 17.0% (Barcelona), 11.8% (Verona), 6.0% (Bratislava), 5.6% (Bucharest), 4.6% (Budapest) and 4.5% (Prague). In the other sample, this indicator was significantly lower among young people than among people aged above 40 years (12.3% vs 0.5 years).

Undiagnosed HIV cases and recent infections: 56% of all HIV+ MSM were not aware of their serostatus. This figure was almost 80% in Bucharest and Ljubljana, and lower than 50% only in Barcelona (46.6%). Considering HIV+ MSM who were tested over the last year and got the result, 49.6% reported an accurate knowledge of their serostatus. At city level these percentages were higher than 80% in Ljubjana and Bucharest while the lowest figures were in Barcelona and Bratislava (near 40%). In Verona and Ljubljana, these values were higher than 60%.

Conclusions: HIV prevalence was higher in Southern European cities than elsewhere. Outreach prevention programmes promoting HIV testing are needed in order to promote HIV testing and detect undiagnosed infections. Data suggest that quite a number of infections was recently acquired, particu- larly in Ljubljana and Bucharest.

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Methods: The stepwise approach was used in the scaling up PMTCT services, coupled with the regionalization of PEPFAR-PMTCT implementing partners and the use of district approach. The sites started with hospitals at regional and districts and later on scaled down to the health centres and dispensaries. Regionalization process involved allocations of regions to each implementing partner. This helped in the distribution of resources and equity of health services. The district approach included building capacity at the current level, ensuring financial sustainability of the programme activities and creating mechanisms for on-going supportive supervision and monitoring.

In addition, adherence to the UNAIDS strategy of Jones, facilitated the rapid expansion of the services.

Results: Results showed that, between 2000 and 2009, the number of sites offering PMTCT services have increased from five to 3,628, pregnant women tested for HIV increased from 8,489,15,472(55%) to 1,194,172(2,223,964(98%)) and those HIV infected pregnant women who received ARV prophylaxis increased from 351,98,000(0.3%) to 8,832,86,000(0.8%) respectively.

Conclusions: More expansion of PMTCT services is needed to achieve universal access. In addition, quality of services along the continuum of care needs to be improved so as to avert Paediatric HIV infection, identify and link those who need HIV care and treatment services.

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Integrating HIV prevention into reproductive health/STI programmes

**LBPE31**

**Related linked response for prevention care and treatment of HIV/AIDS, STI and reproductive health issues in Cambodia: results after 18 months of implementation**

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Issues: In Cambodia, despite a decreasing HIV prevalence (0.9% in 2006), and improved access to HIV care and treatment services, coverage of preven- tion of mother-to-child transmission (PMTCT) services remained low. The addi- tion, a high maternal mortality reflects limited coverage of quality reproduc- tive health services. The main objectives of the Linked Response (LR) are to increase access to comprehensive HIV prevention, testing, care and treatment and to strengthen existing reproductive health services, including PMTCT.

Description: The LR approaches on strengthening linkages between services offered at public health facilities but also between communities and health facilities and within community-based organisations. The practical steps included baseline assessment, intervention development, training health staff and monitoring progress.

Lessons learned: Overall, the proportion of pregnant women tested for HIV was
in the five districts increased from 7% (1489/21377) in 2007 (before implement-
ing the LR) to 85% (18388/21569) in 2009. Antenatal care (ANC) cov-
ervation (at least one visit) increased by 25% and health facility delivery rates
increased from 26% to 46% between 2007 and 2009. While 55% (45/82) of
HIV-positive women entering the PMTCT programme were newly identified
during ANC, 45% of them were already known as living with HIV. Out of 53
women who delivered, 33 received antiretroviral (ARV) therapy, 14 ARV pro-
phylaxis and 6 did not use ARVs. The majority of infants (51/53) received ARV
prophylaxis. Out of 26 babies tested at 30 weeks, 2 were HIV-positive.
Next steps: The LR in 5 districts improved PMTCT coverage but also other
reproductive indicators. The follow-up of HIV-positive women and their chil-
dren was strengthened.

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Community mobilization, social mobilization
LBPE32

Using cultural platforms for HIV-prevention and
behavior-change interventions in Southern Africa

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Background: HIV prevention in Africa is often implemented in ways impervi-
ous to local cultural context. Culture is often viewed only as an obstacle to
overcome in order to achieve an effective, gender-equitable, human rights-
based set of interventions. The result is health and development programmes
which often circumvent Traditional Political Authorities (TPAs). TPAs, such as
chiefs, remain influential in Africa and are often eager to collaborate in efforts
that potentially benefit their areas of authority. This study was conducted
in four countries in Southern Africa, where levels of HIV prevalence are the
world’s highest.

Methods: This qualitative study used focus group discussions and in-depth
interviews with TPAs and ‘ritual specialists’ to better understand cultural pat-
terns and to discover more effective ways of working in ways that build upon
the strengths of culture and develop partnerships with indigenous leaders in
HIV-prevention efforts. Among 117 participants, 73 traditional leaders
took part in six focus group discussions and 44 participated in in-depth in-
terviews.

