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Abstract Book

6th International Workshop on HIV & Women

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Abstracts
Oral Presentations

Abstract: 1

Special Populations: Sexworkers, Transgenders, etc.

Exploring contexts of HIV vulnerability and protective factors among young transgender women in Kingston, Jamaica

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Background: Stigma and discrimination targeting transgender women are global phenomena. There is limited understanding of how transgender women are conceptualized and treated within Jamaican society despite reports of stigma and violence directed towards this population. Transgender women are overrepresented in new HIV infections across the globe, and this overrepresentation has been contextualized within social drivers of the epidemic, including stigma and discrimination in health care, housing, employment, family and community settings. Our study explored contexts of HIV risk and protective factors among young transgender women in Kingston, Jamaica.

Methods: In this community-based research project we conducted individual, semi-structured interviews with young (<29 years of age) transgender women (N = 20) and key informants (individuals who work in community agencies serving transgender women) (N = 13) in Kingston, Jamaica. We also held a focus group with young (<29 years old) transgender women (N = 8) in Kingston. We digitally recorded and transcribed verbatim the focus group and interviews. Data were analyzed using narrative thematic techniques.

Results: Findings revealed a) a lack of understanding about transgender persons and b) pervasive stigma and discrimination across family, social, healthcare, employment and housing contexts. Narratives highlighted confusion over transgender women's gender identity. While some of the persistent verbal abuse participants reported was transgender specific ('he/she', 'she-male'), other verbal abuse revealed perceptions of transgender women as gay men ('faggot', 'batty-boy'). Participant narratives highlighted the complexity of gender identity as many chose to dress up as men in certain contexts to enhance safety. Widespread physical, verbal and sexual abuse restricted freedom of movement and employment opportunities. This converged with family exclusion to result in homelessness and survival sex work, further elevating vulnerability to sexual violence. Police were described as perpetrators of additional violence if transgender women attempted to report violence and abuse, leaving no recourse for accessing justice. Poverty, substance use and fear of violence reduced the ability of transgender women engaged in survival sex to negotiate condom use with clients. Transgender women highlighted many barriers to accessing HIV testing, including negative experiences accessing health care and HIV testing, including mistreatment by health care providers, and pervasive HIV-related stigma. Facilitators of accessing HIV testing included: the belief that knowledge was power; positive experiences with health care providers; accessibility of HIV testing services (e.g. cost, location, hours); and non-judgmental social networks.

Conclusions: Social contexts of marginalization shape HIV vulnerability, and underscore the need to address multiple levels of exclusion to promote health and human rights among young transgender women in Jamaica. Findings highlight the need to: create and implement targeted HIV testing and health care services; challenge the stigma, discrimination and violence experienced by transgender women; increase community knowledge of transgender women's lived experiences; address poverty, housing and access to justice among transgender women. HIV prevention interventions can also build on strategies that are already working for young transgender women in Jamaica, including social networks, the belief that knowing one's HIV status is empowering, and provision of affordable and convenient HIV testing services.

No conflict of interest

Abstract: 2

Special Populations: Sexworkers, Transgenders, etc.

Social drivers of HIV vulnerability among lesbian, bisexual, queer and transgender women in Swaziland

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Introduction: Swaziland has an HIV prevalence rate of 27.4%, one of the highest in the world. While the epidemic is driven by heterosexual transmission, recent quantitative studies show high rates of HIV among men who have sex with men (MSM). Globally, sexual and gender minorities (SGM) are at higher risk of HIV transmission due to social and structural contexts of risk. Sexual stigma, for instance, impacts the ability of SGM to negotiate safer sex and limits access health care. While there is some research on MSM in Swaziland, there is less understanding about HIV vulnerabilities among women who have sex with women (WSW) and transgender persons (TG) in Swaziland.

Methods: This was a community based research partnership with the Rock of Hope in Swaziland, a SGM agency. We conducted 28 semi-structured interviews with SGM women (16 WSW, 12 TG) and 13 interviews with key informants. Data was analyzed using thematic analyses techniques.

Results: Our study found social ecological factors that impacted HIV vulnerability. *Intrapersonal* factors included internalized stigma, low HIV awareness and HIV risk perception, safer sex practices; *network* factors included multiple and concurrent partnerships, substance use; *community* level factors included HIV attitudes, community agencies, perceived and symbolic stigma, and sexual violence; and *structural* level factors included healthcare discrimination, laws, and sexual health education. Protective factors included social support at the network level, the impact of community organizations on providing support/resources, and government support at the structural level. Overall, WSW had less access to preventive technologies, and TG populations were less integrated into communities and faced increased stigma. Current HIV prevention programming focuses nearly exclusively on MSM populations.

Discussion: We found that HIV vulnerabilities among WSW and TG populations in Swaziland were largely determined by: the inability of the health care system to cater to their health needs; high rates of stigma and sexual violence; limited uptake of protection technologies, in part shaped by substance use; lack of clear and targeted sexual health education; limited access to HIV prevention technologies. Social structures contribute to HIV vulnerability through stigmatizing laws that criminalize same-sex behaviour, this in turn reduces access to health care and sexual health education tailored for SGM. Strong social support systems that can help to build self-confidence and increase access to health care can serve as protective factors to mitigate HIV risk.

Conclusion: There is a dearth of information on HIV vulnerabilities of WSW and TG women in Swaziland, despite having the among the highest prevalence rate in the world. Furthermore, there are no studies we could locate that examine the sexual health of WSW in Swaziland. This study provides a necessary exploration into the social and structural risk factors of HIV for these populations of women. HIV prevention programs need to include a focus in their work on WSW and TG populations, increase HIV education outreach for SGM populations, and work towards sensitization of health care workers to increase access to health care services, HIV prevention technologies and sexual health education.

No conflict of interest

Abstract: 3

HIV prevention in women

Comparison of Adherence Measures in a Phase 1 Clinical Trial of PC-1005 Vaginal Gel

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Introduction: Accurately measuring adherence is challenging in HIV prevention trials. Self-reports of product use are often inflated. Alternative measures include applicator counts, Wisebag™, Dye Stain Assay (DSA), and measuring active pharmaceutical ingredients (APIs). We compared 4 adherence measures in a 14-day Phase 1 safety and PK trial: self-report, counts of returned applicators, DSA, and API in plasma.

Materials and Methods: PC-1005 (MIV-150 and zinc acetate in a carrageenan gel) and HEC placebo gels were packaged in single-use HTI applicators, modified to include a groove to facilitate the DSA. Participants (n=25) inserted gel under clinical supervision or at home. Select visits included blood draws pre-dose and at multiple time points up to 24h post-dose to measure MIV-150 in plasma. The DSA was performed on all applicators inserted in the clinic (positive controls) and those returned opened by participants. Positive and negative controls were used to measure DSA sensitivity and specificity. Plasma MIV-150 was quantified using LC-MS/MS. Participant adherence was defined as the total number of inserted applicators divided by the number expected to be inserted at home. Spearman correlation between self-report, applicator counts, and DSA was calculated. MIV-150 detection in plasma pre-dose (as an indication that the previous home dose was used) was compared with DSA results.

Results: Adherence based on self-reports and applicator counts were both 98% (range 82-100%; r=1.000). Per the DSA, which yielded 92% sensitivity and 92% specificity, adherence was lower than either self-report or applicator counts (83%; range 0- 100%). There was a weaker but still positive correlation between adherence per the DSA versus both self-report and applicator counts (0.614). 80% (16/20) of the specimens with MIV-150 detected corresponded to a positive DSA result. 29% (2/7) of the specimens with no MIV-150 detected corresponded to a negative DSA result.

Conclusions: Self-reported adherence and applicator counts yielded similar results; both were inflated compared to DSA results. Discrepancies between DSA and MIV-150 detection were likely due to rapid clearance of MIV-150. Although API detection is valuable, implementation requires unblinding of study staff, is costly for a large-scale clinical trial, and may not be appropriate for all APIs. We recommend evaluating the DSA on applicators inserted rectally and incorporating the DSA into future vaginal and rectal gel trials.

No conflict of interest

Abstract: 4

HIV prevention in women

MIP-3a is detectable constitutively in female genital tract tissues; however, endogenous hormonal fluctuations do not impact on its levels

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Background: Human and non-human primate studies suggest that there is an increased vulnerability to HIV and SIV infection, respectively, during the post-ovulatory phase when levels of progesterone predominate. MIP-3α, a chemoattractant for plasmacytoid dendritic cells (pDCs), was shown in a landmark study to be elevated in the endocervix in the first three days post viral inoculum and prior to accumulation of viral-containing CD4+ T cells in macaques. We investigated baseline levels of MIP-3α in the endocervix and other female genital tract (FGT) sites and assessed whether fluctuations in endogenous hormones over a single menstrual cycle impacted on its levels, thereby potentially altering the risk of HIV infection in women.

Methods: We prepared endocervical explant tissues (EET) and primary epithelial cells (EPEC) from uterine specimens collected from women undergoing a hysterectomy for a benign lesion. We collected a concentrate of cervicovaginal secretions (CVF) and serum at three time-points of a single menstrual cycle from each woman participating in the CASHIR study: estrogenic, mid-ovulatory, and progestogenic phases. Using the Transwell® system, we grew HEC-1A cells and EPEC and studied constitutive secretion of MIP-3α in supernatants of basal and apical compartments harvested when maximal transepithelial electrical resistance (TEER) was reached. We analysed MIP-3α levels by a sandwich quantitative ELISA and Luminex immunoassays.

Results: We showed that MIP-3α is secreted constitutively at high levels in the endocervical tissue models, 941pg/mL (SD±221) and 715pg/ml (SD±84.7) in the EET and EPEC, respectively. Levels were lower at a mean of 106pg/mL (SD±121,7) in the CVF and lowest in HEC-1A cells, an endometrial cell line, at 36,6pg/mL (SD±10,6). Contrary to various FGT tissues, levels were below the level of quantitation in serum using this assay. There were no significant differences in mean MIP-3α levels in CVF over the three different visits of a single menstrual cycle on one-way ANOVA, (F1.23, 8.63)=6.96, MS=19177, p=0.3076. Presence of underlying CVF abnormalities influenced MIP-3α levels - levels were five-fold higher in the presence of macroscopically bloody and purulent secretions. MIP-3α expression was apically polarised, a pattern of secretion that was enhanced stimulating with Poly I:C, a TLR3 ligand.

Conclusion: We confirmed the epithelial source of MIP-3α. We also confirmed that MIP-3α is secreted constitutively in four FGT matrices albeit at varying concentrations. Hormonal variation is not likely to be a driver of MIP-3α secretion, whereas underlying CVF abnormalities suggesting pathology are. Given the constitutive levels of expression of MIP-3α by human epithelial cells (unlike in macaques), its role in modulating initial events of HIV-1 infection remains to be defined. It is hence important to consider the extent of influence of these expression modifiers in understanding the full mediatory role of MIP-3α in the association between HIV exposure and the outcome of infection.

No conflict of interest

Abstract: 5

HIV prevention in women

Reduced activation of emtricitabine and tenofovir in cervical and vaginal explants from post-menopausal donors

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Background: Although nearly one-third of new HIV infections in the United States are in adults aged 45 or over, post-menopausal women are underrepresented in clinical trials of pre-exposure prophylaxis. Previous explant work has suggested tenofovir may not provide equal protection from HIV infection in explant tissues from post-menopausal donors; whether this is due to altered susceptibility, altered drug activity, or both is unclear. Here we describe the influence of menopause status on the metabolism of nucleotide analogs tenofovir (TFV) and emtricitabine (FTC) to their intracellular active metabolites (TFV-dp and FTC-tp) in cervical and vaginal explants.

Materials and Methods: Cervical (n=8) and vaginal (n=3) specimens were procured from pre-menopausal (ages 32-51) and post-menopausal (ages 52-68) donors through the University of Minnesota Tissue Procurement Facility and the National Disease Research Interchange. One donor was of Asian descent while the remainder were Caucasian. Explants were created from specimens using 3mm biopsy punches and incubated in 100 ug/mL of tenofovir or emtricitabine for 24 hours. Following incubation, tissues were snap frozen in liquid nitrogen and stored at -80°C until analysis. Intracellular concentrations of phosphorylated metabolite were measured using a previously validated LC-MS/MS assay with a 0.02 ng/mL lower limit of quantification. Median (range) data are reported. Concentrations were compared between groups using the Rank Sum Test.

Results: The median conversion of parent to metabolite concentrations was 0.02 (0.00-0.12)% for FTC and 0.03 (0.002-0.59) % for TFV. FTC-tp was detectable in 100% (7/7) of explants from pre-menopausal donors compared to only 20% (1/5) of explants from post-menopausal donors. FTC-tp in pre-menopausal tissues was 77.4 (23-485) fmol/mg vs 0.0 (0.0-22.6) fmol/mg ($p<0.01$). TFV-dp was detectable in all explants regardless of menopause status but was 64% lower in explants from post-menopausal donors (n=4) compared to pre-menopausal (n=6). Measured TFV-dp was 214 (8.2-2051) fmol/mg in pre-menopausal tissues and 76.7 (7.5-246) fmol/mg in post-menopausal tissues ($p=0.35$).

Conclusion: Menopause status was a significant predictor of intracellular nucleotide metabolism in cervical and vaginal explants. Compared to explants from pre-menopausal donors, post-menopausal explants achieved lower concentrations of active metabolites, suggesting a potential for reduced protective efficacy against HIV infection. If validated, these results could have implications in the use of current pre-exposure prophylaxis strategies targeted to post-menopausal women.

No conflict of interest

Abstract: 6

Contraception, pregnancy, breast feeding, and PMTCT

Use of HIV pre-exposure prophylaxis during conception, pregnancy and lactation at 2 U.S. medical centers

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Background: Maternal HIV acquisition during pregnancy and lactation is associated with increased risk of perinatal transmission. Observational studies suggest an increased risk of HIV acquisition in pregnancy. Use of pre-exposure prophylaxis (PrEP) periconception, in pregnancy and lactation may protect women during periods of increased HIV susceptibility, preventing maternal and neonatal infection. The Center for Disease Control and World Health Organization support consideration of PrEP use in and around pregnancy, but data is limited, and there are no published reports of continued PrEP after pregnancy diagnosis. We describe PrEP use pre-conception, during pregnancy and breastfeeding to highlight implementation challenges and prompt future study.

Methods: Chart review was performed on all women identified as eligible for PrEP pre-conception, during pregnancy and lactation at 2 academic medical centers in California and New York from 2010-2015.

Results: Twenty-seven women, 30 referrals (3 repeat referrals in subsequent pregnancies), and 25 pregnancies were identified. Ninety-six percent of women (26/27) had an HIV-infected partner, 73% (19/26) of whom were on antiretroviral therapy, and 42% (11/26) of whom were virally suppressed at initial consult. One woman was in a relationship with a man who had sex with men.

Women were referred by obstetricians, midwives, primary care providers, partners' providers, health educators, and public health departments for PrEP counseling. In 27% of cases (8/30), women were eligible for post-exposure prophylaxis (PEP) at referral, of whom 4 were offered PEP; in 30% of cases (10/30), last exposure was not assessed by the referring provider. Median time from identification as PrEP-eligible to consultation and initiation of PrEP was 30 days (IQR 2-62). Delays included time to consultation and awaiting drug coverage.

In 70% of cases (21/30), women were pregnant at consultation. None of these women received safer conception counseling. In 57% (17/30) of cases, women took PrEP: 5 preconception, 15 during pregnancy, and 10 postpartum of whom 5 breastfed. Median length of time on PrEP was 30 weeks (IQR 20-53). Common adherence challenges included side effects and social stressors. In 44% (11/25) of pregnancies, women did not follow-up postpartum. No pregnancy or neonatal complications were identified related to PrEP-use. Three women were identified as PrEP-eligible but referral did not occur and they were lost to follow-up. Reasons for these missed opportunities included complex pregnancy conditions consuming provider and patient attention, complex social situations resulting in infrequent presentations to care, and lack of referring provider knowledge. One of these women re-presented and was diagnosed with HIV 10 months postpartum; her infant was confirmed to be HIV-negative. No other sero-conversions were identified.

Conclusions: When offered pre-conception, during pregnancy and lactation, women at 2 U.S. centers frequently chose PrEP to reduce risk of HIV acquisition. Many types of providers identified and referred women, though critical gaps in care linkage remain. Side effects and adherence challenges occur in pregnancy; the postpartum period is particularly vulnerable to loss to follow-up. Prospective studies are urgently needed to identify best practices to offer women safe and effective HIV prevention methods in and around pregnancy.

No conflict of interest

Abstract: 7

Special Populations: Sexworkers, Transgenders, etc.

Use of injectable hormonal contraception independently predicts HSV-2 acquisition in a cohort of street- and off-street sex workers in Vancouver, Canada

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Background: Observational studies have suggested that depot medroxyprogesterone acetate (DMPA), one of the most effective and widely used long-acting reversible contraceptives (LARCs), may increase the risk of HIV acquisition among women. Although the underlying mechanisms are not well understood, increased risk of herpes simplex virus 2 (HSV-2) has been proposed as a possible indirect pathway. Despite heightened vulnerability to HIV and HSV-2 among women sex workers (SWs), research on the effects of DMPA on STI acquisition among this population is limited.

Methods: Longitudinal data (baseline and semi-annual follow-up questionnaires) were drawn from an ongoing prospective cohort of 744 street- and off-street SWs recruited across Metropolitan Vancouver ('An Evaluation of Sex Workers' Health Access') between 01/2010 and 02/2014. This analysis was restricted to women who were HSV-2 seronegative at baseline and had at least one follow-up visit. Extended cox regression analyses were used to model the independent effect of DMPA use on HSV-2 seroconversion, adjusting for individual, interpersonal and structural characteristics.

Results: The present analysis was restricted to 149 women who were followed for a median of 18.6 months (interquartile range [IQR]: 8.4-29.9). The median age at baseline was 34 years (IQR: 27–41), and 19 (13.3%) reported DMPA use during the study period. There were 39 HSV-2 seroconversions, resulting in an overall incidence rate of 17.1 cases per 100 person-years (py) (95% confidence interval [CI]: 12.4–23.6). Incidence rates were higher among users of DMPA (57.4 cases per 100 py, 95% CI: 31.4–105.0) compared to not users (13.1 cases per 100 py, 95% CI: 8.9–19.1). After adjusting for key confounders, use of DMPA remained an independent predictor of HSV-2 acquisition (adjusted hazard ratio [AHR] = 4.43, 95% CI: 1.90–10.35).

Conclusion: The high observed incidence rates of HSV-2, coupled with a strong association between DMPA exposure and HSV-2 acquisition, raise serious concerns about the provision of optimal reproductive and sexual health care to this highly marginalized population, suggesting an urgent need for women sex worker-tailored health services. Given the known links between HSV-2 and HIV, our findings further underscore the need for research on the biological and social pathways through which DMPA could increase the risk of HSV-2 and other STIs to help inform the development of safer reproductive choices, including LARCs for women worldwide.