Results: The indigenous leaders participating in the study largely felt by-
passed and marginalised by organised efforts to prevent HIV infections. They
believed that HIV-prevention programmes typically confronted, circumvented,
criticised or condemned traditional culture. Yet indigenous leaders offered in-
novative ideas about addressing behavior, especially multiple and concurrent
partnerships. Participants discussed ways to revive traditional social struc-
tures and cultural mechanisms as ways to incorporate HIV-prevention and
gender-sensitivity training into existing cultural platforms, such as rites of
passage, chiefs’ councils and traditional courts.

Conclusions: If behaviors known to be transmitting HIV, such as multiple
and concurrent partnerships, are to be targeted through interventions, en-
gagement with the indigenous sector leaders and organizations is imperative.
Incorporating TPAs in the development and implementation of HIV-prevention
programmes could be an effective method of accessing the behaviours which
prevention programmes are seeking to change, especially among the rural
majority of Africans.

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Social class, social structures,
poverty and socioeconomic
stratification
LBPE33-LBPE34

Sick over fashion or sick with fashion? Gendered
associations of family wealth and the consumption of
“modern goods” with transactional sex among
young men and women (15-24) in Antananarivo
and Antsiranana, Madagascar

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Background: There is current interest in “sex for consumption,” or young
women pursuing transactional sex (TS) for modern goods, as opposed to poor
women practicing “survival sex.” Related are ongoing deliberations over the
relationship between wealth and/or poverty and HIV in sub-Saharan Africa.
We contribute to the understanding of these complex relationships with data
collected from youth in Madagascar.
Methods: We conducted a three-tiered cluster design population-based sur-
vey of 2,255 youth in two regions in December, 2009. Using sex-stratified
multivariate logistic regression analysis, we predicted the odds of reporting
having engaged in three outcomes: 1) multiple sexual partners in the last
year, 2) one or more sexual behaviors characterized by exchange (reported gift/gift-
exchag "for no specific reason" or "for household"), and 3) formal transac-
tional sex. We examined the associations with asset-based family wealth,
disposable income, and perception of self as fashionable, along with other
co-variates (e.g., education, marital status, ethnicity, age).
Results: Of young participants, 74% responded to questions regarding wealth,
income, and perception of self as fashionable, along with other covariates
(e.g., education, marital status, ethnicity, age). We discuss concerns regarding wealth, inequality and HIV; poverty and
marital status were also important.
Conclusions: Positive associations between wealth, self-identifying as fash-
ionable, and multiple partners or exchange relationships among women sug-
gest that women may be "sick with fashion," rather than in order to acquire
it. We discuss concerns regarding wealth, inequality and HIV; poverty and
social exclusion for women; and gendered implications of wealth determining
women's health and social behaviors.
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LBPE34
Social vulnerability contexts and the meanings of the HIV risk exposure amongst young infractors, in fulfilment of educational social measure in the city of São Paulo, Brazil

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Issues: a) In Brazil, adolescents under 18 years who infractor of the law are not charged criminally, and meet educational measures, led by care psychosocial
protection (NPPE). As a rule they live in social contexts marked by poverty and violence, among others, also responsible for HIV infection.
Description: Since 2009 a specialized healthcare service in HIV / AIDS and a NPPE of the city of São Paulo develop a prevention project in pairs involving
young infractors as agents of prevention, and public and other community youth. During this process of training agents and during activities undertaken
by them has been possible to better understand the psychosocial contexts that made vulnerable by HIV/AIDS, known as cycles of violence, or pockets of violence. Among these are the following: -lack of school, unemployment, leisure, drug dealing, among others. Brokering the sale of drugs, young people are exposed to daily violence from drug traffickers and police, leading them to grasp the concept of a risk
quite peculiar. Their claims and actions are marked by immediacy and there is little concern about the dangers of a general death. Living dangerously is a value and they seek to demarcate their identities in the world of crime, for example, the body tattooed symbols of the offenses committed.

Next steps: It seems important to consider the particularities of differ-
ent "youths" and in the case of young offenders, educational work can have
the main axes to expand their repertoire of knowledge and values by employing
actions that encourage building projects by moving them from the immediate to the long term, and vice versa.

Lessons learned: In this context, to ignore the risks is a value in the forma-
tion of identities and therefore does not draw on projects or thinking about the future, HIV infection becomes irrelevant to these people.

LBPE35
Violence exposure among urban youth living with HIV: implications for their health risk behaviors and care

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Background: Urban adolescents living with HIV are often confronted with a variety of difficulties as they struggle to proceed through life while carry-
ing a heavy burden of a highly stigmatized and life-threatening illness. Violence exposure is just one of the many environmental stressors faced by these
youth that present added challenges to the already difficult task of adhering
to a lifelong treatment program. Health outcomes have been associated with
exposure to violence including substance abuse, psychosocial problems, and
sexual risk-taking practices. However few research studies have characterized
the prevalence of violence exposure among a heterogeneous population of urban youth living with HIV (YHL) and described its potential impact
on their health risk behaviors.

Methods: The preliminary data being presented here includes 112 partici-
pants who have completed their initial visits of a study assessing coping styles as predictors of adherence in urban YHL. The sample was recruited from two clinics in Washington, D.C. that serve adolescents with perinatal and risk-ac-
quired HIV. The youth range from age 13 -22 years of age. Study participants
responded to questions regarding their past and present history of violence exposure as well as the degree to which these experiences affected them.

Results: Results indicate that 36.6% knew of someone who had been robbed or mugged, and 17.9% knew of someone who had been killed through violence, 26.8% within the last year. Significant
associations were found between violence exposure and effects on women's health outcomes among different demographic groupings of YHL (e.g., mode of transmission, age, gender, sexual orientation).