No conflict of interest

Abstract: 8

Contraception, pregnancy, breast feeding, and PMTCT

Strategies to improve the uptake of effective contraception in HIV-positive adolescents

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Introduction: The study assessed the uptake and use of a highly effective contraceptive method (EC), including short-acting contraception (contraceptive pills or depot medroxyprogesterone acetate injection) and long-acting reversible contraception (LARC) (hormonal implant or intra uterine device, IUD), by HIV-positive female adolescents, and the factors associated with it.

Material & Methods: Between June 2013 and August 2014 we enrolled 77 HIV-positive and sexually active female adolescents 12-24 years old, post-menarche and not pregnant from five sites in Thailand. Participants were followed every 12 weeks until week 48. At the baseline visit all participants received standardized safe sex education through a study-specific animated video, contraceptive information brochures, and individual counselling. Safe sex knowledge was assessed with a pre- and post-education test. At baseline and follow-up visits participants could choose between an EC in addition to male condom use vs. male condom use only. We applied McNemar's test of paired proportions to assess the significance of changes in EC use from baseline to week 48, and logistic regression to assess predicting factors.

Results: Most participants (95%) were perinatally HIV-infected; 91% were on antiretroviral therapy with 72% having HIV-RNA < 1000 copies/mL. Median age at first intercourse was 16 years; 69% had a history of more than one sexual partner, and 30% had been pregnant prior to enrolment.

All but one participant showed improvement in at least one of the 12 questions in the post-test in comparison to the pre-test. Rating each educational method from 'least' to 'most' helpful, individual counseling was most often rated 'most helpful' (62%), followed by the educational video (46%) and brochures (22%).

The percentage of male condom only vs. EC use was 71% vs. 29% (9% of EC was LARC) at the screening visit; 45% vs. 55% (14% of EC was LARC) at the baseline visit, and 26% vs. 74% (31% of EC was LARC) at week 48. The increase in EC use was statistically significant at baseline vs. screening ($p < 0.0001$ for any EC, $p=0.046$ for LARC), and at week 48 vs. baseline (p-value=0.006 for any EC, p-value=0.0009 for LARC). Over half of the participants changed their contraceptive choice at least once during the study period. No participant requested removal of a hormonal implant. No participant chose an IUD. EC use was significantly associated with having ever used EC prior to study entry, at baseline visit ($p<0.0001$), and at week 48 ($p=0.024$). An additional predictor for EC use at baseline visit was the study site ($p<0.0001$). Having ever used EC was significantly associated only with having been pregnant ($p=0.015$).

Conclusions: HIV-positive adolescents need continuous free access to a variety of contraceptive methods, and education about the benefits of LARC as a first choice. Short-acting methods could still be an important initiation to contraception. Safe sex education, including addressing the main predictor for EC use by adolescents, should be introduced as a standard of care. Continued contraception-related training should be made available to health care providers, as they play a significant role in the process.

No conflict of interest

Abstract: 9

Contraception, pregnancy, breast feeding, and PMTCT

Does delivery after 40 weeks gestation increase maternal to child transmission of HIV in well controlled HIV-infected pregnant women? A prospective cohort study

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Background: Given concern for risk of maternal to child transmission (MTCT) of Human Immunodeficiency Virus (HIV), current standard of care is to deliver women with well-controlled HIV (viral load (VL) <1000) before 40 weeks estimated gestational age (EGA). We hypothesized that the proportion of MTCT associated with delivery at or after 40 weeks EGA would be equivalent to that of delivery prior to 40 weeks of gestation in women with VL<1000 at delivery.

Methods: We performed a secondary analysis of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) International Site Development Initiative (NISDI) Perinatal/Longitudinal Study in Latin American Countries (LILAC) cohort to evaluate HIV-infected pregnant women with VL<1000 at time of delivery. Delivery between 38 and <40 weeks EGA ('<40wks'), compared to spontaneous or planned delivery at or after 40 weeks EGA ('≥40wks'), the exposure of interest. Our primary outcome of interest was MTCT. Secondary outcomes included indicators of maternal and neonatal morbidity. Associations between EGA and outcomes were examined through univariate analyses, with Fisher's exact or Wilcoxon nonparametric p-values.

Results: Among 1630 women enrolled in the NISDI Perinatal/LILAC cohort, 915 virally-suppressed mothers with singleton, live-born, term neonates with known HIV status were included in the analysis. There were 6 cases of MTCT (transmission rate 0.7%). Four transmissions occurred among 612 pregnancies <40wks (0.7%), compared to 2 transmissions among 303 pregnancies ≥40wks (0.7%, p=1.00). Median VL at delivery was lower among pregnancies ≥40wks (93 vs. 200 copies/mL, p=0.0473). A higher proportion of pregnancies <40wks were delivered by elective caesarean section compared to pregnancies ≥40wks (45.1% vs 25.1%), while vaginal births were more common among pregnancies ≥40wks (58.1% vs. 36.6%, overall p<0.0001). A slightly higher proportion of infants <40wks were low birth weight (8.2% vs. 4.0%, p=0.0173). A higher proportion of infants ≥40wks had EGA at delivery determined by the Capurro method (81.8% vs. 75.0%) and a lower proportion had EGA determined by pediatric newborn exam (Ballard; 5.6% vs. 11.9%, overall p=0.0068). Although, the most common neonatal antiretroviral prophylaxis in both groups was zidovudine, use of other prophylaxis regimen was more common among infants ≥40wks (5.0% vs. 1.6%, p=0.0081). Duration of rupture of membranes, maternal age, breech delivery, postpartum length of stay, small for gestational age, and receipt of breastmilk did not differ significantly by EGA group. There were no maternal deaths recorded in the analysis population. We are currently working to incorporate the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) P1025 data into the analysis for our primary outcome of interest.

Conclusions: The risk of MTCT did not differ by EGA. Although the secondary analysis was not powered to demonstrate conclusively the rates were equivalent, this finding challenges the current standard of care of delivery prior to 40 weeks EGA.

No conflict of interest

Abstract: 10

Contraception, pregnancy, breast feeding, and PMTCT

PK of FTC, TFV and 3TC in Ugandan and Nigerian breastfeeding mother-infant pairs

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Background: Under WHO Options B and B+, increasing numbers of HIV-positive women receive antiretroviral therapy (ART) during breastfeeding. The pharmacokinetics (PK) of nucleoside reverse transcriptase inhibitors (NRTIs) to breastfed infants are incompletely understood. We present intensive PK profiles of emtricitabine (FTC), tenofovir (TFV) and lamivudine (3TC) in maternal plasma (MP), breast milk (BM) and infant plasma (IP) from Ugandan and Nigerian cohorts.

Methods: Breastfeeding mothers receiving a once-daily efavirenz or nevirapine-based ART regimen were enrolled, together with their exclusively breastfed infants. Paired dried blood spots (DBS; maternal and infant) and dried breast milk spots (DMS) were collected pre-dose and serially up to 12 h post-dose. All three NRTIs were quantified by a validated simultaneous LC-MS/MS assay. Non-compartmental PK analysis was performed using WinNonLin and milk-to-plasma (M:P) ratios were calculated arithmetically.

Results: 21 Ugandan and 27 Nigerian mother-infant pairs were enrolled. Populations were similar for mean maternal age (30 years) and weight (60 Kg), and infant age (100 days) and weight (6 Kg). T_{max} of FTC was 4h in MP and 5.1 h in BM, reaching median C_{max} of 493 (IQR 467-627) and 933 (716-1238) ng/mL, respectively. The AUC_{0-12} of FTC was 2492 (511-3260) and 4134 (824-7286) ng.h/mL in MP and BM, with a M:P AUC ratio of 2.13 (SD 1.77). FTC was detected in 18.7% of exposed infants with a median concentration of 18.5 (SD 3.4) ng/mL. TFV had a T_{max} of 1 h in MP and 4 h in BM, reaching C_{max} of 186 (109-240) and 7.3 (5.5-9.6) ng/mL in these compartments, respectively. The AUC_{0-12} was 1014 (738-1394) and 41.5 (23.2-56.1) ng.h/mL in MP and BM, giving a M:P AUC ratio of 0.034 (SD 0.09). No infant had measurable TFV. 3TC had a C_{max} of 991 (574-1129) ng/mL in MP and 572 (386-710) ng/mL in BM. The AUC_{0-12} of 3TC in MP and BM was 3916 (2985-6780) and 4001 (1951-4577) ng.h/mL, respectively, with a M:P AUC ratio of 1.02 (SD 0.79). 3TC was detectable in 41% of exposed infants with a median concentration 16.4 (SD 8.5) ng/mL.

Conclusion: This is the first report of full PK profiles of FTC and TFV in plasma and BM of breastfeeding mother-infant pairs, indicating higher concentration of FTC in BM compared to MP but transfer to IP only in a minority. TFV is measurable in BM but is not detectable in IP. Consistent with previous studies, 3TC levels in BM were comparable to MP with transfer to IP in almost half the infants.

No conflict of interest

Abstract: 11

Diagnosis and treatment of HIV infection

Treatments and co-morbidities in German female HIV-infected patients in 2015 - a comparison to 2008

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Background: We characterized HIV-infected women in Germany, evaluated antiretroviral therapy (ART) use and co-morbidities and compared results to those of a similar analysis in 2008 in order to further identify special requirements of this particular patient population.

Materials & Methods: Cross-sectional multicentre evaluation of HIV-positive women receiving medical care in Germany between 10/2014 and 11/2015. All HIV-specialty practices and ambulatory care centres in Germany were invited to participate. Data acquisition was performed anonymously using an online questionnaire. Results were compared to a similar analysis performed in 2008. Initial ART regimen choice was compared to that of a general population in one centre for the years 2006 through 2013.

Results: 781 HIV-positive (n=447 from 10 centres, n=334 from anonymous centres) were included. Mean age was 45 years, 30% smoked, 67% had a partner (of which 65% were HIV-discordant), 61% had child(ren) (of which 20.6% had ≥ 3 children). Most common routes of transmission were heterosexual contact (40%) and origin from a high-prevalence country (36%) (no change from 2008). One-half had a migration background (46% in 2008), the majority (39%) from Africa. HIV-Subtype was documented for 369 of the patients; 56% were infected with subtype B and 12% with subtype C. 10.9% of women were CDC classified stage C3, 13.5% had presented with C3 at time of HIV-diagnosis. 22.8% had a history of AIDS-defining illness(es), P. jirovecii infections and esophageal candidiasis being the most prevalent, followed by mycobacterial infections and toxoplasmosis. 60% reported co-morbidities, where psychiatric conditions especially drepession (30%), hypertension (16.7%) and an abnormal estrous cycle (10.5%) deserve special mention. Hypertension could be correlated with age, but not ethnic back-ground. Alcohol and illicit drug use are reported by 2% and 3.3% respectively. 13% of women were co-infected with hepatitis B/C. 91% were currently on ART (77% in 2008), most commonly on non-nucleoside reverse transcriptase inhibitor- (37%), boosted protease inhibitor- (32%) and integrase inhibitor- (26%) based regimens. 16% started ART due to pregnancy. Initial ART class choice has been comparable to that of a general population since 2008. Prior to 2008, it appears that PI-based regimens were initially prescribed less frequently. HIV-1 RNA was<50 copies/ml in 88% of women on ART (48% in 2008). Median detectable viral load in treated women was 68 copies/ml [IQR: 38-350]. Median CD4 cell count was 621 cells/µl [IQR: 437-828].

Conclusions: We found an improvement in the treatment of HIV-infected women in Germany since 2008 as reflected by an increase in both the number of ART treated HIV-positive women in Germany and, more importantly, in the number of successfully treated women. We attribute this to an increasing awareness of women issues in this field, to specific measures taken in the meantime with positive outcomes as well as to the updates in treatment guidelines and to novel treatment options.

No conflict of interest

Abstract: 12

Epidemiology of HIV in women and girls

Patient characteristics, duration on antiretrovirals (ARVs) and adherence in an insured US population receiving ARVs in 2010-2014: a focus on women

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Background: Current evaluations of ARV therapy adherence in women are important since one in four people with HIV in the US are women.

Objective: To describe patient characteristics, ARV duration and adherence for women (in reference to men) in a large insured US population receiving HIV treatment between 2010-2014.

Methods: Claims were analyzed for insured patients in the Optum Research and Impact National Benchmark Databases. Adults aged ≥18 years with an HIV diagnosis, ARV receipt between 1/2010-12/2014 and 6 months continuous health plan enrollment pre-ARV initiation (baseline) were included; those with HIV-2 or who received only nucleos(t)ides (NRTIs) were excluded. Descriptive analyses were performed for patient characteristics, therapy duration and three adherence measures: Proportion of Days Covered (PDC) by ≥1 ARV (PDC1), PDC by ≥2 ARVs (PDC2) and Medication Possession Ratio (MPR). Adherence measures were evaluated from ARV initiation (index date) to the earlier of end of enrollment or 12/31/2014. Regimens consisted of all ARVs filled <14 days of index date; treatment episodes were defined as therapy periods with the same regimen until ARV switch or ≥90-day treatment gap. To simplify analyses, calculations excluded boosting agents (BAs).

Results: Of the 25,320 patients included, 15.6% (n=3,949) were women with 6,681 treatment episodes (21,371 were men with 32,390 treatment episodes).The mean±standard deviation [SD] age for women was 45.2±11.2 years; 47.3% from the South; 34.4% ARV naïve (men: mean±SD age=45.3±10.8 years; 42.7% from South; 35.3% ARV naive). Approximately 20.7% of women (men=19.0%) had ≥1 baseline condition measured by the Quan-Charlson comorbidity index (excluding HIV/AIDS). Except viral infections, hypertension (23.5%), respiratory infections (22.4%) and lipid disorders (22.3%) were most common comorbid conditions among women using the Agency for Healthcare Research & Quality classification (18.8%, 20.5% and 28.3%, respectively among men). Excluding BAs and NRTIs, most common ARVs among women were efavirenz (in 30.2% of treatment episodes; men=37.1%), atazanavir (19.4%; men=14.5%), raltegravir (17.6%; men=17.9%), darunavir (13.4%; men=13.3%) and lopinavir (12.5%; men=7.9%). Mean±SD post-index follow-up was 727.1±538.9 days for women (men=759.1±562.6 days), 36.4% of women (men=29.6%) had >1 treatment episode in follow-up and the mean±SD treatment episode duration was 418.9±469.9 days (men=504.2±514.0 days). Among women, mean±SD adherence was 0.80±0.26 for PDC1, 0.76±0.27 for PDC2 and 0.84±0.22 for MPR (0.86±0.22, 0.83±0.23, 0.89±0.18, respectively for men). Approximately 34.1% of women had a PDC1 <0.80, 39.5% had a PDC2 <0.80 (53.6% had a PDC2 ≤0.90), and 27.8% had an MPR <0.80 (39.6% had an MPR <0.90). For men, 23.5% had a PDC1<0.80, 27.5% had a PDC2<0.80 and 19.1% had an MPR <0.80.

Conclusions: Findings provide insights into possible variations in real-world adherence across gender from a large, insured HIV population. In this analysis, ≥1 out of 4 women had an adherence level <0.80 regardless of the measure used (PDC1, PDC2, or MPR); when higher adherence thresholds were employed, nearly 40% had an MPR <0.90 and over 50% had a PDC2 ≤0.90. Since claims-based adherence analyses reflect medication receipt but do not assess patient medication-taking behaviors, findings warrant additional research further elucidating adherence and outcomes by gender.

Conflict of interest: employees of Janssen Scientific Affairs and employees of Optum

Abstract: 13

Women living with HIV

mHealth to improve health: a weekly text messaging intervention to improve ART adherence and HIV viral load in a Canadian context: WelTel OAKTREE

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Introduction: Antiretroviral therapy (ART) improves health and survival of HIV-positive individuals; however, engagement in care and medication adherence are essential to prevent resistance, morbidity and mortality. It is acknowledged that women have a unique set of challenges and barriers to adherence requiring creative support solutions for successful engagement in care. In a randomized control trial in Kenya, (WelTel Kenya1), a weekly mHealth (mobile phone technology for health care) intervention improved ART adherence and HIV viral load (VL) suppression. To examine this in our population, we conducted a repeated measures study of weekly interactive text-messaging intervention effectiveness using the WelTel model with 85 participants on ART at the Oak Tree Clinic (OTC), the provincial referral center for women and families located at BC Women's Hospital and Health Centre in Vancouver, Canada.

Materials & Methods: Between April 2013 and May 2014, 85 participants were recruited from the OTC. Inclusion criteria included age ≥14 years old, qualify for ART, detectable HIV VL (>200 copies/mL), and 'vulnerable' (i.e. ≥1 of: unstable housing, active addiction, domestic violence, poor care engagement or adherence, advanced HIV infection/AIDS, or mental health factors). Participants without a cell phone were given one with unlimited texting capability. Participants received a weekly interactive SMS/text message check-in for one year. A clinic nurse triaged responses and recorded data on all interactions. Demographic and clinical data were collected for pre-intervention and intervention years. Adherence data was obtained from pharmacy refill records and patient report. Repeated measures mixed-effects linear regression was used to take into account repeated measures on the same subject from pre-study to intervention years. Linear regression was used for CD4 count and VL (log_{10} transformed), while logistic regression was used for ART adherence and appointment attendance.

Results: Demographics included median age 39 years (range 15-60), 90.3% female, 3.2% transgendered, 6.5% male. Participant ethnicity was 37% Caucasian, 34% Aboriginal, 21% Black and 8% South Asian. 53.1% of participants at baseline had their own phone. At study end 35/85 participants had VL <40, while 46 were <200. Mean ART adherence improved from 61.7% to 68.3% ($p<0.0001$), and median population HIV log_{10}VL declined by 0.70 log ($p=0.007$) from the pre-intervention to intervention year. Mean CD4 count and appointment attendance did not change. As there was a 50% median response rate to the weekly message, participants were dichotomized into responders (≥50% response rate) and non-responders (<50% response rate). Adherence improved by +13.7% and +0.8% in the responders and non-responders respectively ($p=0.008$), and median VL dropped -1.03 log for responders versus -0.39 log for non-responders ($p=0.03$). The intervention required 53 minutes of clinic provider time per high-risk, vulnerable participant enrolled for the entire study year.

Conclusions: Results suggest the WelTel SMS service is an effective tool for reducing HIV VL and improving ART adherence in poorly engaged, vulnerable Canadian women. Those who engaged more frequently with the intervention showed significantly better improvement in health outcomes. Engaging in weekly contact with patients did not significantly add to the work load of the clinic.

Conflict of interest Gilead; Telus and WelTel

Abstract: 14

Contraception, pregnancy, breast feeding, and PMTCT

The use of antiretroviral agents during pregnancy in Canada and compliance with North-American guidelines

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Introduction: Adult HIV guidelines have evolved to include many new antiretroviral medications among the list of recommended or alternative therapies, while the evolution of recommended regimens for prevention of vertical HIV transmission has been historically delayed due to concerns regarding their safety in pregnancy. Moreover, treatment-experienced patients, such as perinatally infected women, are now entering pregnancy with multidrug resistance. Hence, many women are conceiving and/or commencing treatment in pregnancy with ART regimens that are not currently recommended for use by pregnant women.

Objectives: To describe trends in Canada for the use of antiretroviral therapy (ART) in pregnancy, by comparing ART received at conception/1st trimester and whenever in pregnancy with US and Canadian guidelines available at the time of pregnancy.

Material & Methods: Mothers on ART during pregnancy between 2004 and 2014 were identified from the Canadian Perinatal HIV Surveillance Program (CPHSP). CPHSP captures data on mother-infant pairs with perinatal HIV exposure in Canada, with data submitted from 22 sites annually.

Results: 2135 pregnancies were identified. The rate of women on ART at the time of conception increased from 24% to 69% between 2004 and 2014. Compliance between ART used at conception and first line recommended regimens as per guidelines was 25% overall. Among women on ART at conception or during the first trimester, 1% (3% in 2014) received ART for which there is insufficient safety data as per 2015 guidelines (dolutegravir, elvitegravir/ cobicistat/ tenofovir/ emtricitabine, fosamprenavir/ ritonavir, maraviroc, and cobicistat). On the other hand, the rate of women who were on ART not recommended because of toxicity or associated with lower virologic efficacy (abacavir/ lamivudine/ zidovudine, stavudine, didanosine, indinavir/ ritonavir, nelfinavir, ritonavir as a single protease inhibitor, saquinavir/ritonavir, and nevirapine) ever in pregnancy decreased from 82% to 8% between 2004 and 2014. Over the same period, the use of recently approved ART (raltegravir, darunavir/ ritonavir and efavirenz) increased from 6% to 28% at conception and from 3% to 34% ever in pregnancy. No cases of perinatal HIV transmission were observed following the use of these newly approved agents.

Conclusion: In Canada, HIV-infected women receiving ART at the time of conception tend to be treated with regimens that would not be considered as preferred first line ART in pregnancy as per US or Canadian guidelines. This is of concern in the context of the licensure of new ART medications for which there is insufficient safety data.

No conflict of interest

Abstract: 15

Contraception, pregnancy, breast feeding, and PMTCT

Viral suppression and retention in care 2-5 years after ART initiation in pregnancy in Uganda

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Introduction: Recent studies have demonstrated that up to 40% of women are lost to follow-up after initiating antiretroviral therapy (ART) during pregnancy in Option B+ programs. Data are limited on long-term virologic outcomes and retention in care, particularly after cessation of breastfeeding.

Methods: We evaluated retention in care and viral suppression (VS) 2-5 years postpartum among previously ART-naïve women who initiated ART during pregnancy (Option B+) at 12-28 weeks gestation in a study (PROMOTE, NCT00993031) in rural Uganda. Participants breastfed and were followed for up to 1 year postpartum, then referred to clinics in surrounding communities. A random sample (n=200) was invited to participate in a cross-sectional follow-up study after completing the trial, including a questionnaire and pregnancy and HIV viral load (VL) testing. Retention in care was defined as having attended an HIV clinic in the last 90 days. Logistic regression models were used to examine factors associated with VS (VL ≤400 copies/ml).

Results: One hundred fifty women (75%) were successfully contacted for follow-up. Median months postpartum was 46 (IQR 37-52) and median CD4 count was 664 cells/mm^3 (IQR 476-870). Of the 150 contacted, 131 (87.3%) were on ART (78 on EFV, 35 on NVP, 18 on LPV). Fifty-eight (38.7%) participants reported ≥1 pregnancy after initiating Option B+; 19 (12.7%) were pregnant at the time of follow-up and 23 (15.3%) were breastfeeding. Long-term retention in care following initiation of Option B+ was 90% (95% CI 84.0%-94.3%), with 135/150 seen in the last 90 days. Assuming those we could not contact had fallen out of care (n=50), retention in care was 67.5% (95% CI 60.5%-73.9%). Among the 150 contacted, 121 (80.7%, 95% CI 73.4%-86.7%) had VS. Assuming those we could not contact had virologic failure, long-term retention in care with VS was 60.5% (95% CI 53.6%-67.3%). Factors associated with VS included disclosure of HIV status to primary partner (OR 5.24, 95% CI 1.21-22.6), no difficulty obtaining ART in the past 3 months (OR 4.16, 95% CI 1.50-11.5), and food security (OR 2.61, 95% CI 1.00-6.88).

Conclusions: Following initiation of Option-B+, long-term (2-5 year) retention in care and viral suppression was observed in 90% and 80.7%, respectively. Women who had disclosed their HIV status to their primary partner were 5 times more likely to be virologically suppressed, indicating a significant need for facilitated disclosure interventions to maintain long-term retention in care with viral suppression.

No conflict of interest

Abstract: 16

Contraception, pregnancy, breast feeding, and PMTCT

Factors influencing Lost to Follow-up in a Prevention of Mother-To-Child Transmission (PMTCT) Program in Northern Nigeria

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Background: Every year, an estimated 590,000 infants acquire Human Immunodeficiency Virus (HIV) infection from their mothers, mostly in developing countries that are unable to implement interventions. Adequate follow up of HIV infected pregnant women is crucial for achieving zero Mother to Child HIV Transmission (MTCT) transmission. Loss to follow up remains a major challenge in many PMTCT programs. This study reviews the factors influencing Lost to follow up among women living with HIV in a Prevention of Mother to Child Transmission.

Methods: A retrospective cohort study using a two stage systematic sampling technique was used to randomly select 421 pregnant women in six health facilities in northern Nigeria between October 2013 to October 2015. Out of the 421 clients who were recruited for this study, 131 (31.1%) were lost-to-follow up. Patients' ?le were reviewed. The retrieved data for variables such as demographics, HIV stage, CD4 count, ART treatment, reasons for lost to follow-up, was analysed and summarized.

Results: Of the 131 lost to follow-up PMTCT clients selected, 49 (30.6%) were on HAART and 114 (87%) on TDF/3TC/EFV adult first line regimen. Majority, 75 (55%) were in the second and third trimester. 125 (95.4%) were in WHO stage 1or 2. 103 (79%) of the clients had attended less than three antenatal care visits. 111 (84.7%) had a phone access. The majority of the client's 87 (64.4%) were staying more than 15km away from the hospital. 51 (39%) had primary education and 67 (51.1%) only were either employed or self-employed, 33(25.2%) had not disclosed their status to a next of kin. 58(44.3%) clients were telephoned, 31(23.6%) of the phones were switched off, 22 (17%) telephone numbers were wrong. 29 (22.1%) promised to come back. 43 (33%) clients who were not reachable through phone were visited at their residence of whom 16 (37.2. %) had relocated; 7 (5.3%) had died; 12 (30%) denied their HIV status and 8 (18.6%) had self-referred to another treatment centre.

Conclusion: This study showed that low education levels, Living long distances from the hospital, unemployment, non-disclosure of HIV status, home relocations and lack of reliable phone contact were major factors influencing loss to follow-up.
Periodic updates of home addresses and telephone contacts including those of at least two next of kin may improve follow up. Phone text message to remind clients about clinic visits could be helpful. Periodic home visits remain useful. Early and consistent tracking of missed appointments is crucial. Creation of more PMTCT centres are needed to avoid long distances.

No conflict of interest

Abstract: 17

Diagnosis and treatment of HIV infection

Retention overtime and reasons for discontinuation of lifelong ART in a group of Cameroonian pregnant and breastfeeding HIV-positive women initiating "Option B+"

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Introduction: The uptake of lifelong antiretroviral therapy (ART) for HIV-positive pregnant and breastfeeding women has significantly increased with the introduction Prevention of Mother to Child Transmission (PMTCT) Option B+. It is also expected to benefits the HIV-infected women, their exposed infants, their uninfected male sex partners and the overall ART programme. However, these benefits hinges on adherence and long term retention in care which tends to vary with settings and overtime. We assess retention overtime and reasons for discontinuing treatment in a pilot project implementing option B+ in Cameroon.

Materials and Methods: We examined retention from ART initiation to 6months and 12 months for women initiating ART between October 2013 and December 2014 in five health facilities in which option B+ was piloted in the Kumba Health District. During followed-up women missing their appointments between 3 weeks and 90 days were traced by peer educators through phone calls and home visits. The tracing outcomes were noted and the reasons for discontinuation documented.

Results: Of all the women who started option B+ (n=268), 86(32.1%) appeared to have discontinued treatment within 12months. Of these 19(22.1%) were actually self-transferred and were confirmed to be on treatment. Of the 67 patients who were declared discontinued, 2(3%) died, 29(43.3%) were lost to follow-up (LTFU) and 36(53.7%) had stopped treatment. Treatment discontinuation was 13% at 6months and 26.3% at 12 months. For women who discontinued treatment within the first 6months, 35% never returned for their second visit. The median [Interquartile range (IQR)] duration to treatment discontinuation was 9 (IQR; 4.5-13.55) months, 6 (IQR; 3-9) months for LTFU and 8.5 (IQR; 4.3-12.8) months for stopping treatment. Younger women were more likely to discontinue treatment [odd ratio (OR) 1.4, 95% confidence interval (CI) 0.76-2.6]. Starting treatment in a low volume site had a significantly higher risk of discontinuation (OR 2.7, 95% CI 1.4-5.4). The main reasons for stopping treatment were; lack of transport 4(11.1%), religious reasons 9(25.0%), stigma and discrimination 19(52.8%) and 4(11.1%) decline giving any reasons.

Conclusions: Retention on option B+ decreases overtime and varies with facilities with low volume sites recording lower retention. Though same day initiation is necessary for the success of option B+ pre and post test counseling and staffing capacity of the facilities need to be improved. Community interventions are needed to reduce stigma and discrimination and religious beliefs to improve retention in the option B+ programme.

No conflict of interest

Abstract: 18

Epidemiology of HIV in women and girls

The Hepatitis C cascade of care in a women-centered HIV clinic in Canada

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Introduction: Worldwide, 5 million people are estimated to be coinfected with human immunodeficiency virus (HIV) and hepatitis C virus (HCV) but few data are available to assess the continuum of care from diagnosis, linkage, engagement and treatment for coinfected women. In this descriptive analysis, we assess the HCV cascade of care for patients in a predominantly women's HIV clinic.

Methods: The Oak Tree Clinic (OTC) is a multidisciplinary HIV clinic in Vancouver, Canada focusing on the care of women and children living with HIV. Data for all HIV positive patients ≥18 years old followed in the OTC was retrieved. We describe the demographics of the cohort with a focus on co-infected patients as determined by HCV antibody (Ab) and RNA status.

Results: A total of 694 patients were included of whom 565 (81%) were female. The mean age of the cohort was 43 years (IQR 36-50) with a median CD4 count of 557 cells/μL (IQR 350-720) and 526 (76%) had an undetectable HIV viral load (VL). HCV antibody status was known in 665 (96%) and 261 (38%) were antibody positive. Of 261 HCV Ab+ patients, 58 (22%) had undergone spontaneous clearance, 33 (13%) were treated with a sustained virologic response, and 13 (5%) had an unknown method of RNA clearance. HCV RNA status was unknown in 8 (3%) patients.
Of 149 HCV RNA+ patients, 145 (97%) had liver fibrosis staging by aspartate aminotransferase-to-platelet ratio index (APRI) and Fibrosis-4 (Fib4) scores, of whom 26 (17%) had evidence of cirrhosis. Sixty-five (43%) have genotype (GT)1a, 14 (9%) GT1b, 10 (7%) GT2, 42 (28%) GT3, and 1 (0.7%) GT4. To date, 28 (19%) have been referred for HCV therapy, and 4 (2.7%) are on treatment. Local guidelines require evidence of ≥F2 fibrosis and our clinic criteria require an undetectable HIV VL to qualify for HCV treatment, therefore 59 (40%) of our HCV RNA+ patients currently qualify for HCV therapy.

Conclusion: In this predominantly female population coinfected with HIV and HCV, 17% had evidence of significant fibrosis despite their relatively young age and 40% would be appropriate for interferon sparing, combination direct acting antiviral HCV therapy. Despite this, few patients with active HCV infection were on HCV treatment. As well, 28% of the cohort have GT3 infection which is currently the most difficult to treat. Enhanced efforts are required to engage and treat HIV/HCV co-infected women to improve outcomes. Gender responsive services may be helpful in optimizing access to treatment for HIV/HCV co-infected women.

No conflict of interest

6th International workshop on HIV & Women

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Abstracts
Guided Poster Presentations

Abstract: 19

Contraception, pregnancy, breast feeding, and PMTCT

Effect of Doravirine (MK-1439) on the pharmacokinetics of an oral contraceptive (Ethinyl Estradiol [EE] and Levonorgestrel [LNG])

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Background: Doravirine is a novel, potent, HIV-1 non-nucleoside reverse transcriptase inhibitor that is primarily metabolized by oxidation via CYP3A4, but has demonstrated no inhibitory or inductive potential on CYPs both in vitro and in clinical studies, and has shown no interaction with enzymes involved in the metabolism of either EE or LNG. The objective of this study was to assess the effect of 100 mg doravirine, the Phase 3 clinical dose, on the plasma pharmacokinetics of an oral contraceptive containing EE and LNG.

Materials & Methods: This was an open-label, 2-period, fixed sequence trial to assess the effect of multiple doses of doravirine on the single-dose pharmacokinetics of a monophasic combination of EE/LNG (Nordette®-28) in healthy female subjects. In Period 1, subjects received a single oral dose of 0.03 mg EE/0.15 mg LNG. In Period 2, subjects received 100 mg doravirine once daily for 17 consecutive days, with a single oral dose of 0.03 mg EE/0.15 mg LNG co-administered with doravirine on Day 14. There was a washout of at least 7 days between dosing in Period 1 and Period 2. Twenty healthy postmenopausal or oophorectomized adult female subjects were enrolled. Safety evaluations were performed throughout the study. Plasma samples for determination of EE and LNG concentrations were obtained for up to 96 hours postdose in each period. The pharmacokinetic parameters of EE and LNG were natural log-transformed and analyzed using a linear mixed-effects model with treatment as fixed effect and an unstructured covariance matrix.

Results: There were no serious clinical or laboratory adverse experiences (AEs). There was one discontinuation due to an AE judged not related to any study drug. Overall, 12 subjects reported a total of 27 postdose clinical AEs, 3 of which were considered drug-related (2 related to doravirine alone [mild erythematous rash, oral herpes] and 1 related to both doravirine and Nordette®-28 [nervousness]) as well as 1 laboratory AE, judged related to doravirine and Nordette®-28 (red blood cells in urine). All reported AEs were judged to be mild or moderate in intensity and were transient. The geometric mean ratio (GMR) (90% confidence interval [CI]) for EE (Nordette®-28 + doravirine/ Nordette®-28) was 0.98 (0.94, 1.03) for $AUC_{0-\infty}$, and 0.83 (0.80, 0.87) for C_{max}; the GMR and 90% CI for LNG (Nordette®-28 + doravirine/ Nordette®-28) was 1.21 (1.14, 1.28) for $AUC_{0-\infty}$, and 0.96 (0.88, 1.05) for C_{max}.

Conclusions: Multiple dosing of doravirine does not alter the plasma pharmacokinetics of EE or of LNG to a clinically meaningful extent. Coadministration of doravirine and a single dose of an oral contraceptive was generally well tolerated. Consequently, there are no restrictions on the use of oral contraceptives in Phase 3 trials of doravirine.

Conflict of interest: employees of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, and may own stock/stock options in Merck. D.R. Armas received fee from Merck as principal investigator.

Abstract: 20

Contraception, pregnancy, breast feeding, and PMTCT

Effective contraceptive use, dual contraception, and contraceptive method choice among women living with HIV in Canada

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Background: Current WHO guidelines recommend dual contraceptive use for women living with HIV (WLWH) to prevent both unintended pregnancy and HIV transmission. We examined the range of contraceptive methods used and measured the prevalence and correlates of effective contraceptive use and dual contraceptive use among WLWH in Canada.

Methods: We analysed baseline cross-sectional survey data for WLWH enrolled in the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS), a longitudinal, community-based research study with 1,425 WLWH enrolled in British Columbia, Ontario, and Quebec. Analyses were restricted to pre-menopausal, non-pregnant, cis-gender women aged 16-49 years, who reported consensual sexual activity in the 6 months before interview. Effective contraceptive use was defined as self-reported use of at least one of the following: oral contraceptive pill, injectable contraceptive, vaginal ring, contraceptive patch, implant, intrauterine device (IUD), intrauterine system (IUS), consistent male or female condom use, and/or permanent methods including hysterectomy, tubal ligation, or primary male partner vasectomy. Multivariable logistic regression examined independent correlates of effective contraceptive use and dual contraceptive use (consistent condom use with use of IUD/IUS, hormonal, or permanent methods).

Results: Overall, 453 participants (32% of total enrolled) met eligibility criteria and were included in this analysis. Median age was 38 years (IQR: 33, 43), 23% identified as Indigenous, 31% as African, Caribbean, or Black Canadian, and 41% as White. 88% were heterosexual and 12% LGBTQ. 50% reported no intention to become pregnant in the future. Of those with at least one regular sexual partner (n=418), 66% had HIV-negative partners and 8% had HIV status-unknown partners. Among all 453 participants, 78% were currently taking antiretroviral therapy, 74% reported an undetectable viral load (VL<50 copies/mL), and 51% reported receipt of HIV care in the last year that she perceived to be women-centred. Prevalence of effective contraceptive use was 72%. Male condoms were the most commonly used method (42%) followed by tubal ligation (19%). By mutually exclusive categories of method type, 27% did not use any effective contraception, 27% used only barrier methods (with 99% using the male condom), 8% used only hormonal methods, 6% used only the IUD or IUS, and 13% used only permanent methods. Only 18% used the WHO-recommended dual contraception (of whom 47% used condoms + permanent methods, 36% condoms + hormonal methods, and 16% condoms + IUD). In adjusted models, women using effective contraception were younger, heterosexual, and had previous pregnancy experience. Women using dual contraception had significantly higher adjusted odds of receiving perceived women-centred HIV care (AOR: 3.13; 95% CI: 1.23-8.13).

Conclusions: Nearly three-quarters of sexually active WLWH in this study used effective contraception, driven by male condom use and tubal ligation. WLWH reported low prevalence and range of hormonal methods and IUD/IUS, highlighting the need to expand options for longer-acting, reversible, and female-controlled contraceptive methods. Less than one-fifth

practiced dual contraception. Associations with receipt of perceived women-centred HIV care suggest a critical opportunity to examine the potential of this care model to prevent both unintended pregnancy and HIV transmission, and improve sexual and reproductive health outcomes of WLWH.