Conclusions: Gaining a better understanding of the impact of violence expos-
ure on YHL has important implications for managing care.
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Religious institutions and faith communities

LBPE36
Holy water sites in Ethiopia: an opportunity for ART scale-up and adherence

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Issues: ART adherence is important for sustained suppression of HIV. Various
reports indicate religious beliefs as one reason for not starting ART and non
adherence to ART. Although concurrent use of ART and holy water is support-
ed by religious leaders, many patients continue to choose between the two.
In one hospital report, using holy water was the reason for 13/17 patients
discontinuing ART. Thousands of holy water sites are found in Ethiopia where
people gather in search of a cure for various illnesses including HIV.

Description: Since 2008, I-TECH has been providing outreach VCT and link-
age services to clients at a rehabilitation center near Rasidane Harim Mon-
astery, one of thousands of holy water sites, where more than 3000 peoples
gather. To assess the progress of VCT and linkages services, a retrospective
analysis of 373 clients who received VCT services from July - December 2008
were compiled through records review.

Lessons learned: High positivity rate and previous test positive history
makes the group different from the general population receiving services at
usual VCT centers; they tend to be tested repeatedly, anticipating cure. HIV
positivity rate was 42%. Women, who comprised 68.6%, had HIV positivity rate
of 48%. Of HIV-positives, 57% knew their status prior to testing. The
positivity rate among 247 newly tested was 27% (national=2.8%). Of all
HIV-positive, 69% accepted a referral to HIV care.

Next steps: These groups deserve special attention from both medical and
faith communities. A different approach from usual counseling and referral
practices is needed and further research is proposed on the approach.
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Specific issues in prevention, treatment, care and support with women and girls

LBPE37
Living with HIV/AIDS in Lebanon: women’s perceptions of meaning

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Background: This study is the first to examine what it means for women to
live with HIV/AIDS in Lebanon. The purpose of the study is to understand how
women living with HIV/AIDS (WHLA) in Lebanon view their sero-status and
the socio-cultural factors that frame these understandings. The main research
question that this study seeks to answer is: What is the meaning of living with
HIV for Lebanese women? A secondary research question that this study
seeks to answer is: What are the contexts in which women’s meanings are

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formed about living with HIV/AIDS?

**Methods:** The primary research question is being examined through semi-structured in-depth interviews with WUWHO in Lebanon. The second research question is being explored through semi-structured interviews with members of the community to triangulate the data. Qualitative inquiry using Constructivist Grounded Theory and Symbolic Interactionism will drive the data collection and analysis.

**Results:** There are several important preliminary findings to date at the study’s current stage of initial analysis. The effects of stigma likely limit willingness to participate among WUWHO. However, preliminary data suggest the need for a context-specific definition of HIV/AIDS-related stigma that does not rely heavily on dichotomized conceptualizations of disclosure. WUWHO in Lebanon represent an extremely hard-to-reach population; there are both advantages and challenges in conducting international qualitative research relevant to the discourse on insider-outsider perspectives among scholars.

**Conclusions:** Final findings will provide information contributing to the understanding of women and leading to implications for policy recommendations, treatment and prevention strategies, and future research.

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**Gay and other homosexually active populations**

**LBPE38**

**Blow the whistle to ensure rights here, right now**

A. Harchan, Gay Men/Transgenders in Chennai

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**Issues:** MSM/Transgenders are among the most repressed categories, and the high prevalence of STI/HIV/AIDS among them add a significant problem which is being reduced and controlled by providing all possible services like condom promotion in the field. Still there are several problems faced by the MSM/Transgender community in the field. These include harassment by rowdys/gangsters, and clients.

**Description:** To address the issues of MSM and Transgender, ICWO- Indian Community Welfare Organization Project team developed a rescue program for the MSM/Transgender in the field area. The MSM project is supported by TANSACS- Tamil Nadu State AIDS Control AIDS Control Society, State Government. As part of a new Advocacy effort, ICWO initiated the BLOW THE WHISTLE CAMPAIGN – A CAMPAIGN TO STOP VIOLENCE AGAINST GAY MEN IN CHENNAI, on 1st December 2009, World AIDS Day. That is 300 common whistles were distributed to the community members who are in the violence prone cruising areas in Chennai. Whenever there is an occurrence of violence or any sort of harassment in the field the MSM/Transgender can blow the whistle, hearing the unique sound of the whistle nearby MSM/Transgender community would come for rescue immediately. It was well appreciated by the community.

**Lessons learned:** This activity helped to provide excellent services to the MSM/Transgender community in the field without any barrier. Condom promotion was strengthened; more information about STI was induced to the community. Thus this served as one of the stepping stone in controlling and preventing STI/HIV/AIDS among the MSM & TG community. Reducing violence eventually increased access to health care services among MSM and Transgender community in Chennai.

Next steps: Since created a good impact in the community, ICWO plans to create better awareness among the community about this programme so that it helps them to react immediately at any crisis.