No conflict of interest

Abstract: 21

HIV prevention in women

Reaching women in serodifferent relationships: safer conception and contraceptive counseling by providers of men living with HIV

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Introduction: Male involvement is associated with women's increased contraceptive use and engagement in prenatal care, including among HIV-affected couples. Healthcare providers of men living with HIV may play a critical role in supporting male engagement in safer conception and contraception by supporting male involvement in women's reproductive health and providing risk-reduction counseling to serodifferent couples. However, knowledge of and attitudes towards contraception and safer conception among providers caring for men living with HIV have not been assessed.

Materials & Methods: A convenience sample of 75 clinicians providing care for HIV-positive men in San Francisco completed an anonymous survey in 2012. Questions addressed practice of assessing fertility desires and knowledge of contraception and safer conception. Descriptive statistics were calculated.

Results: Of 88 providers approached, 87 consented, and 75 reported caring for HIV-positive men. Sixty-three respondents (84%) were physicians and 9 (12%) were nurse practitioners. Providers practiced in public, private and Veterans Administration clinics. Seventy-two (96%) provided primary care to HIV-positive men; clinicians cared for a median of 57 HIV-positive men annually (IQR 30-106).

Forty-five providers (60%) asked some male patients at least once about desiring children; 5 (7%) asked all male patients at least once; 19 (25%) never asked; and 6 (8%) declined to answer. Main reasons for never discussing fertility included lack of time (37%), caring exclusively for men who have sex with men or older patients (42%), believing it wasn't important (32%), or waiting for patients to broach the subject (32%). Forty-two providers (56%) had a male patient spontaneously ask about fertility.

Twenty-four providers (32%) asked some male patients at least once about preventing unwanted pregnancies; 34 (45%) asked all male patients at least once; 4 (5%) never asked; 13 (17%) declined to answer. Sixteen providers (21%) had a male patient spontaneously ask about contraception.

Half of providers (39/75) had ever counseled a serodifferent male/female couple together; three-quarters (29/39) discussed contraception and half (19/39) discussed safer conception during those visits. Thirty-three providers (45%) had received any training on contraception. Median level of confidence in contraceptive knowledge (100 representing maximum confidence) was 62 (IQR 40-77). Confidence in knowledge of safer conception was similar (60, IQR 36-69). When discussing safer conception, all respondents discussed treatment as prevention, 64% (25/39) discussed pre-exposure prophylaxis, 67% (26/39) discussed sperm washing, and 31% (12/39) discussed timed intercourse. When queried if HIV providers should ask male patients about fertility and contraception, median scores (100 being providers should definitely ask) were 89 (IQR 74-100) and 93 (IQR 74-100) for fertility and contraception, respectively.

Conclusions: Providers of men living with HIV in San Francisco are expanding their roles to include fertility and contraception counseling. While the majority believe these domains are within their scope of work, fewer feel confident in their knowledge. More research is needed into the quality of contraception and safer conception counseling offered by these providers in order to identify and meet training needs, and support provision of integrated sexual and reproductive healthcare for serodifferent couples.

No conflict of interest

Abstract: 22

Contraception, pregnancy, breast feeding, and PMTCT

Pregnancy outcomes for women using regimens including darunavir or other protease inhibitors: Findings from the Antiretroviral Pregnancy Registry

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Introduction: Darunavir (DRV) was recently added to a list of recommended antiretroviral (ARV) agents for pregnant women per the United States Department of Health and Human Services (DHHS) Perinatal Guidelines. This was primarily based on DRV efficacy and safety seen in non-pregnant adults, and pharmacokinetic data from 2 clinical trials in pregnant women. This analysis of Antiretroviral Pregnancy Registry (APR) data examined birth defect prevalence for women using ARV regimens including DRV and other protease inhibitors (PIs) during pregnancy.

Material & Methods: The overall and drug specific birth defect prevalences for women receiving DRV and other PIs (atazanavir, indinavir, lopinavir, nelfinavir, and ritonavir) during pregnancy were calculated based on the number of live births. Prevalence is reported for individual drugs with ≥200 reported 1st trimester–exposed live birth outcomes. Any individual regimen may have been used in combination with other regimens; therefore, the counts represent the number of exposures to the individual regimen, and are not mutually exclusive across individual regimens. Birth defect rates and 95% confidence intervals (CIs) were determined for ARV drug use during the 1st and 2nd/3rd trimesters of pregnancy.

Results: Through January 2015, the APR had evaluable data from 17,332 ARV-exposed pregnant women and 17,630 birth outcomes. The median (range) age was 28 (13-55) years, and 15%, 57%, and 18% of women were white, black, and Hispanic, respectively. CD4+ counts at the start of pregnancy (for 14,951 [86%] women with available data) were <200 cells/μL for 17% of women, 200-499 cells/μL for 48%, and ≥500 cells/μL for 35%. There were a total of 4677 birth outcomes exposed to an ARV regimen including a PI during the 1st trimester of pregnancy and 5803 during the 2nd/3rd trimesters of pregnancy, including 4224 and 5703 live births, respectively. The overall prevalence (95% CI) of birth defects for exposure to an ARV regimen including a PI during the 1st trimester of pregnancy was 2.89% (2.40%-3.44%), and during the 2nd/3rd trimester was 2.95% (2.52%-3.42%). The prevalence (95% CI) of birth defects with use of DRV during the 1st trimester of pregnancy was 2.87% (1.32%-5.37%; 9 birth defects in 314 live births) and 1.66% (0.34%-4.77%; 3 birth defects in 181 live births) during the 2nd/3rd trimesters of pregnancy (P = 0.549). Birth defect prevalences (95% CI) for other PIs with use during the 1st and 2nd/3rd trimesters were as follows: atazanavir, 2.22% (1.41%-3.31%) and 2.46% (1.35%-4.09%), respectively; indinavir, 2.42% (0.98%-4.93%) and 1.84% (0.38%-5.28%); lopinavir, 2.33% (1.57%-3.34%) and 3.03% (2.39%-3.78%); nelfinavir, 3.87% (2.86%-5.12%) and 3.15% (2.53%-3.87%);

and ritonavir, 2.36% (1.81%-3.01%) and 2.93% (2.37%-3.58%).

Conclusions: This analysis of the APR data demonstrated that the prevalence of birth defects for ARV regimens including DRV versus those including other PIs was comparable. The difference in birth defect prevalence for 1st versus 2nd/3rd trimester exposures for DRV was not statistically significant. The APR concludes, 'The Antiretroviral Pregnancy Registry finds no apparent increases in frequency of specific defects with 1st trimester exposures and no pattern to suggest a common cause; however, potential limitations of registries should be recognized.'

Conflict of interest : WRS is a speaker and consultant for Gilead Sciences and Janssen. JDA, TSC, and CG are salaried employees of INC Research®, LLC, which manages the daily operations of the APR and conducts the statistical analyses, but were not compensated for their participation as co-authors of this work. Dr. Scheuerle is a paid consultant to the APR. HHT is a senior epidemiology consultant for the APR and provide consultation to many of the participating companies (last year: BMS, GSK, Novaritis, and Gilead). BB is an employee of Janssen Research and Development, LLC. DS, RP, MBH, SV, and KB are employees of Janssen Scientific Affairs, LLC.

Abstract: 23

Contraception, pregnancy, breast feeding, and PMTCT

Use of antiretroviral regimens including darunavir during pregnancy: Findings from the Antiretroviral Pregnancy Registry

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Introduction: Preclinical darunavir (DRV) studies have shown no embryotoxicity or teratogenicity in animal models; human studies in pregnancy have thus far focused on pharmacokinetics. The current analysis evaluated birth outcomes for women exposed to antiretroviral (ARV) regimens including DRV or excluding DRV during pregnancy in the Antiretroviral Pregnancy Registry (APR).

Material & Methods: Cumulative APR data through January 2015 for primary prospective enrollments were assessed (data as reported to the APR). The overall birth defect rate in DRV-exposed pregnancies was compared with 2 population-based birth defect rates (Metropolitan Atlanta Congenital Defects Program [MACDP] and Texas Birth Defects Registry [TBDR]).

Results: The APR analysis included 17,332 women: 535 on ARV regimens including DRV, and 16,797 on ARV regimens excluding DRV. The median (range) ages for these groups were 29 (16-45) years (ARV regimens including DRV) and 28 (13-55) years (ARV regimens excluding DRV). At the start of pregnancy, CD4+ counts for women on ARV regimens including DRV (for the 447 [84%] women with available data) were <200 cells/μL for 19%, 200-499 cells/μL for 37%, and ≥500 cells/μL for 28%; for women on ARV regimens excluding DRV (for the 14,504 [86%] women with available data), baseline CD4+ counts were <200 cells/μL for 15%, 200-499 cells/μL for 42%, and ≥500 cells/μL for 30%. Among 542 DRV-exposed and 17,088 DRV-unexposed pregnancy outcomes (including single and multiple births from a pregnancy), 91.9% and 93.2% were live births, 4.5% and 2.9% were spontaneous losses (P = 0.035 for ARV regimens excluding DRV vs ARV regimens including DRV), 0.8% and 1.3% were stillbirths (P = 0.425), and 3.0% and 2.8% were induced abortions (P = 0.789), respectively. Comparing live births without defects among DRV-exposed and DRV-unexposed pregnancies, 20.6% and 15.8% were low birth weight (for 441 DRV-exposed and

13,793 DRV-unexposed births with known birth weight; *P* = 0.008), and 13.1% and 12.3% were premature births (for 465 DRV-exposed and 14,876 DRV-unexposed births with known gestational age; *P* = 0.566), respectively. Overall, the relative risk (RR) of birth defects for DRV-exposed versus DRV-unexposed pregnancies was 0.98 (95% confidence interval [CI], 0.57-1.68; *P* = 1.00). The prevalence of birth defects was 2.87% (95% CI, 1.32%-5.37%) for earliest DRV exposure during the 1st trimester and 1.66% (95% CI, 0.34%-4.77%) for earliest DRV exposure in the 2nd or 3rd trimester (RR, 1.75; *P* = 0.549). MACDP and TBDR birth defect rates were 2.72% and 4.17%, respectively.

Conclusions: Although the number of women in the APR using DRV was small, no differences were observed in rates of adverse birth outcomes for ARV regimens including and excluding DRV, with the exception of spontaneous losses and low birth weight. Observed birth defect rates were consistent with those in the MACDP and TBDR. The APR concludes, 'The Antiretroviral Pregnancy Registry finds no apparent increases in frequency of specific defects with 1st trimester exposures and no pattern to suggest a common cause; however, potential limitations of registries should be recognized.'

Conflict of interest: WRS is a speaker and consultant for Gilead Sciences and Janssen. JDA, TSC, and CG are salaried employees of INC Research®, LLC, which manages the daily operations of the APR and conducts the statistical analyses, but were not compensated for their participation as co-authors of this work. Dr. Scheuerle is a paid consultant to the APR. HHT is a senior epidemiology consultant for the APR and provide consultation to many of the participating companies (last year: BMS, GSK, Novaritis, and Gilead). BB is an employee of Janssen Research and Development, LLC. DS, RP, MBH, SV, and KB are employees of Janssen Scientific Affairs, LLC.

Abstract: 24

Women living with HIV

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

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Background: Worldwide women experience extraordinary high rates of violence related to entrenched gender inequities. This violence includes coercive sex, which may lead to the acquisition of sexually transmitted infections, including HIV. Discrimination between coercive non-consensual sex versus consensual sex as a mode of HIV transmission is too often disregarded. We assessed the prevalence of and factors associated with HIV acquisition via coercive sex among women with HIV enrolled in a large Canadian cohort.

Methods: Baseline survey data were analyzed for women with HIV (≥16 years), enrolled in a longitudinal, community-based research cohort study in British Columbia (BC), Ontario (ON), and Québec (QC). Coercive sex was assessed

through self-report of 'non-consensual sex' as a mode of HIV acquisition or violence as a child or adult resulting in HIV. Univariate and multivariable logistic regression analyses were used to identify factors associated with self-reported coercive vs. consensual sex as the mode of HIV acquisition.

Results: Of 1,070 participants, 25% were from BC, 53 % ON, and 22% QC, median age was 42 (IQR=35-50) years, 26 % identified as African/Caribbean/Black, 39% as Caucasian, 25% as Aboriginal. Coercive sex was the second dominant mode of HIV transmission at 17% (N=185) (vs. 57%-consensual sex, 15%-sharing needles, 4%-blood transfusion, 4%-perinatal, 4%-other). Amongst the women who acquired HIV from coercive sex, 38% (N=70) report the assault occurring during times of war. In univariate analyses, covariates significantly associated with acquiring HIV from coercive vs. consensual sex included: female sex at birth (p=0.009), birth country, year of arrival in Canada, ethnicity, sexual orientation (p=0.05), education (p=0.048), regional residence (p=0.005), living in an urban area, ever in foster care, being under Child Protection Services care (p=0.006), attending/having a family member who attended residential school, being incarcerated (p=0.022), recreational drug (p=0.010), illicit drugs (p=0.029) and injection drug (p=0.021) use, hepatitis C diagnosis (p=0.034) and taking antiretrovirals (p=0.010) (p-values<0.001 if not stated). In the multivariable analysis, covariates significantly associated with acquiring HIV from coercive vs. consensual sex were: being from BC vs. ON [aOR=2.6; 95% CI=1.5-4.3]; being diagnosed with HIV>10 years ago [aOR=2.2; 95% CI=1.2-3.95] and between 5-10 years ago [aOR=1.9; 95% CI=1.03-3.3] compared to women diagnosed <5 years ago; women who were ever in foster care [aOR=2.1; 95% CI=1.2-3.6] compared to women who had not; and finally, year of arrival to Canada after 2010 [aOR=8.1; 95% CI=2.9-22.5] and between 2000-2010 [aOR=3.6; 95% CI=1.5-9.2] compared to Canadian-born women.

Conclusions: Coercive sex is a significant yet under-considered risk factor and mode of HIV acquisition among women with HIV. In our cohort, 17% of the women had acquired HIV through coercive sex. Given the high rates of self-reported coercive sex as a mode of HIV acquisition, it should be considered a distinct HIV risk factor. Correlates of coercive sex as the mode of HIV acquisition included a number of intersecting social determinants, particularly related to immigration and care as a child; these are HIV risk factor that warrant particular attention by policy makers and care providers.

No conflict of interest

Abstract: 25

HIV prevention in women

"This might be the only place for those kinds of needs": a qualitative study of U.S. family planning providers' attitudes towards PrEP for HIV prevention

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Background: Family planning clinics have been identified as key access points for women to obtain HIV prevention services. However, family planning providers may not see pre-exposure prophylaxis (PrEP) provision within their scope of work or may have other attitudes that pose barriers to PrEP implementation. A quantitative survey of family planning providers in the United States (U.S.) demonstrated while 75% believe HIV prevention education is essential to family planning care, only 20% believe educating patients about PrEP is within their scope of practice. There have been no qualitative studies of providers regarding attitudes towards integrating PrEP into family planning care.

Methods: Focus groups were conducted with family planning clinicians and counselors recruited at a national meeting and at clinics in San Francisco. Interviews were taped and transcribed. Open-coding was independently performed by two investigators. Codes were grouped into themes, and thematic analysis was performed.

Results: Five focus groups were conducted in 2015. Subjects worked at free-standing and hospital-based family planning clinics. The majority of groups were conducted in San Francisco. Key themes included 1) tension between desire for efficient screening tools and need for in-depth risk assessment 2) discomfort with 'high-risk' patients and 3) commitment to providing PrEP at family planning clinics.
While providers wanted screening tools to improve efficiency, they recognized that risk assessments are 'sensitive conversations' taking time and skill to facilitate. Working in reproductive health, they regularly navigate these conversations and know risk is not easily summarized with a checklist. Consequently, time was perceived as a significant barrier to PrEP implementation. However, while ideas like screening tools were proposed to improve efficiency, there was consensus that comprehensive assessment required in-depth conversations.
While most providers initially stated their clinic populations were 'low risk' and would not qualify for PrEP, many clinicians had examples of female patients who would be eligible. Providers expressed a lack of familiarity with HIV and 'high-risk' patients. Even when describing women who would meet 'high-risk' criteria by most guidelines, providers were hesitant to label them as such. Reasons for this hesitation included not wanting to blame or stigmatize patients. Providers also identified systems barriers to caring for these patients.
Despite concerns about time and discomfort with labeling risk, subjects concluded that PrEP should be provided at family planning clinics. Clinicians noted that their patients often do not see other healthcare providers and family planning providers are uniquely equipped to navigate conversations about sensitive topics related to sexual and reproductive health. Finally, subjects expressed responsibility for providing women-centered care and concluded that PrEP, as an empowering choice for women, should be incorporated into family planning care.

Conclusions: Family planning providers in the U.S. identified barriers to PrEP implementation including lack of time and tools to efficiently screen patients, and need for training on HIV and related risk. Despite these barriers, providers were committed to integrating PrEP into family planning care. Family planning provider-specific training is needed on HIV and related risk allowing providers to more efficiently incorporate PrEP into their practice.

No conflict of interest

Abstract: 26

Women living with HIV

Bacterial vaginosis and HIV RNA vaginal shedding in women living with HIV in Denmark – Results from the SHADE Cohort

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Background: Bacterial vaginosis (BV) is the most common vaginal infection among women of reproductive age. Several studies have found an association between BV and HIV acquisition and transmission.
Although plasma HIV RNA levels are correlated to vaginal HIV RNA load, some studies suggest that vaginal HIV RNA shedding may vary over time, independently of plasma levels. This may suggest a small risk of transmission, even with undetectable plasma viral load.
We examined the prevalence of BV in Women Living with HIV (WLWH) in Denmark, and whether vaginal HIV RNA shedding and other factors were associated with BV.

Materials & Methods: Two hundred WLWH >18 years were recruited from six Departments of Infectious Diseases in Denmark during enrolment in the SHADE cohort, which is a prospective, observational cohort study of WLWH attending regular outpatient care for their HIV infection. Inclusion was between February 2013 and March 2014.
Categorical variables were reported as counts and percentages and compared by chi-square test or Fisher's exact test. Continuous variables were summarized as median and interquartile ranges (IQR) and compared using the Wilcoxon rank sum test. Univariate and multivariate logistic regression analyses were performed to identify predictors of HIV RNA vaginal shedding.
Cervical swabs were evaluated and scored according the Nugent system where stage I is normal vaginal flora, stage II is intermediary stage and stage III is the definition of BV.
Real-time Polymerase Chain Reaction (RT-PCR) was made for *Atopobium Vaginalis*, *Megasphaera type 1*, *Bacterial Vaginosis Associated Bacterium Type 1* and *Prevotella species pluralis.*
Finally, HIV RNA was measured in cervical swabs.

Results: Median age of the 200 included women was 44 years, ethnicity was predominantly white 93 (47 %) or black 78 (39 %). The majority (191 (96 %)) of women were on Anti-Retroviral Treatment (ART) and had undetectable plasma HIV RNA, 156 (84 %).
Symptoms from the lower abdomen were reported by 42 (21 %) women. Bacterial vaginosis, according to the Nugent system, was found in 54 (27%) women, 70 (35 %) were positive with PCR and 77 (39 %) were positive when microscopy and PCR were combined. No significant difference in BV diagnosis between women of white and black ethnicity was found (p-value 0.98).
Nine (12 %) of the 77 women positive for BV by either microscopy or PCR diagnosis had detectable HIV RNA vaginal shedding.
Overall, 24 (12 %) women had detectable (>66 copies/vaginal swab) vaginal HIV RNA. Most were well treated on ART (20 (83 %)).
Both before and after adjustment for age, ethnicity, latest peripheral HIV RNA, latest CD4 cell count, use of hormonal contraception and BV we found no significant predictors of HIV RNA vaginal shedding.

Conclusion: In this well treated population of WLWH in Denmark, we found a 39 % prevalence of BV.
The fact that we didn´t find a correlation between BV and vaginal HIV RNA shedding, especially among well treated patients, may indicate that a BV diagnosis in a fully suppressed HIV infected woman, is not as worrisome as assumed.

No conflict of interest

Abstract: 27

Diagnosis and treatment of HIV infection

Navigational Spatial Memory Test (MI) as a Cognitive Marker for HIV-associated Neurocognitive Disorder

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Introduction: In the era of combined antiretroviral treatment, HIV-seropositive (HIV^+) patients increase survival, however, a high

neurocognitive impairments prevalence was observed. Memory Island (MI) is a computer based test useful in identifying susceptibility to cognitive impairments, especially, in spatial learning and memory with the advantage of being a non-invasive test that can be easily administered. Since MI is not affected by culture, its validation and characterization in neurocognitive disorders represent a good screening test for HIV-associated Neurocognitive Disorder (HAND). The major **aim** of this study is to determine the validity of MI as a reliable instrument in the characterization of spatial learning and memory in HIV$^+$ women.

Methods: 61 women were recruited, 45 HIV-seropositive and 16 controls. HIV$^+$ women were evaluated for viral-immune profiles, MI, neuropsychological tests (NP), and BDNF. Cognitive performance was determined using the HAND criteria and stratified into HIV$^+$ women with normal cognition, asymptomatic (ANI) and mild (MND) neurocognitive impairment. A subgroup of women was evaluated with MRI for hippocampal volume. Parametric and non-parametric statistics were performed.

Results: No differences were observed in speed of navigation in trials to locate a clearly visible target, spatial learning trials to locate a target by using a spatial map of the environment among controls and HIV$^+$ women in MI. However, during the spatial learning trials, HIV$^+$ women with symptomatic neurocognitive impairment (SNI=ANI and MND) required more time and moved longer distance than controls and HIV$^+$ women with normal cognition. Thus, HIV$^+$ women had less efficient acquisition (learning) and worse performance when compared with HIV-seronegative and normal HIV$^+$ women. When memory retention was assessed in the probe trial (no target present), HIV$^+$ women with SNI spent less time in the quadrant of the island that previously contained the target than the controls and normal HIV$^+$ women. These measures demonstrate significant sensitivity and specificity (learning: 60% & 77%; memory: 70% & 77% respectively) in women with HAND, and correlated with NP test performance and hippocampus volumetric measures.

Conclusion: The use of MI test is a valid non-invasive, non-culturally sensitive tool, to detect spatial learning and memory deficits in HIV$^+$ women with HAND.

No conflict of interest

6th International workshop on HIV & Women

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Abstracts
Poster Presentations

Abstract: 28

Contraception, pregnancy, breast feeding, and PMTCT

Mother-to-child HIV transmission and its predictors among HIV-exposed infants: A retrospective follow-up study in Southwest Ethiopia

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Background: Despite the marked progress in coverage of prevention of mother to child HIV transmission (PMTCT) programs, high rate mother to child HIV transmission (MTCT) was documented among exposed infants. This raised questions about the effectiveness of PMTCT program and the need for more research on identifying predictors of MTCT of HIV. This study aimed to quantify MTCT rate and identify predictors among HIV-exposed infants at PMTCT clinic in Southwest Ethiopia.

Methods: Institution based retrospective follow up study was carried at Jimma University Specialized Hospital PMTCT clinic. Data were extracted from medical records of HIV-infected women and exposed infants between September 2010 and December 2012. Univariate and multivariate logistic regression analyses were carried out to identify potential infant and maternal factors predicting mother to child HIV transmission.

Result: A total of 146 infants born to HIV-infected mothers were included in the analysis. Majority, (83.6%), of HIV infected pregnant women were enrolled in ANC and 78.8% either were started on HAART or received a single dose of nevirapine (NVP) during labour. More than 80% of HIV-exposed infants received ARV prophylaxis (single dose of NVP plus AZT) for 7 days after birth. Out of 146 HIV-exposed infants, 25 (17%, 95% CI: 11%- 23.2%) were HIV positive. In the adjusted multivariate logistic regression analysis, mothers on late AIDS stage (stage 3 or 4) during child birth (OR=5.8; 95% CI: 1.6-16.5), absence of maternal PMTCT interventions (OR=4.9; 95% CI: 1.4-16.5), home delivery (OR=8.1; 95% CI: 2.1-31.9) and mixed infant feeding (OR=5.6; 95% CI: 1.4-41.2) were independently associated with mother to child HIV transmission among exposed infants.

Conclusion: We documented a high rate of mother to child HIV transmission among exposed infants on follow up at the PMTCT clinic in Southwest Ethiopia. All pregnant HIV positive mothers should be enrolled in PMTCT program at earlier stage and receive antiretroviral therapy. In addition, delivery at health center and exclusive breast feeding should be encouraged so as to decrease mother to child HIV transmission.

No conflict of interest

Abstract: 29

Contraception, pregnancy, breast feeding, and PMTCT

HIV status disclosure on antiretroviral treatment adherence in HIV positive pregnant women taking Option B+ in Moshi Municipality

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Background: In September 2013, Tanzania Ministry of Health and Social Welfare adopted the new World Health Organization 2012 prevention of mother-to-child transmission (PMTCT) guidelines option B+ and transitioned its national standard of care from option A to B plus. All HIV positive pregnant women were initiated on antiretroviral therapy for life irrespective of their CD4 counts (Option B+). As part of standard of care, HIV sero-positive women are advised to disclose their HIV status to their partners and refer them for testing. Disclosure of HIV status to

sexual partner is associated with improved adherence to PMTCT regimens. We aimed to assess the effect of HIV status disclosure on antiretroviral treatment adherence in pregnant women taking option B+ in Moshi Municipality.

Materials and Methods: This was a cross sectional study done in three Antenatal clinics (ANC) in Moshi Municipality which were systematically selected. Newly diagnosed HIV infected women in the ANC who were on Option B+ for at least one month were asked if they had disclosed to anyone their HIV status using a well structured questionnaire after consenting for the study. The questionnaires consisted of both open and closed ended questions. Adherence was measured by patient self report using Morisky 8-Item Medication Adherence Questionnaire, where by a score of more than 2, 1 to 2 and 0 were considered as low adherence, moderate adherence and high adherence respectively. Descriptive statistics was used to summarize the findings. A pearson chi square value (P-value) of <0.05 was used as a measure of association between independent variables and disclosure of HIV serostatus to partners and relatives .

Results: Sixty two HIV-1 positive pregnant women were screened, 56 (90.3 %) consented to participate in the study with a mean age of 29(±5.8) years. 87.5% had disclosed their status to either their partners and/or relatives. The odds of disclosure of their HIV status to partners were 1.2 times higher in HIV positive pregnant women who received counseling before and after testing than those who did not receive counseling before and after testing (odds ratio=1.2, 95% confidence interval: 0.9 to 1.6; P=0.008). From the self-report questionnaire using Morisky Medication Adherence Scale 44 (78.6%) of the HIV pregnant women demonstrated high antiretroviral treatment adherence while 3(5.4%) had low adherence.

Conclusion: There was no statistical evidence to support any associations between HIV status disclosure and antiretroviral treatment adherence as the proportion of HIV pregnant women who reported to have high adherence among those who disclosed and those who did not disclose their HIV sero-status to anyone was 79.6% and 71.4% respectively.

No conflict of interest

Abstract: 30

Contraception, pregnancy, breast feeding, and PMTCT

Raltegravir in pregnancy.

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Background: A Review of the Efficacy, Safety, and Pharmacokinetics of Raltegravir in Pregnancy
Background: Raltegravir was previously considered an alternative agent in pregnancy due to limited data, but recently updated pregnancy guidelines now recommend raltegravir as a preferred integrase treatment option to prevent maternal to child transmission of HIV.

Methods: A search was performed on March and June 2015 in EMBASE, Google Scholar, MEDLINE, PubMed, and Web of Science using the combination keywords (raltegravir OR RAL OR Isentress OR MK-0518), (pregnan*) AND (HIV OR HIV-1 OR human immunodeficiency virus). Results of all languages, published after 2001, were included. Proceedings from the following conferences were accepted: Annual Conference of the British HIV Association; Conference on Retroviruses and Opportunistic Infections; Interscience Conference on Antimicrobial Agents and Chemotherapy; Romanian National HIV/AIDS Congress; and World AIDS conference. Reference lists were hand-searched. An additional proceeding from the 2015 International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention was included. A total of two prospective pharmacokinetic studies, eight retrospective studies, and 15 case reports are included in this review.

Results: A total of 256 maternal-infant pairs were reported. The majority of literature is comprised of case studies and retrospective chart reviews and two small prospective pharmacokinetic studies. The raltegravir regimens were administered both to naïve and experienced women, but most

commonly in the third trimester with the goal of rapid viral reduction prior to delivery. Multiple physiological changes during pregnancy can account for highly variable but overall reduced maternal plasma raltegravir levels, but given the inherent pharmacokinetic variability of this drug, these changes do not appear to affect viral suppression, and dose adjustments have not been recommended. Raltegravir is highly transferred across the placenta and has prolonged elimination in the neonate, two properties that support its efficacy in preventing MTCT. There is evidence for maternal safety with the exception of possible rare, reversible, and transient increase in maternal transaminases. Baseline liver transaminases should be performed in women before starting raltegravir, and if elevated the drug should used with caution and more frequent monitoring of liver transaminases should be considered. No infant adverse effect was consistently reported except for one study observing 14% of infants being small for gestational age, but the relationship to raltegravir was unclear. The viral decay associated with raltegravir treatment is reliably rapid and most women delivered at undetectable viral levels.

Conclusions: Our findings summarize the data leading to the recommendation of the DHHS treatment guidelines to consider raltegravir as the preferred integrase inhibitor in ARV-naïve pregnant women. The limited pregnancy data should be considered when counselling ARV naïve patients on her best option. Available evidence supports the recommendation of continuing raltegravir-based treatment in virologically suppressed women who are anticipating pregnancy. There is insufficient evidence to recommend switching to integrase inhibitors in women planning pregnancy if alternate effective strategies are in place.

Conflict of interest: Merck Canada

Abstract: 31

Contraception, pregnancy, breast feeding, and PMTCT

Invasive pre-natal diagnosis in HIV positive women

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Introduction: Until recently invasive pre-natal diagnostic procedures (IPNP) was not advised in hiv pregnant women due to the risk of vertical transmission. With the widespread use of cART, with sustained virologic suppression this risk could be considered to be negligible.

Material & Methods: Retrospective analysis of the files of HIV infected pregnant women who underwent amniocentesis at our institution, from January 2004 to December 2014. The baseline demographic, clinical and obstetric data were collected.

Results: During this period 16 amniocentesis were performed of a total of 238 pregnancies of HIV infected women. Median maternal age was 34,5 years. Eight women were born in Portugal, seven in Africa and one in France. In 15 cases infection was acquired by sexual transmission, in one case by substance abuse.14 were HIV1 infected and two HIV2 infected. In 15 women HIV infection was already known and in one HIV infection was diagnosed during pregnancy, only after IPNP was performed. HIV infection CDC staging revealed that 7/16 fulfilled Aids definition criteria,81% presented with LTCD4<350/mm^3. Indication for amniocentesis was advanced maternal age(10), positive combined screening(5) and suspicion of toxoplasmosis infection(1). Median gestational age at IPNP was 17.5 weeks. In all the known cases of HIV infection cART was introduced prior to the procedure, in the 11 women already on cART it was continued or optimized (one was in virologic failure). There were no complications following IPNP.RNA-HIV1

was evaluated at enrollment, amniocentesis and delivery (table 1). HIV2 viral load was not available. The woman diagnosed during pregnancy presented with the highest viral load (6.29log) at IPNP, and was the only one with a viral load above 1.000 cp/µL at delivery.All the pregnancies ended at term , with 16 newborns. There were no cases of vertical transmission.
Conclusion: According to this data, in HIV infected pregnant women virologically suppressed on ART, and that fulfill the indications to perform IPNP, this procedure should be offered.

No conflict of interest

Abstract: 32

Contraception, pregnancy, breast feeding, and PMTCT

HIV and reproductive health care engagement among pregnant and postpartum HIV-infected women in Atlanta, Georgia, 2011-2014

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Background: HIV infection during pregnancy is associated with maternal and fetal risks, particularly in underserved populations with barriers to access to HIV and reproductive health care. We sought to describe pregnancy and postpartum HIV and reproductive health care engagement among HIV-positive women who delivered in a large public hospital in the Southeastern United States.

Methods: Data were retrospectively collected via electronic medical record review on all pregnant HIV-infected women who delivered above 24 weeks gestation at Grady Memorial Hospital, a large public teaching hospital in downtown Atlanta, Georgia, from 2011 to 2014. We evaluated the proportion of women retained in HIV care and with suppressed HIV viral load (VL<200 copies/mL) at 6 and 12 months postpartum. A woman was not considered retained in HIV care at 12 months postpartum if she was not retained in the first 6 months.

Results: A total of 183 deliveries occurred above 24 weeks gestation among HIV-infected women. The majority of women were African-American (84.9%), with a mean maternal age of 27.5 (SD 5.7) years. Of the 140 women with a previous HIV diagnosis, only 70 (50%) were receiving antiretroviral therapy before entry into prenatal care. Patients had an average of 8.0 (SD 3.7) prenatal care visits, and 170 (92.9%) received antiretroviral therapy during pregnancy. Among the 180 women with VL available at the time of delivery, 159 (88.3%) had VL<1000 copies/mL and 131 (72.8%) had VL<200 copies/mL. Overall, 135 (73.8%) women presented for a postpartum obstetrical appointment. Among the 172 women who were not known to follow-up for HIV care outside of our healthcare system, 83 (48.3%) attended at least one HIV care appointment within 6 months postpartum, and 54 (31.4%) were retained in HIV care at 12 months postpartum. Only 59 (34.3%) women achieved VL <200 copies/mL at 12 months postpartum. A total of 146 women (78.9%) received some method of contraception within 6 months postpartum, but only 58 (31.7%) received a highly-effective method, such as an IUD, contraceptive implant, or tubal ligation, and 36 (21.8%) women experienced a subsequent pregnancy during the follow-up period.

Conclusion: Despite a high level of care engagement during pregnancy, postpartum retention in HIV care, viral suppression, and use of highly effective contraceptive methods were low in this cohort of HIV-infected women, putting mothers at high risk of morbidity and subsequent unintended pregnancy. Interventions are urgently needed to engage and retain HIV-infected women in both HIV and reproductive health care postpartum.

No conflict of interest

Abstract: 33

Contraception, pregnancy, breast feeding, and PMTCT

Long acting reversible contraception: facility data mapping to understand utilization and health programme implementation

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Background: Effective, long-acting contraception methods has been identified as a key priority intervention in Sub-Saharan Africa to address high rates of unwanted pregnancies, particularly in HIV positive women. Commonly used contraception such as the oral pill and injectable, requires significant user adherence hence suffers from high rates of interruption. Therefore, South Africa launched Implanon NXT in February 2014, a promising non user-dependent method offering superior protection from pregnancy compared to such methods.
The South African National Department of Health (NDoH) reports approximately 900 000 insertions and 4937 removals since roll-out; however anecdotal reports from healthcare providers suggest a rise in early removals coupled with a steady decline in uptake. There is a significant gap in literature in South Africa regarding implementation and reporting of this method. Therefore, this preliminary facility mapping exercise aimed to determine: (1) how implant insertions and removals are recorded and if this is adequate for reporting, (2) whether the prescribed data collection forms are being utilized and (3) barriers and challenges with delivery of this method.

Materials and Methods: Facilities in the City of Johannesburg, Gauteng Province and Dr Kenneth Kaunda District in the North West Province were selected based on volume of insertions extracted from the District Health Information System (DHIS). Four high volume insertions clinics and 3 low volume insertion clinics were selected. Clinics were scored using a 6 item checklist for data adequacy which captured the presence or absence of data elements specific to recording of implant insertions and removals. In addition, researchers engaged in an informal discussion with family planning providers to understand data collection processes, barriers and challenges.

Results: The data mapping revealed that insertions and removals are recorded in an adhoc manner through the use of home-made tools thus leading to under-reporting. Furthermore, reasons for removal are not systematically recorded and in some cases not at all. Six out of the 7 facilities where not familiar with the nationally prescribed data collection tool for recording implant insertion, removal and adverse reaction, called the Active Surveillance Reporting Form for Sub-Dermal Implants. Health care workers cited that they had not been oriented about the guidance for data collection and reported therefore adopted local solutions. From the informal discussions, healthcare providers stated that clients were presenting within a short time frame after insertion (under 6 months) for removals with reasons such as partner dissatisfaction, side effects or because pregnancy was discovered. They also highlighted that only a limited number of staff were trained on insertions and removals and therefore was a barrier to scaling up the programme and meeting the increased demand.

Conclusions: The data on implant removals currently being collected is not adequate for reporting which will lead to under-reporting of the magnitude of this occurrence at the National level. In order for the data to inform effective decision making in respect of the roll-out of Implanon NXT there is a need for standardized recording procedures and reporting guidelines, strengthened communication, reinforcement of practice and increased coverage of training to capacitate all relevant cadres of health personnel.

No conflict of interest

Abstract: 34

Contraception, pregnancy, breast feeding, and PMTCT

Pregnancy incidence by pregnancy intention and ART status among women living with HIV in Canada: A retrospective cohort analysis

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Introduction: Research suggests that fertility intentions and pregnancy incidence among women living with HIV (WLWH) have increased over time as a result of access to combination antiretroviral therapy (cART) and associated improvements in health outcomes, life expectancy, and lowered perinatal HIV transmission risks. However, the relative role of unintended pregnancies in driving these trends remains unclear, in addition to which factors may explain these trends.