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**Access and availability of HIV/AIDS treatment and care, health services and mental health**

**LBPE39**

**Lessons learned from the mediation within a care center in HIV/AIDS in Senegal**

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**Issues:** In Senegal, prevalence of HIV in general population is still low (0.7%). However, it is very high within vulnerable groups (men having sexual relations with other men (MSM) 21, 8%). This underlines the relevance of taking actions towards these populations. The recruitment of community mediators in a care center, called Center of Ambulatory Treatment in Fann’s Hospital is a result of these needs. These mediators are here to facilitate access to care.

**Description:** After a study of prevalence among MSM in 2004, the CAT decided to ensure the care of MSM. 120 MSM were referred to CAT. Four mediators take turns every week to welcome MSM and to support them. They carry out actions of counseling for HIV testing, for therapeutic education... They organize focus groups, community meals and realize actions of prevention on HIV in which they distribute condoms and lubricants.

**Lessons learned:** The presence of peer educators in the care center allowed MSM to feel confident and to share their experiences. During last three months, the CAT carried out 88 screenings of HIV and counseling among MSM. It seems that MSM are less afraid about HIV testing since the presence of mediators. They are more interested of their health and come more easily at the CAT. In the same way, the request for condoms and explanations of their use has increased. In three months, 1,100 condoms were distributed.

Next steps: The mediation can contribute effectively to ameliorate the universal access to care and to prevention especially among vulnerable groups. However, it is very important to promote the creation of an enabling legal and social environment in order to achieve well these actions among MSM, because the context in the Senegal is too repressive and stigmatizing concerning to homosexuality.

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Effect of HIV funding/programming on other services e.g. maternal health, child health, chronic non-communicable conditions

LBPE40
Can foreign assistance positively affect health outcomes? PEPFAR and maternal mortality in Africa

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Background: At its inception in 2003, President’s Emergency Plan for AIDS Relief (PEPFAR) of the United States government was a major initiative to expand access to highly active antiretroviral therapy (HAART) in countries with generalized HIV epidemic. The efficacy of that foreign assistance in HAART coverage is clear; PEPFAR is responsible for providing HAART to nearly 2 million patients. New research suggests that the HIV might be a driving force in increases in maternal mortality. This research examines that effect PEPFAR has had on this disturbing trend.

Methods: New maternal mortality data were released by the Lancet on April 12, 2010. They were used in panel set of 40 African countries at four time points (1980, 1990, 2000, 2008). A statistical model using both panel corrected standard errors and fixed effects were used.

Results: PEPFAR had a positive and substantial effect on reducing maternal mortality; if a country received PEPFAR funding, maternal mortality was lower by 13% in the panel corrected standard errors model and 9% in the fixed effects model. Both results surpassed the 95% percent level of statistical confidence. In Southern Africa, maternal mortality ranges from 469 to 1,140 deaths per 100,000 births, and the effect of PEPFAR is large. Democratic governance or the number of medical doctors did not have an effect on maternal mortality.

Conclusions: The effectiveness of foreign assistance has been challenged, and this research shows a clear, positive outcome directly related to aid. It is disappointing that democratic governance has not led to great fiscal health effort or more responsive policies towards the Millennium Development Goals. If foreign assistance in HIV-related activities has value, the fiscal sustainability of these programs in recipient countries becomes paramount.

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Adapting HIV programmes to systems with limited health care personnel

LBPE41
Working with what we have: early identification of HIV exposed children at community OVC centers using simple pediatric algorithm by frontline social workers

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Issues: Early identification of infants and children exposed to HIV is a critical step in pediatric HIV care. Without treatment, 50% of HIV infected infants will die before their second birthday and only 8% of infants born to HIV-positive women initiated co-trimoxazole prophylaxis according to WHO guidelines. In low resource setting, early virologic diagnosis using PCR-DBS is not universally available. Using a simple algorithm exposed children could be identified at community level and referred for HIV testing and clinical evaluation.

Description: The number of medical doctors did not have an effect on maternal mortality. Without treatment, 50% of HIV infected infants will die before their second birthday and only 8% of infants born to HIV-positive women initiated co-trimoxazole prophylaxis according to WHO guidelines. In low resource setting, early virologic diagnosis using PCR-DBS is not universally available. Using a simple algorithm exposed children could be identified at community level and referred for HIV testing and clinical evaluation.

Results: Children identified at community OVC centers increased from 64 to 229 and those enrolled on cotrimoxazole prophylaxis increased from 340 to 922 over a period of one year.

Lessons learned: The OVC center is an ideal community platform for early identification of pediatric HIV patients. Frontline health care providers with adequate training are essential in identifying exposed children and linking them to HIV testing and further clinical evaluation.

Recommendations: Expand the use of all maternal and child health entry points to identify and test infants and children for HIV including OVC centers. Link OVC program to ART, TB, and HBC programs through referral systems and training. Institutionalize co-trimoxazole prophylaxis as early as possible (4-sweeds) for children exposed or infected with HIV. Institute early virologic HIV testing at 6 weeks wherever possible (including using DBS-PCR).

Introduction earlier antibody testing (9-12 months).

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Working with what you have: improving local data systems to support HIV programmes

LBPE42
Electronic linkages between the national death registration and the national antiretroviral treatment (ART) program to monitor patient survival in Thailand

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Background: With Thailand universal health care coverage policy and program goals to reduce mortality of persons living with HIV (PLHIV), Thailand’s national ART program has been successfully scaled up. About 180,000 PLHIV were receiving ART at the end of 2009. An effective information system to monitor program outcomes will provide key information for policy and program planning.