Material & Methods: We analyzed cross-sectional survey data for WLWH enrolled in the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS), a longitudinal, community-based research study that enrolled 1,425 WLWH in British Columbia, Ontario, and Quebec between 2013-2015. Assessment of pregnancy incidence was restricted to cis-gender women and measured by self-reported pregnancy history from time of HIV diagnosis until time of CHIWOS interview (up to a maximum of eight pregnancies). Person-time methods were used to compute incidence rate as number of pregnancies per 1000 woman-years (WYs) from time of HIV diagnosis. Pregnancy incidence was computed overall and by pregnancy intention (unintended vs. intended) and cART status at time of pregnancy (on cART prior to pregnancy vs initiated cART during or following). Bivariate analyses using Chi-square or Fisher Exact test compared demographic and clinical characteristics of WLWH with a current or most recent pregnancy that was self-reported as unintended vs. intended.

Results: Overall, 1099 WLWH were included in this analysis with 262 women reporting a total of 466 pregnancies after HIV diagnosis. Of the 466 pregnancies, 59% were unintended and 66% of women had initiated cART prior to the start of pregnancy. The overall pregnancy incidence rate was 41.1 per 1000 WY (95% CI: 36.1-46.8), with no statistically significant difference between intended (17 per 1000 WY, 95% CI: 14.1-20.6) and unintended pregnancies (23.7 per 1000 WY, 95% CI: 20.1-27.9). Pregnancy incidence among women on cART prior to pregnancy (28.6 per 1000 WY, 95% CI: 24.5-33.4) was significantly higher than among women not on cART prior to pregnancy (11.9 per 1000 WY, 95% CI: 9.4-15.0). In comparison to WLWH with an intended recent or current pregnancy, those with unintended pregnancies were more likely to be currently single (vs married or in a relationship) (61.5% vs. 46.7%, p=0.020), identify as LGBTQ (vs. heterosexual) (14.7% vs. 6.5%, p=0.043), identify as Indigenous (vs. White) (19% vs. 11%, p=0.002), have incarceration history (vs. no incarceration history) (46% vs. 26%, p=0.001), and have a self-reported mental health disorder diagnosis (vs none) (48% vs. 32%, p=0.011). A higher proportion of unintended pregnancies resulted in pregnancy termination compared with intended pregnancies (29.4% vs. 1.9%, p<0.001).

Conclusions: Nearly 60% of all pregnancies that occurred after HIV diagnosis among WLWH in this study were self-identified as unintended pregnancies. Given that unintended pregnancies are associated with poorer perinatal outcomes and potential adverse maternal health outcomes, efforts must be made to ensure that the sexual and reproductive care needs of all WLWH are prioritized, which includes access to effective contraception.

No conflict of interest

Abstract: 35

Contraception, pregnancy, breast feeding, and PMTCT

Socio-demographic determinants affecting uptake of PMTCT services among pregnant women attending antenatal care in Abia state, Nigeria

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Background: Transmission of HIV from pregnant mothers to their children is a key route of HIV transmission in Nigeria. About 4.1% of women attending ANC are infected with HIV, resulting in mother-to-child transmission accounting for 10% of all HIV infections in the country. MTCT can occur during pregnancy (10 – 25%), labour and child birth (40 - 60%) and breastfeeding (20 – 40%) as a result several factors which may increase the risk of transmission at each of the 3 phases such as viral, maternal, obstetric, fetal and breastfeeding. Nigeria contributes about 30% of the global PMTCT gap and coverage of PMTCT services has remained low at <19% - falling short of both the universal access and National Strategic Plan targets. The study aims to identify factors underlying the low uptake of PMTCT interventions in rural and urban public primary health facilities of Abia state, Nigeria.

Method: A comparative cross-sectional analytical study design was used with three stage sampling method to select 350 clients in 10 of 74 health centers that offer PMTCT services in the state. Clients were women who attended antenatal care in the facilities. Outcome measures were knowledge, attitude and practice of PMTCT services.

Result: Their mean and standard deviation for knowledge score were 17.85(3.61) and 13.85(4.33), attitude 4.83(0.51) and 4.22(1.07), practice 6.89(1.44), 6.74(2.29), for urban and rural areas respectively. There were significant differences for knowledge and attitude p <0.001 but not significant for practice p=0.451.There were significant associations between socio-demographics: (education in urban p<0.001, employment p<0.001 and income for rural p=0.039) and mean knowledge, (age in urban p=0.001 and income for rural p=0.017) with mean attitude and income for urban p=0.043 with mean practice. Predictors of PMTCT uptake were income (AOR=4.7, 95% CI: 1.9-11.5) for knowledge and employment (AOR=3.7, 95% CI: 1.2-10.7) for attitude.

Conclusion: Education, employment and income influences PMTCT uptake. Empowering women with quality education will improve utilization of PMTCT services as it determines their employment status as well as earnings.

No conflict of interest

Abstract: 36

Contraception, pregnancy, breast feeding, and PMTCT

Factors associated with intimate partner violence in pregnant women with HIV in a hospital in Mexico.

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Background: UNAIDS 2015 reports that the economic and social dependence of women towards your partner generates less access to educational and economic opportunities, inability to inherit or own property and lack legal protections that often limits the ability of women to refuse to have sex.
Gender violence associated with abuse, and contracts in exchange for goods or money sex often decrease the possibility of safe sexual practices which increase the risk of infection. The objective was to identify the factors associated with intimate partner violence in pregnant women with HIV in Mexico.

Material and methods: This is a cross-sectional study in which 180 women with HIV who attended prenatal care and control of HIV disease in the Hospital de Infectología, 'La Raza' National Medical Center, for the period 1990-2015 were selected. Some variables were analyzed regarding maternal and partner sociodemographic variables, neglect, emotional, sexual and physical violence was included using a validated instrument for Mexican population Index of Spouse Abuse (ISA) 5 Severity of Violence Against Women Scale (SVAWS) plus explore economic violence. It is noteworthy that these scales, consists of four subscales which measure the frequency of violent actions in the last 12 months (1 = never, 2 = sometimes, 3 = several times and 4 = often).

Results: median age was 25 years (IQR 21-24), 70% of the cases diagnosed were during pregnancy, there was a higher proportion in urban areas, compared with rural areas (2.1% vs. 1.0%), 35% with incomplete high school and 21% with incomplete elementary education, 40% are engaged in housework and the most frequent marital status was married in 60%, economic dependence on their partners were found in 73% of women.
Factors associated with maternal-child transmission of HIV were violence [OR 1.5 (95% CI 0.67-3.67), p <0.29], neglect [OR 2.2 (95% CI 0.94-5.36), p <0.06], emotional violence [OR 2.2 (95% 0.94-5.36), p <0.06], physical violence [OR 2.7 (95% CI 1.11-6.79), p <0.02], sexual violence [OR 1.38 (95% CI 0.53 - 3.59), p <0.5], economic violence [OR 2.7 (IC95 1.2%-6.3), p <0.01] respectively.

Conclusions: Relationship between violence and HIV remains very common. Violence limits women's ability to prevent HIV or AIDS for several reasons: threats or limit the use of force as appropriate decisions leaving the dangerous relationship. The same economic limitation is related, as it could cause a woman to stay in an abusive relationship.

No conflict of interest

Abstract: 37

Contraception, pregnancy, breast feeding, and PMTCT

Risk factors associated with maternal–child HIV transmission in a third level hospital in Mexico

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Background: Mother to child HIV transmission (MTCT) continues around the world; in 2014 were reported 260,000 cases worldwide, 188 of them in Mexico.
The identification of risk factors for MTCT and the application of preventive strategies are the most effective intervention available. The objective was to identify sociodemographic, maternal, and clinical factors associated with maternal-child HIV transmission in Mexico.

Material & methods: This is a case-control study conducted in the Hospital de Infectología, 'La Raza' National Medical Center, a third level and reference center in Mexico City from May 1, 2008 to December 31, 2015. We included cases of HIV infected mothers who transmitted HIV infection to their children, and controls HIV mothers with children with negative results for HIV. We excluded patients with incomplete records. We analize sociodemographic, maternal, and clinical factors associated with maternal-child HIV transmission (MCT). OR and CI95% was obtained with chi squared test.

Results: 60 cases and 120 controls were analyzed, median age was 25 years (IQR 21-24), 89% of the cases were diagnosed after pregnant and 60% of controls were diagnosed at this time. Median weeks under ART in controls was 17 (IQR 11-24). The most common regimen of treatment was zidovudine/lamivudine + lopinavir/ritonavir. Risk factors associated with MCT were vaginal delivery (OR 8: $IC_{95\%}$ 4.0 - 18.9, p<0.001); premature rupture of membranes (OR: 2, $C_{95\%}$ 0.52 - 13.55, p = 0.310); mothers who practiced breastfeeding (OR 18, $IC_{95\%}$: 7.71- 42.44, p = <0.0001), and mothers who practiced mixed breastfeeding (OR 9, $IC_{95\%}$ 4.01 - 23.7, p = <0.0001). No cases of maternal-infant transmission of HIV occurred was initiated ART before delivery.

Conclusions: Maternal-Child Transmission of HIV is preventable if a series of documented efficiency strategies is applied. Breastfeeding was a high risk to transmission of HIV infection.

No conflict of interest

Abstract: 38

HIV prevention in women

Promoting the use of transparent soap sculptures as a communication tool for HIV/AIDS care and awareness among female headed households affected by HIV/AIDS.

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Background: Compounded by gender disparities as a consequence of social-cultural construction, women and girls have been known to be more vulnerable to the HIV/AIDS scourge in Uganda. Moreover traditionally, women are submissive and discussing sex related matters amongst themselves is considered obscene, leading to a communication barrier that limits women's access to HIV treatment and care services.

Transparent soap sculptures were developed by a Ugandan woman inspired by personal experiences after caring for people living with HIV as well as literature on HIV/AIDS. The soap images depict the male and female genitalia in abstract form and were aimed to overcome the taboo of displaying reality sexual organs in public. The use of these soaps is being pioneered by Family Support Initiative (FASI) a community based organization working with families affected by HIV and AIDS in Uganda.

The Transparent soap sculpture model (TSSM) facilitates the discussion of sex and HIV related issues and identifies the communication gaps and assessment of knowledge levels within the target groups. Important information highlighting the challenges and barriers to information access, uptake and utilization of HIV treatment and care services was identified.

The main objective of this presentation is to introduce another information, communication and education (IEC) material in relation to HIV treatment, care and support; as we share the findings.

Method: The project uses transparent soap sculptures in three strategic areas of implementation namely study circles (groups of 10-15), focus group discussions and counseling. Grouping is done using a peer model for example women on ART, Youth on ART, discordant couples, widows in new relationships, members open or not open on HIV status and the un tested. In counseling, the tool is used to help participants explore personal issues in relation to sexuality, vulnerability among others.

Results: The soaps offer a simple, cheap and culturally appropriate model of HIV/AIDS information dissemination that is easy to understand and interpret, even by the semi-illiterates.
Their abstract nature renders them culturally appropriate and enticing to touch when presented, as compared to other materials, thus simulating discussion while avoiding the cultural 'awkwardness' related to discussing sex.
They also depict real life experiences in association with HIV infection, transmission and progression in relation to HIV/AIDS treatment care and support.
Their transparent nature represents purity or cleanliness of oneself, soul and body, according to the perception given during sessions.

Conclusion: The model is a kind that facilitates assessment of awareness levels on the topic of discussion, while leaving a longer lasting impression in the minds of participants, hence enhancing behavior change as the individuals relate what they learnt, to their own life situations. They are a great contribution designed by a woman in the fight against HIV/AIDs. They deserve to be promoted beyond FASI so that they contribute to behavior change and breaking of communication barriers in relation to HIV/AIDS, the world over.

No conflict of interest

Abstract: 39

HIV prevention in women

Acceptability of PC-1005 vaginal microbicide gel: a mixed-method study and conceptual framework from a Phase 1 trial

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Introduction: Scientists have been developing vaginal microbicides to provide women with a female-controlled option for preventing HIV and other sexually transmitted infections. For a microbicide to be effective, it must be used consistently and correctly, which implies it is acceptable to users. Conceptualizing and assessing acceptability in the context of microbicide trials is complex, with different domains lending themselves to measurement at different clinical testing phases. As part of a Phase I trial, quantitative and qualitative methods were used to explore PC-1005 vaginal gel acceptability.

Materials & Methods: In 2014-15, 23 non-pregnant, HIV-negative women aged 19-49 were enrolled in a randomized, placebo-controlled, double blind trial testing the safety, pharmacokinetics, and acceptability of PC-1005. Participants were instructed to apply one 4 mL gel dose daily for 14 days. Each participant completed a self-administered, quantitative acceptability interview (Day 14), and participated in a qualitative in-depth exit interview (IDI) (Day 21). This analysis is restricted to the 14 women randomized to PC-1005 who completed both interviews. To guide analyses, we developed a conceptual model focused narrowly on areas of influence relevant in a Phase I trial: individual factors, trial context, and product characteristics. Based on the quantitative data, scores were created for three acceptability domains: product-associated, application-associated, use-associated. A score for overall opinion was also created. For each domain, a score (range 0-1) was calculated per participant as the average number of favorable/neutral responses. Two analysts independently coded qualitative data

using thematic analysis based on the conceptual model.

Results: Median participant age was 28.5, 10/14 women were black, and 4/14 were white. One was married, and 8 were unmarried but had a partner. Half had had vaginal sex in the past three months, and eight had been tested for HIV within the past year. Participants' mean scores for the acceptability domains were generally high: 0.84 for product-associated acceptability, 1.0 for application, 0.69 for use. The mean score for overall opinion was 0.77. The lower use domain score was driven by nine women who were bothered by gel leakage. In IDIs, individual factors that influenced acceptability included HIV risk perception and relationship factors; women felt the gel was most acceptable for those who felt they were at high HIV risk or who had multiple partners. Several women felt gel volume and leakage were undesirable product characteristics, and that applying the gel daily at the same time was challenging. Trial-specific contextual factors influencing acceptability included the desire to contribute to science, and appreciation for clinic staff. Product-associated factors included favorable characteristics of the gel, such as its lack of odor or color.

Conclusions: Although users found gel application highly acceptable, overall, some were bothered by gel leakage, which may have been due to the volume. These findings suggest the volume of gel delivered should be reduced in future trials. Acceptability findings from a Phase I trial – at a stage when product characteristics and use protocols can still be refined – reinforce the importance of exploring acceptability in depth in early testing to inform future product development.

No conflict of interest

Abstract: 40

HIV prevention in women

Does participation in harm reduction program exclude risky behaviors of female IDUs in Georgia?

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Introduction: Needle sharing practice remains the main factor for spreading HIV (47.3%) among people who inject drugs (PWIDs) in Georgia. Estimated number of injecting drug users (IDUs) have been increasing during recent years in Georgia and is considered to be 49,700. No size estimation for female IDUs exists in the country. In spite of 5 times increased coverage of female IDUs in Needle and Syringe program (NSP) women IDUs remain the most stigmatized and hard to reach population for existing NSP in Georgia. The objective of this study is to analyze risky injection and sexual behavior of PWIDs and among them female IDUs who are the clients of NSP, for to assess how participation in NSP program results in their risky behavior, as well to assess if there exists significant difference in risky behavior between male and female IDUs.

Methods: Consecutive sampling was used to recruit PWIDs during 5 months in 2015. The selection criteria was: a) Drug injection practice during last month; b) be a beneficiary of NSP program for more than 6 month; c) age should be 18 or more and d) willing to participate voluntarily into study. Sample size was 1032, among them female IDUs were 129 (12,5%) totally beneficiaries from 13 NSP sites participated in the study. Structured standard questionnaire of Risk Assessment Battery (RAB) was used to assess Drug Risk and Sex Risk Items separately and calculate RAB Score (Drug Risk Total+Sex Risk Total). SPSS 15.0 was used for data analyses.

Results: Female IDUs revealed using drugs not in a close environment, they inject drugs with more than 2 person (mean 2.9, median 3, mode 2), they mostly don't share injectable equipment (94.9%) in comparison with men who (38%)

stated Needle sharing practice at least once during last month, among them 43.8% shares with only 1 and 56.1% with more than 2 persons (p<0.05). As referring to sexual practice, 15.97% female IDUs had more than 2 sex partners during 6 months and with whom they use condoms mostly 22.69%, sometimes 21.01%, always 32.77 (men participants revealed risky sexual behavior regarding condom use and number of partners during last 6 months). Meaningful was to reveal, that 10.08% (2 times less than men) of study participants had never tested on HIV and 34.45% was tested more than a year ago. Total RAB Scale Score is equal to 0.26 (Range=0-1).

Conclusion: The study results demonstrate that female IDUs practice risky behavior despite involvement in harm reduction program, but in comparison to man IDUs their risky behavior is less risky. This refers to both sexual and risky injection behavior. HIV testing rate among female PWIDs is attempted and needs further investigation of reasons for it. The findings of this study will be used to address needs of female IDUs, modify program direction or implement new approaches to attract, retain and increase safe behaviors of female IDUs

No conflict of interest

Abstract: 41

HIV prevention in women

Decision-making about self-protection from HIV when engaging in risky sexual behavior in the southern USA

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Introduction: A high number of women continue to represent new cases of HIV, particularly in the Southeastern United States. Despite widespread knowledge about the ways to prevent sexual transmission of HIV through the use of barrier protection, the epidemic continues to impact many Americans, with minority populations disproportionately affected. Largely, there is a dearth of information on the decision-making process that women use to guide their use of self-protective measures.

Material & Methods: This study was conducted using a qualitative grounded theory method to examine the decision-making process about using self-protective measures when engaging in activities that could put one at risk of acquiring HIV. Participants included 20 women living in the South who were infected or uninfected with HIV and are part of a cohort of the Women's Interagency HIV Study (WIHS). HIV-infected women were limited to those diagnosed in 2005 or later. Uninfected women in WIHS had to have risk factors for HIV transmission in the 5 years prior to their enrollment in WIHS which began in this cohort in 2013. Theoretical sampling was used to generate a sample of primarily African American women, ages ranging from 26 to 56, living in rural and urban areas. Constant comparison analysis was used to generate themes of factors that guided their decision-making process.

Results: Themes that were revealed included:

- A Surrounding Silence About Sex;
- The Importance of Relationships, including
    - Feelings of Love/Trust;
    - Filling the Void; and
    - Don't Rock the Boat
- Perception of Risk, including
    - Faulty Reasoning about HIV,
    - It Couldn't Happen to Me, and
    - It Never Crossed My Mind

The Surrounding Silence about Sex in the society where a woman lives, as well as within her intimate relationships, was found to impact her ability to make decisions to protect herself. The Importance of Relationships made it difficult for women to perceive HIV risk, and to attend to this risk through self-protection measures. Faulty reasoning about HIV motivated her to be tested for HIV frequently, but did not necessarily lead her to engage in prevention activities or demand that

her partner be tested, even in situations where she was aware of her risk.

Conclusions: This information can be used to guide additional research and interventions to impact these three main factors and thus lower the rate of HIV transmission in women.

No conflict of interest

Abstract: 42

Special Populations: Sexworkers, Transgenders, etc.

Understanding the factors associated with alcohol use among female sex workers in a high HIV prevalence northeast state of India

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Background: The intersection between alcohol use and female commercial sex work has been identified as an important factor that responsible for rising HIV prevalence among female sex workers (FSWs) in several north-eastern states of India. But, little is known about the factors associated with the use of alcohol among FSWs in this region. The paper illustrates the factors associated with alcohol use among FSWs in Dimapur, an important commercial hub of Nagaland, which is a high HIV prevalence state of India.

Material & Methods: Data from *Integrated Behavioural and Biological Assessment (IBBA*) round 2 is used.This study is a cross sectional among FSWs was conducted in the Dimapur district of Nagaland in 2009-2010 as a part of large multi-center study known as the Integrated Biological and Behavioural Assessment (IBBA) Analysis is based on 417 FSWs aged above18 years or older. The dependent variable is consumption of alcohol. Other variables of interest were socio-demographic characteristics, pattern of sex work, sexual risk Behaviour, volume of clients per week and knowledge about HIV. Chi-square statistics were used to see whether there is any association between the dependent and independent variable. Further binary logistic regression were used to identify the factor that which variable playing the important role to fuel filling the alcohol consumption and HIV sero-positivity among female sex worker. Logistic regression has also used to see, weather alcohol use is a factor that influence the HIV among female sex worker or not. Three models have been used to identify the factor associated with alcohol consumption and HIV sero-positivity among female sex worker in Dimapur.

Results: There is significant association between ever consumption of alcohol use among female sex worker and education , ever drug use, needle / syringe changing behaviour, age at first sex, age at first started sex work, volume of clients per week and condom use with occasional, regular clients($p<0.05$). Alcohol use among FSWs found that greater than 25 years of FSWs (2.2 times, $P\leq0.10$), divorced/Separated (0.41 times, $p\leq0.10$), $>10^{th}$ standard of education (0.311 times, $p\leq0.001$), drug use (5 times, $p\leq0.001$), sharing of injecting drugs with the partner (3.7 times, $p\leq0.001$) were independently associated with Alcohol use respectively. Those FSWs have first sex and first started sex work at age 15-20 years were 6.3times ($p\leq0.05$) and 2.4 ($p\leq0.05$) times more likely to use alcohol respectively. Alcohol using older (25+ years) FSWs were more likely to have HIV sero-positivity almost 9 times. And those alcohol using FSWs aged at first sex was 15-20 years, are at 5 times more likely to have HIV sero-positivity.

Conclusion: Several factors such as drug use, marital status, educational status, age at first sex, larger volume of clients, and sexual partners' drug injecting status were identified as having association with drug use among FSWs. The findings suggest a need to integrate intervention for alcohol use and related problems in multilevel contexts and with multiple components in order to effectively reduce alcohol use and to mitigate inconsistent condom use.

No conflict of interest

Abstract: 43

Special Populations: Sexworkers, Transgenders, etc.

Identifying strategies to combat HIV-related stigma in women living with HIV/AIDS in the Dominican Republic: the role of sex work

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Introduction: Internalized stigmas related to HIV negatively impact the mental and physical health of women living with HIV/AIDS (WLWHA). The present work aims to increase our understanding of how WLWHA overcome internalized HIV-related stigmas by documenting the strategies they use to do this. Additionally, this work will shed light on how involvement in sex work complicates and/or changes these strategies for WLWHA. Findings will provide outreach workers and clinicians with new insights to improve their ability to help diverse HIV-positive clients manage internalized stigma.

Materials & Methods: This study took place in San Felipe de Puerto Plata, Dominican Republic. All participants were Spanish-speaking, not pregnant, at least 18 years old, and HIV-positive. Since this study was a secondary analysis of a larger project looking at motherhood, stigma and HIV, respondents had at least one child under the age of 16. Investigators verbally administered the Internalized AIDS-Related Stigma Scale (IA-RSS) to 233 WLWHA. Participants who reported the least internalized stigma possible on the IA-RSS (N=7) or reported ongoing sex work (N=13) were selected for semi- structured open-ended interviews to identify internalized stigma minimization strategies. Interviews were conducted in Spanish and audio recorded. Interviewees were probed about several themes including: their reactions to stigmatization from family, friends, neighbors and community members; how stigmatizing events made them feel; if and how they were able to alleviate emotional stress associated with stigmatizing events; how often they experienced stigma and by whom; and potential reasons why some people might stigmatize WLWHA. Interview transcripts were analyzed separately by three trained independent coders to identify recurring themes.

Results: All WLWHA employed stigma minimization strategies such as adopting a superior identity (e.g., highlighting that stigmatizers lack the capacity to understand/accept interpersonal differences), educating oneself and others about HIV, viewing HIV as a manageable condition, looking to family and friends for social support, and Christian faith. WLWHA who reported sex work employed additional stigma minimization tactics such as consciously choosing to ignore stigma, taking strategic precautions to avoid potentially exposing clients to HIV, and seeking out HIV-positive relationship (e.g., non-paying) male partners. Participants reported that stigma was most severe following their HIV diagnosis and lessened with time, indicating that participants may become increasingly adept at deploying stigma minimization tactics. HIV disclosure in this study was complicated; some participants reported they did not feel stigmatized for living with HIV because they hadn't told anybody due to fear of rejection and gossip. WLWHA who reported involvement in sex work went to great lengths, such as moving away from their hometowns and limiting communication with friends and family, to ensure that their involvement with sex work and HIV diagnosis remained secret. This emphasizes the need for clinicians to work closely with WLWHA to understand their life circumstances when designing disclosure plans.

Conclusions: WLWHA engaged a broad range of stigma minimization strategies and involvement in sex work prompted WLWHA to deploy additional tactics. Findings suggest that counseling WLWHA about stigma minimization strategies early on could lessen internalized stigma and subsequently, its negative effects.

No conflict of interest

Abstract: 44

Women living with HIV

HIV Positive Widows in New Delhi, India: A Perspective on Psycho-Social Challenges using Qualitative Approach

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Introduction: Widowhood is very stigmatizing. With an estimated number of 40 million, India is the home to the largest number of widows in the world. Widows in India endure social and psychological deprivation in addition to economic hardship. Deeply engrained patriarchal customs and orthodox social milieu push the widows towards deprivation, stigmatization, abuse and marginalization from the mainstream. HIV positive diagnosis further compounds the problems as now they get doubly marginalized by virtue of being a widow and of being HIV positive. The HIV positive widows struggle with complex social and psychological issues and strive to make ends meet with little or absolutely no income. Though literature is available regarding issues confronted by HIV positive women in general, but, there is paucity of literature related to HIV positive widows.

Material and Methods: The current study used qualitative approach to learn about various psycho-social issues which influence the lives of HIV positive widows. Purposive sampling was used to select 10 HIV positive widows from HIV clinic at New Delhi, India. Open-ended interviews were used to gather the relevant information from the respondents. The major domains that were focused upon were knowledge about HIV/AIDS; everyday worries; reactions towards realization about HIV; psychological challenges such as feelings of sadness, hopelessness, and anxiety; social issues ranging from relationship with family and neighbours; challenges in raising their children who may or may not be HIV infected; stigma or discrimination due to HIV or any other reason; and economical condition. Thematic analysis was used to decode the acquired data.

Result and Conclusion: Analysis showed that HIV positive widows face wide-range of psycho-social issues and troubles in day-to-day life. The awareness about HIV was found to be incorrect. Also, disillusionment, dejection and fear of rejection were the first reactions of the patients when they become aware of their HIV-status. The most striking part of results showed that no severe form of stigma or discrimination due to HIV per say was reported by the respondents. Instead, it was the financial dependence of widows upon in-laws which led to their abandonment and social exclusion. Natal families and neighbours were reported to be supportive. Financial crisis also emerged as an important issue among all the respondents. Besides these, future concerns about their children, role of natal family as emotional and financial supporter, and role of NGOs in providing support emerged as important themes during the course of interviews.

No conflict of interest

Abstract: 45

Women living with HIV

Transition from Pediatric to Adult HIV Care in a Population of Young, Canadian Women with HIV Acquired in Childhood

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Introduction: A well-planned transition from pediatric to adult HIV care is imperative to optimize patient health and avoid negative care outcomes. There is limited research on this topic, particularly in the Canadian context. Among young women living with HIV (WLWH) who had ever received pediatric HIV care we measured personal preparedness for transition to adult care and perceptions of quality of HIV-related care. We hypothesized that the majority of participants would report: (1) feeling unprepared for transition; and (2) poorer HIV-related care post-transition.

Methods: Baseline data were analyzed for WLWH (≥16 years) enrolled in the Canadian HIV Women's Sexual and Reproductive Cohort Study (CHIWOS), an ongoing, longitudinal cohort in British Columbia (BC), Ontario (ON), and Quebec (QC). Peer research associates administered web-based questionnaires that collected socio-demographic, behavioral, and clinical data. Previous engagement in pediatric HIV care was assessed through self-report, and those identified as ever being engaged in pediatric HIV care were asked questions about their transition. Preparedness for transition and perception of HIV-related care post-transition were compared by key socio-demographic and provincial covariates using Fisher's Exact test.

Results: 44 WLWH reported previous engagement in pediatric HIV care, and 4 were still in pediatric care. Of the 48 WLWH, 17% were from BC, 63% from ON, and 21% from QC. Median age was 23 (IQR=20-25). 40% identified as Caucasian, 40% as African, Caribbean, or Black, 12% as Aboriginal, and 8% as another ethnicity. 60% of women reported feeling that their pediatric HIV care prepared them for adult HIV care, including 38% of participants from BC, 70% from ON, and 50% from QC ($p<0.05$). 84% of the women now in adult care (n=44) reported feeling that their HIV-related health issues were being cared for equivalently or better since transition. Women who reported feeling prepared for transition were more likely to perceive that their HIV-related health issues were being well addressed in adult care ($p<0.005$). WLWH with CD4 counts >500 were more likely to report feeling prepared for transition ($p<0.01$) and to perceive better or equivalent care of their HIV-related health issues in adult care ($p<0.05$). Overall, 88% of WLWH reported suppressed viral load at last measurement, with 93% of those who felt prepared for transition versus 79% of those who did not feel prepared being suppressed ($p=0.197$).

Conclusions: These findings suggest acceptable but heterogeneous transitions across Canada. To ensure optimal clinical outcomes, an evidence-based, uniform transition plan is necessary to allow for preparation of all WLWH.

No conflict of interest

Abstract: 46

Women living with HIV

Envisioning Women-Centred HIV Care: Perspectives from Women Living with HIV in Canada

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Background: Women now account for nearly a quarter of people living with HIV in Canada, and over half of those who have acquired HIV worldwide. Despite advances in antiretroviral treatment, which have transformed HIV into a manageable chronic disease, women continue to experience difficulty achieving the level of engagement in care necessary to benefit fully from treatment advances. These gendered health inequities prompt the need for tailored approaches to care.

Methods: Peer and academic researchers from the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) conducted focus groups to understand women's lived experience of accessing health and social care, and what key characteristics define a women-centred approach to HIV care. Between August 2011 and April 2012, eleven focus groups were conducted with seventy-seven Women Living with HIV (WLHIV) across three Canadian provinces (Quebec, Ontario, British Columbia). Peer Research Associates (PRAs) facilitated the focus groups with support from an investigator. PRAs were WLHIV trained in community-based research and focus group facilitation. Participants self-identified as women, living with HIV, being 16 years of age or older, and residing in one of the three study provinces. Focus groups lasted two to three hours and were audio-recorded for verbatim transcription. We adopted an inductive thematic content analysis approach. PRAs were involved in each stage of the research process including focus group facilitation, data analysis and interpretation, and communication of the findings.

Results: Women who participated in the focus groups represented various ethnicities, age groups, languages, and lived experiences. Of note, 44% identified as White, 30% as African, Caribbean or Black, and 22% as Aboriginal women. Participants also varied greatly between provinces reflecting the heterogeneity of the HIV-epidemic across Canada. Women's experiences of care and their recommendations for how to devise health care services were structured around care that respond to their complex needs as a patient, a person, a woman, and as a woman living with HIV. Drawing from their lived experiences of care, women elucidated the three central characteristics of a women-centred HIV care approach. These include: (i) coordinated and integrated services that are devised to address both HIV and women's health care priorities, as well as to prevent exclusion from essential care through HIV-related stigma; (ii) care that recognizes and responds to structural barriers to care, such as violence, poverty, motherhood, and HIV related disclosure and stigma; and (iii) care that fosters peer support and peer leadership in its design and delivery as means to overcome isolation, cater to the diversity of WLHIV's lived experiences, and prioritize women's ownership over key decisions that affect their lives.

Conclusion: Women's care experiences provide insight into the current gaps in care for WLHIV in Canada, suggesting that, despite overall advances in treatment and care for people living with HIV, some aspects of the current care landscape do not yet meet women's health care needs. A gendered approach to care could respond to these deficiencies and ensure that women's comprehensive needs are met, in order to ensure that health care advances benefit populations equitably.

No conflict of interest

Abstract: 47

Women living with HIV

Medical challenges for women aging with HIV

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Introduction: With improved outcomes in HIV therapy, more PHA are living into middle and older age. Studies have estimated that in North America, more than 50% of PHA are now > 50 years. Cohort studies have shown an increased incidence of comorbidity in those with HIV relative to the general population. This study seeks to describe demographic and clinical characteristics of HIV positive women aged 50 and over.

Methods: This analysis used a retrospective, observational cohort of HIV positive women from the Toronto General Hospital (TGH), Immunodeficiency Clinic in Canada. Included individuals were currently active female patients aged 50 and above. Demographic variables and clinical information including cumulative ARV exposure, ARV resistance, prescriptions and comorbidities were collected from the TGH clinic database and through individual chart review. Summary data are described.

Results: Of 1269 active clinic patients, 273 (21%) were women and 628 (49%) were > 50 years of age. A total of 88 women > 50 years were eligible for analysis. The median (IQR) age of these women was 58 (53-62) years. Of these women, 49% were black, 32% were white, and 19% had other racial origins with 88% reporting heterosexual transmission as their risk factor for HIV. 20% were current smokers. The majority (98%) of the women were currently on ARVs. Of women on ARVs, 94% had viral suppression to < 50 copies/ml, with a median (IQR) length of suppression of 6.4 (3.6-10.9) years. The median CD4 count was 565 cells/mm3. The most commonly reported comorbidities included dyslipidemia (33%), hypertension (23%), osteoporosis (16%), coronary artery disease (13%), diabetes (11%), and cancer (10%).

Conclusions: Increasing numbers of women in our clinic are aging with HIV. The relationship of the post-menopausal status to comorbidity requires further study. Strategies will be required to appropriately manage ARV therapy; to minimize comorbidity; address potential drug interactions and consider options for long term care in this population.

No conflict of interest

Abstract: 48

Women living with HIV

Modeling relationships between stigma, housing insecurity and wellbeing among HIV-positive African and Caribbean black women in Ontario, Canada

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Introduction: African and Caribbean Black (ACB) women in Canada have new HIV infection rates 7 times higher than their white counterparts. This overrepresentation is situated in structural contexts of inequities that result in social, economic and health disparities among ACB populations. Economic insecurity is a distal driver of HIV vulnerability, reducing access to HIV testing, prevention and care. Less is known about how economic insecurity indicators, such as housing security, continue to influence the lives of women living with HIV (WLWH) following a HIV-positive diagnoses. We did not find quantitative studies with people living with HIV (PLHIV) that examined associations between housing insecurity and forms of stigma beyond HIV-related stigma—such as racism. More research is needed to conceptualize the complex relationships between different forms of stigma and discrimination, housing insecurity, and wellbeing among ACB WLWH. The aim of this study was to test a conceptual model of the pathways linking HIV-related stigma, racial discrimination, housing insecurity, and wellbeing (depression, social support, self-rated health [SRH]).

Methods: As part of a community-based study, we implemented a cross-sectional survey with ACB WLWH in 5 Ontario cities, and included 157 participants with complete data in the analyses. We conducted structural equation modeling using maximum likelihood estimation to evaluate the hypothesized conceptual model. We hypothesized that: racial discrimination would be associated with increases in HIV-related stigma; HIV-related stigma and racial discrimination would be associated with increased housing insecurity; racial discrimination, HIV-related stigma, and housing insecurity would contribute to reduced wellbeing, specifically higher depression, lower social support and lower SRH.

Results: One-fifth (22.5%; n=39) of participants reported housing insecurity. As hypothesized, racial discrimination had significant direct effects on: HIV-related stigma (standardized regression weight: 0.279, p=0.005), depression (standardized regression weight: 0.164, p=0.020), and social support (standardized regression weight: -0.182, p=0.013), and an indirect effect on SRH (standardized regression weight = -0.066, p=0.028). HIV-related stigma had a significant direct effect on depression (standardized

regression weight =0.183, p=0.035), social support (standardized regression weight = -0.261, p=0.002), and SRH (standardized regression weight = -0.198, p=0.032). Housing insecurity had significant direct effects on depression (standardized regression weight=0.152, p=0.024) and social support (standardized regression weight= -0.165, p=0.019). The model fit the data well: χ^2 (45, n=154)=54.28, p=0.387; CFI=0.997; TLI=0.996; RMSEA=0.016.

Conclusions: This is the first study to examine associations between housing insecurity, racial discrimination, HIV-related stigma, and several indicators of wellbeing among WLWH. Housing insecurity had direct effects on both increased depression and reduced social support. Experiencing racial discrimination was associated with a greater likelihood of experiencing HIV-related stigma. This highlights intersectional stigma, the intersection of social exclusion based on multiple marginalized identity categories. Racial discrimination and HIV-related stigma were associated with depression and lower social support, and HIV-related stigma was correlated with lower SRH and mediated the relationship between racial discrimination and SRH. Findings highlight the need to address housing insecurity and stigma among WLWH. Understanding the complex relationships between housing insecurity, HIV-related stigma, racial discrimination, and wellbeing can inform multi-level interventions to reduce stigma and enhance health.

No conflict of interest

Abstract: 49

Women living with HIV

Determinants of sexual dysfunction among HIV infected women

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Introduction: Sexuality is an important aspect of life that is often neglected in clinical practice. Female sexual dysfunction (FSD) affects women's health and their relationships. Very little is known about FSD in the context of HIV-infection, particularly in resource-limited settings. We examined the prevalence and factors associated with FSD in a cohort of HIV-infected women in Jos, Nigeria.

Materials and methods: We conducted a cross-sectional survey of 370 women receiving care and treatment at the HIV outpatient clinic of the Jos University Teaching Hospital (JUTH), Jos, Nigeria. FSD was evaluated using the female sexual function index (FSFI) questionnaire. An FSFI score <26.55 was defined as FSD. Baseline variables were compared between women with and without FSD. Linear regression was used to determine interdomain correlation and logistic regression to assess the factors associated with FSD.