Methods: A web-based monitoring system was implemented in April 2007 to prospectively monitor program services and outcomes. The Ministry of Interior national death registration system was centrally online-linked to the ART monitoring data by 13-digit unique personal identifications. An encrypted network security system was set up to protect personal information. Structured query language was written to obtain dataset without any personal identification for analysis. Cohorts categorized by year at ART initiation were analyzed. Kaplan-Meier survival analysis and Cox Proportional Hazard Regression modeling were used to estimate survival rates and factors associated with death.

Results: Since Oct 1, 2007, 40,720 naïve PLHIV registered for ART at 901 hospitals nationwide. Of those, 2,684 died within the first 18 months of ART. Survival rate at 6, 12 and 18 months were 93.3% (95%CI 93.0-93.6), 90.6% (95%CI 90.3-91.0) and 88.5% (95%CI 87.9-89.1) respectively. Patients with CD4 > 200 /mm3 at ART initiation had higher death rates than those with CD4 201-350 /mm3 (adjusted Hazard Ratio (HR) 5.8% (95%CI 4.1-8.2). Other factors significantly associated with death included male sex (adjusted HR 1.3% (95%CI 1.2-1.4), age >45 years (adjusted HR 1.2% (1.1-1.4) and having TB disease (adjusted HR 1.2% (95%CI 1.02-1.4). No significant difference in mortality was observed among those who initiated with 2NRTI+1NNRTI regimen and PI-based regimens (p > 0.05).

Conclusions: Electronic linkages of the national death registration system with the national ART monitoring system are feasible. This can provide accurate and timely information on survival and associated factors for deaths.

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Quality improvement interventions to improve systems performance

LBPE43
Challenges of implementation of integrated national laboratory wuality improvement in Uganda

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Issues: The quality of laboratory service is crucial in patient management and disease surveillance. Due to many parallel laboratory strengthening programs, implementation of an integrated laboratory quality improvement system is difficult. In 2009, we initiated an integrated external quality assessment for HIV, malaria and TB proficiency testing together with audit in 214 laboratories. Our objective was to improve quality of services using an integrated approach.

Description: National reference laboratories for HIV/AIDS, TB, and the public health prepared and validated the proficiency tests that were centrally dis-
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Sustainability.

Ining them to better judge the trade-off between rapid scale-up and financial cost, the costs of HIV care and treatment remain substantial. Detailed data

Conclusions: The costs of antiretroviral therapy in Tanzania: evidence from ten health facilities.

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Background: Almost 6% of Tanzanians aged 15 to 49 years are infected with HIV. Expanding access to HIV care and treatment for these individuals poses a grave financial challenge to the government, local communities and international donors. This paper estimates the per-patient cost of HIV treatment services in the Tanzania national HIV treatment program.

Methods: This study collected empirical data on the recurrent and capital costs of service delivery at 10 outpatient HIV treatment facilities across Tanzania in 2007 and 2008. Cost data were collected on all activities involved in the provision of HIV care and treatment, and categorized according to source of support; expenditure component, and program activity. Data on patient volume and service delivery characteristics was collected from routine reports and key informant interviews. Analyses adopted a programmatic perspective, and estimated annualized economic costs for major patient types.

Results: The median economic costs per patient-year were $434 (2008 USD) for established adult ART patients, ($160 excluding ARVs costs), and $119 for pre-ART patients. Costs were higher for newly initiated (first 6 months) and pediatric patients compared with established adult patients. The largest single cost component among ART patients was ARVs (median annual cost = $216), followed by personnel ($72) and laboratory supplies ($46). The Tanzanian government (which includes budgetary support from other funders) was the largest source of funding (49%) followed by US ($43). The latter devoted 35% of its total spending to ARVs and Tanzanian government (including sup-

Conclusions: Although recent studies show a reduction in the per-patient cost, the costs of HIV care and treatment remain substantial. Detailed data on per patient treatment costs provides policy-makers with a concrete infor-
mation base for resource allocation and financial planning decisions, allowing them to better judge the trade-off between rapid scale-up and financial sustainability.

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Insurance schemes for HIV

(LPBE45)

Insurance for PLHIV: experience from a pilot health insurance model in India

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Issues: Out of pocket expenses for accessing quality healthcare services have been a challenge for PLHIV in India. In the absence of evidence on the viability, companies perceive insurance for PLHIV beyond the scope and exclude from generic insurance products. National AIDS Control Programme envirions mobilising private sector insurance companies to define their role and contribution in the programme.

Description: Project Connect led by PSI funded by USAID in partnership with Star Health and Allied Insurance and Karnataka Network for People Living with HIV/AIDS facilitated a group health insurance policy for PLHIV in India. The sum assured is $667 at an annual premium of $34. The policy covers a maxi-
mum of $333 for in-patient treatment and an equal amount is dispersed at AIDS stage. Tuberculosis and Gastroenteritis are excluded in first four years. Policy was launched in 2008. Connect reached out to 15949 PLHIV under the insurance literacy campaign and 5202 PLHIV were enrolled covering southern Indian states by April 2010.

Lessons learned: Nearly 200 PLHIV who required hospitalisation were able to avail quality private healthcare services. The average amount of claim set-
tied was $149. Initial findings from the assessment of quality of life of insured PLHIV in Karnataka in comparison with a control group reveals that PLHIV insured were significantly more likely to perceive better physical quality of life. Four out of every five PLHIV insured during 2009-2010 renewed the policy in April 2010 for another year.

Next steps: Stigma and discrimination by healthcare providers, poor pay-
ing capabilities of PLHIV and limited insurance awareness are challenges. Sensitising providers, strengthening systems of PLHIV networks, gathering and disseminating strategic evidence to advocate for insurance solutions, est-
tablishing synergies with social protection schemes and exploring alternate community health financing mechanisms are next steps. Pilots to mainstream PLHIV insurance with general population are on.

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Co-payments and out-of-pocket expenditures: impact on adherence and outcomes

(LPBE46)

Factors contributing to delayed initiation of ART: the case of Lilongwe, Malawi

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Background: Malawi has been greatly affected by the HIV pandemic with a prevalence rate of 12% among the 15-49 age groups. It is estimated that 85,000 people die each year due to HIV related diseases. Amongst those who remain alive while on antiretroviral therapy, it is estimated that about 70% die in the first three months of treatment which is mainly attributed to late treatment initiation. The study therefore aimed to understand the patient health care seeking pathway to HIV and AIDS care and treatment and its associated social and economic costs.

Methods: A structured questionnaire was administered to patients initiat-
ting treatment in seven randomly sampled health facilities in urban and rural areas.

Results: A total of 453 HIV-positive patients were recruited into the study. The health care seeking pathway to antiretroviral initiation was characterized by multiple and repeated visits to different health providers. Only about 55% of the patients were initiated on treatment by their sixth visit to a provider. The choice of provider was mainly influenced by distance to a health facility, low cost or free treatment and perceived effectiveness of treatment provided.

The poor were more likely to make more visits to a health provider than the non-poor. Costs of care seeking were high for patients from rural areas who on average spent a month’s of their income before they could initiate ART.

Conclusions: There is need to promote HIV testing among patients seeking care at health facilities to reduce health system related delay. Health services need to be more equitable and more efforts are required to influence the care seeking patterns both among communities and within the health system in order to promote early HIV testing and ART initiation.

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Cost-effectiveness of HIV prevention and management strategies

LBPE47

Cost effectiveness of targeted HIV prevention interventions for female sex workers in India

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Background: Targeted Interventions for high risk groups form the mainstay of preventive activities and budgetary outlay under National AIDS Control Program (NACP) in India. We conducted a study to ascertain cost effectiveness of targeted interventions for female sex workers (FSW). Method: We used a compartmental mathematical Markov state model over a 20 years time horizon (1995-2015) to estimate cost effectiveness of FSW targeted interventions, with a health system perspective. We compared incremental costs and effects of FSW targeted interventions against a baseline scenario of mass media for general population alone. Incremental cost effectiveness ratio was computed at 3% discount rate using HIV infections averted and disability adjusted life years (DALY) as benefit measures. We assume that the transmission of HIV virus moves from high risk group (FSW) to client population and finally to general population (partners of clients).

Results: Targeted interventions for FSWs would result in reduction of 47% (1.6 million) prevalent and 36% (2.7 million) cumulative HIV cases respectively in 2015. Adult HIV prevalence in India, with and without (mass media only) female sex worker interventions, would be 0.25% and 0.48% in 2015. Conclusions: Targeted interventions for female sex workers are a very cost effective strategy for HIV prevention in India.

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Economic evaluation of prevention, care and mitigation programmes (including cost effectiveness)

LBPE49

A cost-effectiveness analysis of centralized care versus decentralized care for HIV/AIDS in Malawi

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Background: Accessible ART has played a key role in reducing AIDS-related deaths. Malawi has made significant progress in scaling-up ART. Cost-effectiveness analysis can assist in assessing treatment delivery mechanisms. Decentralized care (DC) is becoming the predominant ART delivery system, on the assumption that it is more affordable than centralized care (CC) and as effective. This study compares these two systems.

Methods: This study was conducted in Zomba District, where Dignitas International (DI) works with the Ministry of Health (MoH). ART provision began with CC at the Zomba Central Hospital in 2004. DC began in 2007 at health centres throughout the district. This study uses data from 2008 when the ART program was stable. A model was developed to evaluate cost-effectiveness.

Results: On January 1, 2008, a total of 3186 patients were on ART. 2063 in the centralized program and 1123 in the decentralized program. By the end of 2008, 5205 patients were on ART. 2616 in the centralized program and 2589 in the decentralized program. The annual cost of CC and DC was £424,000 and £340,000 respectively. In CC, DI had borne 18% of the cost, MOH 38% and the patient 44%. In DC, DI had borne 12%, MOH 58% and the patient 30%. For CC, the cost per patient on ART was £15.02/month and for DC, £13.68. The likelihood of defaulting and death was lower in DC than CC.

Conclusions: Our model suggests that DC is more cost-effective than CC. Patients bear a significant proportion of the overall cost. For them, DC is more affordable. Key limitations of this study include the assumptions made in costing the programs and the use of retrospective data. While we recognize that DC cannot exist without CC, these results can assist policymakers in allocating resources across systems to their best effect.

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Outcome evaluation for HIV programmes

LBPE48

Mass campaign "Bachte hole jaante hobe" (Know to Live) campaign effectively reached the youth to bring about changes in their knowledge and behavior related to HIV and AIDS

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Background: Ministry of Health & Family Welfare (MOHFW), Bangladesh and Save the Children, USA initiated a collaborative project, Prevention of HIV/AIDS among Young People in Bangladesh® supported by GFATM. One of the components of the project was a nation wide mass awareness raising campaign "Bachte hole Jaante Hobe." This campaign was linked with life skill education, class room education and Youth Friendly Health Services. In 2008 an end line survey was done showing huge exposure of youth to this campaign with some changes in knowledge and behavior among the young people.

Methods: The end line survey used a nationally representative sample of youth aged 15-24 (by sex and marital status) selected by two-stage cluster sampling. The sample was drawn from 366 clusters. To ensure maximum precision and minimum bias all 2005 sample clusters retained.

Results: Exposure to the campaign was high. Among the respondents 90.5% of unmarried males and 92.5% of unmarried females saw the advertisement. Majority (97.5% males and 97.4% females) had seen the advertisement through television. Among those young people studying in a school, 46% of unmarried males and 57% of unmarried females attended classes related to HIV. The result also shows 96% of males and 90% of females had heard about condoms. Compared to baseline the proportion of males who could mention dual use of condoms doubled (16.6% to 38%), condom use during higher risk sex increased significantly in end line survey compared to baseline survey (53% compared to 41%, p < .005).

Conclusions: The mass campaign reached huge number of youth and there was associated change in knowledge and behavior of the youth. The project started gradual unfolding of messages with specific message about what to practice to be free of HIV in the next phase.

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Policy determinants and constraints LBPE50

LBPE51

Influencing policy development LBPE51-LBPE52

Monitoring and evaluation of policies and their impact on people living with HIV, affected communities and vulnerable populations LBPE53
Policy analysis and indicators of policy effectiveness

**LBPE54**

Uganda’s national HIV and AIDS policies: a gender analysis

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**Background:** Global stakeholders increasingly recognize that to achieve significant reductions in new HIV infections, HIV/AIDS policies and programs must be implemented that reduce gender inequalities, change harmful gender norms and empower women must be implemented. We assessed how national HIV policies address gender inequalities and gender norms in Uganda, as part of a larger initiative in Cambodia and Uganda.

**Methods:** Using a gender analytic framework, we analyzed 16 of Uganda’s current HIV policies, strategies, plans and proposed legislation.

**Results:** Harmful gender norms and inequalities are mentioned in many HIV policies and planning documents, but specific responses are often lacking. For example, the draft National AIDS Policy (NAP) notes a number of gender-specific vulnerabilities, such as female genital cutting, widow inheritance, widow cleansing, child marriage, and sexual and gender based violence, but in the National HIV and AIDS Strategic Plan (NSP) there are no specific programmatic strategies, objectives, or targets. There are also contradictions among documents; the draft NAP explicitly states that HIV testing shall not be mandatory but the NSP implies mandatory testing and the draft HIV Prevention and Control Bill being debated in Parliament has explicit provisions for mandatory testing. Women are more frequently exposed to testing due to pregnancy than men. The Roadmap Towards Universal Access to HIV Prevention suggests that HIV-positive women should not have children although the Road Map and the NSP support human rights of individuals living with HIV, which implies reproductive rights.

**Conclusions:** National policies, strategies, and plans should be harmonized with existing policy and planning documents. There is a need to revise the NSP to reflect gender issues raised in policy documents. A process to analyze the potential effects of proposed legislation on women and men in order to prevent contradictions between policies, strategies, and plans is needed.

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**LBPE55**

Analyzing and promoting accountability of stakeholders

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**Issues:** Under the Global Fund’s (GF) performance-based financing process, Country Coordinating Mechanisms (CCMs), acting in the national interest, have the responsibility for ensuring grants (PRs) accountable for management and performance of grants to fight AIDS, tuberculosis and malaria. CCMs are responsible for overseeing timely, effective use of resources to expand quality services, assisting PRs to identify and resolve issues hindering performance. Since 2002, many CCMs have failed to establish effective oversight; in 2008, the GF Board provided guidance strengthening oversight of CCMs.

**Description:** From 2008 to 2009, the GF and a U.S. Government-funded project, Grant Management Solutions (GMS), conducted a feasibility pilot testing a new oversight approach using a “grant oversight tool” or “dashboard.”

1 A generic Microsoft Excel®-based template including key financial, programmatic and management indicators was designed to give CCMs periodic snapshots of grant performance. Dashboards were developed for 18 grants in six countries. CCM oversight committees and procedures were established in all six. By January 2010, 5 of 6 CCMs had used dashboards for grant oversight in 2 consecutive quarters.

**[1] Please go to http://www.theglobalfund.org/en/ccm/guidelines/

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**LBPE56**

Laws and policies regarding or affecting HIV prevention and treatment and/or care for people living with HIV

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**Issues:** In Rwanda sexual minorities and commercial sex workers are not legally recognized. Draft penal codes have recently been developed by the Rwanda's National Strategic Plan (NSP 2009-2012) for HIV and AIDS, Sex workers, MSM to legal protection

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**LBPE57**

Achieving HIV and AIDS prevention and ensuring sexual minorities’ human rights through advocacy against criminalization targeting most at risk population (MARPs) in Rwanda - towards universal access 2010

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**Issues:** In Rwanda sexual minorities and commercial sex workers are not legally recognized. Draft penal codes have recently been developed by the Rwandan parliament to criminalize MSM and Sex Workers. According to the Rwandan National Strategic Plan (NSP 2009-2012) for HIV and AIDS, Sex workers and sexual minorities are believed to account for the higher proportion of new HIV infections. RNGOF on AIDS & HP has a mission to advocate for human rights for HIV Most At Risk Populations to access HIV services and reduce significantly the incidence of HIV in Rwanda.
Indigenous people(s) and HIV

International indigenous peoples and HIV/AIDS: policy and practice implications of work-to-date

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Issues: Indigenous peoples globally are over-represented in the HIV/AIDS epidemic. Despite the astonishing diversity between and among them, indigenous peoples share a common experience of poverty, marginalization, and colonization that renders them acutely vulnerable to HIV. Indigenous peoples working globally have designed and delivered several community-driven initiatives to address their common concerns. However, the global epidemic of HIV continues to attract little attention domestically or internationally.

Description: With support from Health Canada, this project analyzed previous international indigenous activities, discussions, and decisions related to HIV/AIDS and identified future priorities for action. An International Advisory Committee provided guidance in all areas, including identifying key documents for review, and interview participants. The document review (n=26) focused on three key events identified by the Advisory Committee and the global indigenous policy context. Interview participants (n=10) were chosen for their experience organizing or participating in international events related to indigenous peoples and HIV/AIDS.

Lessons learned: Colonization is a key feature of many indigenous peoples’ experiences regarding HIV/AIDS and strategies to address its damaging legacy must be central to a coordinated international response. International policy directives and indigenous peoples’ work-to-date suggest that supporting indigenous-driven HIV/AIDS initiatives are essential to addressing HIV among indigenous peoples. Adopting international human rights instruments into indigenous-driven HIV/AIDS initiatives are essential to addressing HIV among indigenous peoples.

Next steps: The International Indigenous Working Group on HIV/AIDS has adopted a five-year strategic action plan to address issues common concern for its member countries. Further funding and support from the international community is required to continue its work beyond 2011. Presenting author email: tprentice@uottawa.ca

International assistance and funding mechanisms

The Global Fund’s resource allocation decisions for HIV programs: addressing those in need

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Background: The Global Fund’s investment in HIV has increased unprecedentedly, reaching US$ 10.8 billion by the end 2009. However, the HIV epidemic continues to be a major challenge for global health. It is vital for the Global Fund not only to scale up the funding to countries but to ensure that it addresses populations that are most in need. This study assessed how the Global Fund investment for HIV programs addressed the needs of key populations including equitable access to HIV interventions.

Methods: An assessment of the funding approved by the Global Fund Board for HIV programs in 2002-2009 was conducted based on the National AIDS Spending Assessment methodology. We analysed the allocation of funding by type of epidemic and intervention. We explored the relation between HIV funding, HIV burden measured as HIV prevalence and disability-adjusted life-years (DALYs) due to HIV, and country gross national income per capita.

Results: The Global Fund investment was positively correlated with HIV burden, indicating that countries with higher HIV prevalence and DALYs receive greater support. Investments were mainly channeled to the countries experiencing generalized epidemics. Countries with concentrated epidemics allocated most funding for prevention for most-at-risk populations. The largest share of HIV investment was allocated to low-income countries to promote equitable access to HIV interventions. Some countries with different levels of national income received similar HIV funding per capita.

Conclusions: The Global Fund HIV investment targets the countries and populations with the highest needs and ensures an optimal balance in prioritizing between disease burden and equity by income. Targeted response to concentrated epidemics will be further addressed through a revised prioritization criteria adopted by the Global Fund Board for Round 10 that will allow wealthier countries to access funding solely for most-at-risk populations.

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Trade, patents and pharmaceutical production and availability

Patents and access to antiretrovirals: the politics of AIDS treatment in Brazil

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Brazil’s widely recognized success in controlling AIDS resulted primarily from its participation of the global access to antiretroviral therapies since 1996. Yet, AIDS treatment in Brazil has, from the outset, been challenged by the high costs of patented antiretrovirals. Local pharmaceutical production has thus far, such treatments, both by offering cheaper, generic anti-AIDS drugs and by enabling the government to make credible threats of compulsory licensing, thereby successfully negotiating considerable price discounts for patented antiretrovirals with brand-name pharmaceutical multinational companies. Domestic and transnational political support helped Brazil resist resulting pressures and retaliations from these multinationals and the US government. Yet, this paper provides qualitative and quantitative evidence, gathered through extensive field research in Brasilia, Rio de Janeiro and Geneva, that such strategy has ceased to be effective since 2005, when India and other suppliers of antiretroviral active ingredients to Brazil adopted stricter patent laws in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It argues that the legal and institutional reforms which enable pre-grant patent opposition by health authorities, more flexible and easier compulsory licensing and expedite post-patent generic entry, while important, remain unable to ensure the sustainability of AIDS treatment in Brazil. Rather, the paper concludes that such sustainability depends crucially on further technological capacity of the Brazilian pharmaceutical industry, without which neither political domestic support nor tax domestic patent rules will suffice in the context of TRIPS. In particular, the command over all phases of antiretroviral production is key for Brazil to exercise bargaining and market power in face of global patent rules and strong external opposition. Such technological capacity in Brazil may help increase access to antiretrovirals in other developing countries as well.

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