Results: The mean age was 33±5 years. 47.1% were married, with a median baseline CD4 count of 192 cells/mm^3. The median duration of HIV infection was 6 years (IQR: 4-7), 25.8% were in WHO stage III/IV at presentation and 94.1% were on highly active antiretroviral therapy (HAART) at the time of the study. 340 (89.2%, 95% CI: 85.6-92.2%) had FSD with an overall FSFI score of 16.36±9.46. The lowest mean sub-score was noted in the arousal domain (2.37±1.71), followed by orgasm (2.60±2.05), pain (2.612±.16), lubrication (2.63±2.04), desire (2.72±1.24) and satisfaction (3.40±2.06) domains. Women with FSD had lower mean values in all domains (p<0.001). The highest interdomain correlations were between lubrication and orgasm (r=0.87), arousal and lubrication (r=0.84), and arousal and orgasm (r=0.81) domains. HIV duration <6 years (aOR=3.72, 95% CI: 1.00-13.77), current sexual activity (aOR=8.82, 95% CI: 1.08-71.98) and current family planning use (aOR=4.14, 95% CI: 1.50-11.39) independently predicted FSD in these women.

Conclusion: FSD was highly prevalent in this cohort. These findings highlight the need for care providers to routinely evaluate HIV-infected women for sexual dysfunction with a view to addressing FSD as part of comprehensive care package for women living with HIV/AIDS.

No conflict of interest

Abstract: 50

Women living with HIV

Hematological abnormalities among HIV infected women in rural South India.

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Introduction: India has the third-highest number of people living with HIV in the world. Hematological abnormalities have been documented as strong independent predictors of morbidity and mortality in HIV-infected. Anemia has been associated with HIV disease progression and an increased risk of death. The objective of the study was to determine the abnormalities in the hematological parameters in HIV infected women.

Materials & Methods: HIV infected mothers who received a single dose nevirapine at the onset of labour were recruited from PMTCT center in Namakkal, Tamilnadu, India. After obtaining written informed consent, the demographic characteristics such as age, occupation, literacy and breast feeding practices were recorded. The blood samples were collected to evaluate the levels of hemoglobin (Hb), hematocrit (HCT), white blood cell count (WBC) and total lymphocyte count (TLC). These parameters were analysed along with the test quality controls using the Sysmex® KX-21 cell counter. The results were compared with HIV negative mothers (controls) who were from similar socio-economic backgrounds. Statistical analysis was done using SPSS, Mean and SD was estimated, *p*-value of less than 0.05 was considered to be statistically significant.

Results: A total of 125 HIV infected mothers and 50 HIV negative mothers were enrolled into the study. The age ranged between 19 and 34 years (25.2±3.6) in HIV infected women and 19 - 30 years (24.8 ± 2.9) in controls. There was no significant difference in the occupation and literacy between HIV infected women and controls ($p > 0.05$). The mean levels of Hb, HCT, WBC and TLC of HIV infected women were 10.65± 1.33, 32.16±3.97, 5399.20 ± 1999.09, 1502.40 ± 643.010 respectively. The mean levels of Hb, HCT, WBC and TLC of controls were 12.13±0.74, 36.38±2.20, 8653.33±1442.39, 3123.33 ±581.130 respectively. All these parameters were found to be significantly lower ($p < 0.001$) in HIV infected women when compared with the controls.
Of 125 HIV infected women, 104 (83.2%) were found to be more anemic (hemoglobin <12.0 gm/dl) than controls (41.66%). The severity of the anemia levels was calculated using Toxicity grading table, 23.2 % of HIV infected women were in grade 1 level (11-12 gm/dl of hemoglobin), 42.4 % were in grade 2 (9.5-10.9 gm/dl), 14.4 % were in grade 3 (8-9.4 gm/dl) and 3.2 % were in grade 4 (< 8.0 gm/dl). Among the controls 18 % were in grade 1 level and none of them were in grade 2, 3 and 4 levels. Neutropenia (WBC <2000 cells/mm^3) was observed in 2/125 (1.6%) of HIV infected women and none had in controls.

Conclusions: The study has demonstrated that anemia was more common than neutropenia in HIV infected South Indian women. Hemoglobin concentration could also be used as a reliable biomarker of the prognosis in HIV-infected patients.Our study suggests that the levels of hemoglobin should be monitored periodically before and after initiation of antiretroviral therapy.

No conflict of interest

Abstract: 51

Women living with HIV

Prevalence and predictors of early menopause among HIV-positive women

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Introduction: There are a few reports indicating that HIV-positive women might be at higher risk for early menopause than their HIV-negative counterparts, but the existing data are relatively scant, particularly in resource constrained settings. We determined the prevalence of early menopause (EM) and its predictors in a cohort of HIV-positive women in Jos, Nigeria.

Materials and methods: This evaluation included HIV-infected women accessing care and treatment at the ambulatory HIV clinic at the Jos University teaching Hospital (JUTH), Jos, Nigeria. Menopause was defined as at least 12 consecutive months of amenorrhea not due to surgery or other obvious cause, such as extreme weight loss. EM was defined as the occurrence of menopause at ≤45 years of age. Logistic regression methods were used to examine independent predictors of EM.

Results: Of 607 women studied, 229 (38.1%) were postmenopausal, of which 64 (27.9%) had EM. The median age of women with EM was 45years (IQR: 42-45) compared to 52 years (IQR; 50-56) for those without EM (p<0.001). Women with EM had been infected with HIV for a shorter period (p=0.007). Baseline CD4+ cell count (p=0.66) and viral load (p=0.15) were similar among those with and without EM. Median CD4+ cell count at the time of the study was similar between the two groups (455, IQR; 312-661 vs 467, IQR; 311-664 for those with and without EM respectively, p=0.93). History of menarche at <11 years of age, current family planning use, current sexual activity, baseline HIV RNA>100, 000c/ml and shorter duration (<5 years) of HAART use were associated with EM in unadjusted analyses. In a logistic regression model adjusting for socio-demographic, clinical and laboratory variables, history of menarche at <11 years of age (OR 16.10; 95% CI: 1.56-165.86), current family planning use (OR-9.18, 95% CI: 2.03-41.53), and current sexual activity (OR-2.12, 95% CI: 1.10-4.08) independently predicted EM.

Conclusion: Over a quarter of our postmenopausal women attained menopause early. No HIV-related factor predicted EM in this study. A better understanding of aging in these women is important to determine a more appropriate disease management approach during this period of life.

No conflict of interest

Abstract: 52

Women living with HIV

Factors associated with condom use in HIV-positive women living in Atlanta, Georgia

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Introduction: Consistent condom use is essential to reducing heterosexual transmission of human immunodeficiency virus (HIV). There is limited data related to the sexual practices of HIV-positive women living in the United States and their barriers to condom use. Our objectives were to evaluate factors associated with self-reported condom use in a cohort of women receiving HIV care in Atlanta, Georgia.

Materials & Methods: This study utilized data from a cross-sectional study of reproductive knowledge, attitudes, and sexual practices among adult, sexually active women receiving HIV care at a single outpatient public HIV clinic in Atlanta, Georgia. Participants completed an audio-assisted questionnaire consisting of items that assessed condom use and other sexual behaviors, demographic and relationship/psychosocial characteristics, and use of antiretroviral therapy. Pearson's chi square, Fisher's exact, and Student's T-test were used to test associations between predictor variables and our two outcomes: condom use at last intercourse and consistent condom use over the last six months. Multivariate logistic regression was performed on those factors independently associated ($P<0.05$) with condom use on bivariate analysis.

Results: Of the 187 women enrolled, 170 reported having vaginal intercourse in the last six months. Seventy-four percent (125/170) used condoms at last coitus, whereas only 53% (91/170) reported always using condoms over the last 6 months. Several factors were associated with condom use, including older age, being single, and having the confidence to discuss condom use with a sexual partner, whereas frequent intercourse, prior drug use, having HIV positive partners, and engaging in unprotected anal sex were associated with non-use. The main reasons cited for unprotected sex were 'not thinking about it' or 'not having a condom.' There was no significant association between antiretroviral therapy and condom use.

Conclusions: Despite known effectiveness in reducing HIV transmission, condoms are used inconsistently among HIV positive women. Improved strategies are needed to educate and empower couples, regardless of HIV serostatus or their relationship status, on the importance of safe sexual practices.

No conflict of interest

Abstract: 53

Women living with HIV

Gender norms and practices: the effect on uptake of HIV/AIDS care and treatment services in Nigeria

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Introduction: People living with HIV (PLHIV) continue to face stigma and discrimination which is deeply entrenched in cultural perceptions, myths and misconceptions. In addition, gender norms that promote masculine hegemony cause women and girls to disproportionately bear the burden of HIV/AIDS related stigma. This negatively affects women's uptake of HIV services as well as outcomes. Strengthening Integrated Delivery of HIV/AIDS Services (SIDHAS) is a five-year PEPFAR funded project through USAID, aimed at providing comprehensive HIV/AIDS prevention, treatment, care and support services in 13 states in Nigeria. The country has 36 states across 6 geo-political zones and has the second highest burden of HIV globally. In line with PEPFAR recommendations, SIDHAS conducted a gender analysis to identify norms and practices that may either promote or limit women's uptake of HIV services in both communities and health facilities.

Method: A total of 48 focus group discussion (FGD)-(12 in each state, 6 PLHIV in each FGD) and 48 key informant interviews with community gatekeepers and health care workers (12 in each state) were conducted in 4 states. The state with the highest prevalence in respective geo-political zones were selected. A total of 288 women and men between 30 and 49 years participated in the focus group discussions. Equal numbers of men and women participated in the FGDs and KII. Interviews were tape-recorded, transcribed and analyzed using themes.

Results: Five major themes emerged from the FGDs and KII. These are spousal disclosure, stigmatization of women living with HIV/AIDS by male partners and family members, participation in support groups, capacity to make financial decisions and family planning. Women were disadvantaged compared to men across these themes. Stronger feelings of stigma and discrimination were expressed by females; where HIV was generally felt to be a disease of females or witchcraft. Many married women do not work or may be restricted to small home-based businesses and cannot make financial decisions without spousal approval. In the Northern states, Islamic religion prohibits men and women from mingling in public. This affects service utilization and female participation. While men are generally reluctant to uptake HIV services, many women only get to know about their HIV status when they lose their husbands or when they fall ill. Disclosure is particularly difficult in polygamous relationships due to fear of blame or possible divorce or violence. Both males and females tend to have a low risk perception even in discordant relationships. It is considered an abomination in some settings for a woman to talk to her husband about condom: '*People will think you are a prostitute if you go to buy a condom'.* Most people will rather not acknowledge the existence of gender minorities in the country but we encountered cases of women marrying women in the South-East.

Conclusion: Future programming in SIDHAS will focus on community education to reduce stigma, empower women to improve access to services, improve client level knowledge and modify behaviour. More research on gender minorities and their access to HIV services is vital.

No conflict of interest

Abstract: 54

Women living with HIV

Association of Antiretroviral Use and Abnormal Uterine Bleeding in Women Living with HIV

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Background: Abnormal uterine bleeding is thought to be more common in women with HIV. Menstrual irregularity is a key health outcome that leads to anemia and poor quality of life. Factors associated with menstrual cycle disruption in HIV-positive women have not been well delineated. We measured the prevalence of abnormal uterine bleeding among women with HIV, and the association with current use of antiretroviral therapy (ART) and other covariates.

Methods: We used cross-sectional questionnaire data from the Canadian HIV Women's Sexual and Reproductive Health Cohort Study (CHIWOS) enrolling women with HIV (self-identified, aged>=16 years) from British Columbia, Ontario and Québec. Eligible participants for this analysis were aged 16 to 45 years, and responded to questions on menstruation and ART use. Participants were excluded if they reported: a history of gynecologic cancer; amenorrhea attributed to spontaneous, surgery-induced, chemotherapy or radiation therapy-related menopause; premature ovarian failure; current pregnancy or hormonal contraception at or within 6 months prior to interview. Our primary outcome was presence of abnormal uterine bleeding, which included amenorrhea, oligomenorrhea, and/or intermenstrual bleeding. Multivariable logistic regression analysis examined independent correlates of abnormal uterine bleeding, including current use of ART.

Results: Of 1335 women enrolled in CHIWOS, 493 (37%) met the eligibility criteria. Overall, 71% reported abnormal uterine bleeding. In adjusted analyses, African, Caribbean and Black Canadian women and women who identify as "Other" or with

multiple ethnicities had increased odds of abnormal uterine bleeding (AOR 5.82, 95%CI:2.99-11.30) compared to Caucasian women (and Indigenous women). Lower odds of abnormal uterine bleeding was found in women with no history of recreational drug use versus current users (AOR 0.06, 95%CI:0.02-0.15) as well as women who were treatment naïve (AOR 0.26, 95%CI:0.12-0.53) compared to women currently on ART.

Conclusions: Abnormal uterine bleeding was commonly reported by women with HIV participating in CHIWOS (71%) as compared to rates in the general population (30%). Correlates of abnormal uterine bleeding included current ART use, reporting an ethnicity other than Caucasian or Indigenous and recreational drug use. The mechanisms for abnormal uterine bleeding with regards to the identified correlates warrants further research in order to identify solutions.

No conflict of interest

Abstract: 55

Diagnosis and treatment of HIV infection

HIV and AIDS associated neurocognitive functioning in Zambia- a gender perspective

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Introduction: Human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS) are frequently associated with neurocognitive impairment (NCI). However, few studies have examined the interrelationship between gender and NCI in the HIV and AIDS population.

Methods: This cross sectional study examined the neurocognitive functioning of HIV infected male and female participants from urban Zambia, the participants included 266 HIV seropositive (HIV+) adults [males (n=107) and females (n=159)]. Participants were subjected to neurocognitive (NC) assessment by means of a comprehensive neuropsychological test battery using normative data from 324 HIV seronegative (HIV-) controls that was corrected for age, education and gender. The test battery measures neurocognitive functioning in the domains of; Attention/Working Memory, Executive Function, Verbal Fluency, Processing Speed, Verbal and Visual Episodic Memory, and fine Motor Skills.

Results: An overall comparison of the HIV+ male and female participants yielded no significant differences on both T-scores and Deficit scores. However, when the sample was stratified on the basis of some disease characteristics, gender related differences in NC functioning were observed notably; in the viral load not detected group, the females were more impaired, (Mean=.5073, SD=.6520) in the domain of Speed of information processing than the between the males (Mean=.2605, SD=.3753), t= (196.164) =-3.387, p=.001, two tailed. The magnitude of the difference was medium at Cohen's *d*=.-0.50.

Conclusion: The findings suggest there are gender related differences in relation to disease characteristics NCI. It was observed that although the females enjoyed better health compared to their male counterparts, they still had worse performance on the NP tests. This implies that HIV has a more damaging consequences for Zambian females than the males.

Conflict of interest: The NOMA funds from The Norwegian Agency for Development Cooperation (NORAD) and Hedmark University College.

Abstract: 56

Diagnosis and treatment of HIV infection

The effect of gender and age on the relative bioavailability of Doravirine: results of a phase 1 study in healthy subjects

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Background: Doravirine (MK-1439) is a novel, well tolerated, once-daily, non-nucleoside reverse transcriptase inhibitor in development for the treatment of human immunodeficiency virus-1 infection in combination with other antiretroviral therapy. Here, we report data from a Phase I study designed to evaluate the effect of gender and age on the pharmacokinetics (PK) of doravirine.

Materials & Methods: This was an open-label, parallel-group study of 36 healthy subjects: 12 elderly males, 12 elderly females, and 12 young females. PK data for young male subjects were obtained from a separate study (Protocol number 001, Anderson et al. *Antivir Ther*. 2015;20(4):397-405; n=6). Elderly subjects were 65-80 years of age, and young subjects between 18-50 years of age. Each subject received a single 100-mg dose of doravirine under fasting conditions, and blood samples were taken at pre-specified timepoints up to Day 4. Key PK parameters were area under the concentration-time curve ($AUC_{0-¥}$), peak plasma concentration (C_{max}), and plasma concentration at 24 hours ($C_{24\ hr}$). For the evaluation of gender on the PK of doravirine, data from young and elderly subjects could be pooled if the 90% confidence intervals (CIs) of the geometric mean ratio (GMR) for elderly/young subjects were contained within pre-specified bounds (0.5, 2.0) and if $p>0.05$ for the between-group comparison. Likewise, for the evaluation of age on the PK of doravirine, data from male and female subjects could be pooled if both criteria were met.

Results: Data from elderly male and young male subjects were poolable, as were data from elderly female and young female subjects. The evaluation of gender was, therefore, based on pooled data from elderly and young subjects. Doravirine $AUC_{0-¥}$ and $C_{24\ hr}$ were similar in male and female subjects. The GMRs (female vs male) and 90% CIs for $AUC_{0-¥}$, C_{max}, and $C_{24\ hr}$ were 119.95% (102.86, 139.88), 141.84% (122.76%, 163.87%), and 101.72% (83.63%, 123.72%), respectively, suggesting that there is no clinically-meaningful difference in the relative bioavailability of doravirine with respect to gender. Data from elderly male and elderly female subjects were not poolable; for this reason, the effect of age on the PK of doravirine was evaluated separately for each gender. For elderly male versus young male subjects, the GMRs and 90% CIs for $AUC_{0-¥}$, C_{max}, and $C_{24\ hr}$ were 85.35% (66.51%, 109.53%), 91.83% (72.95%, 115.59%), and 81.20% (59.15%, 111.47%), respectively. For elderly female versus young female subjects, the GMRs and 90% CIs for $AUC_{0-¥}$, C_{max}, and $C_{24\ hr}$ were 96.98% (79.35%, 118.52%), 118.05% (97.82%, 142.45%), and 93.79% (72.41%, 121.47%), respectively. Thus, the relative bioavailability of doravirine was similar in young and elderly subjects for both genders. Overall, 8 subjects (22%) had at least one adverse event (AE) following treatment with a single dose of doravirine. Almost all were of mild intensity; one was of moderate intensity. No AEs were serious, and none led to premature discontinuation from the study.

Conclusions: Neither age nor gender affected the relative bioavailability of a single dose of doravirine in healthy subjects. Doravirine was generally well tolerated, irrespective of age and gender.

Conflict of interest: Employees of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA, and may own stock and/or stock options.

Abstract: 57

Epidemiology of HIV in women and girls

Socio- economic and demographic factors associated with HIV Infection in pregnant women from 15 to 49 years old, Mozambique, 2009

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Background: In countries with generalized epidemics, national estimates of HIV prevalence levels and trends in the adult population are generally derived indirectly from surveillance of pregnant women attending selected antenatal care (ANC) clinics. ANC data however, come from a subset of the population, and has been the primary source of data for monitoring trends of HIV and syphilis to provide estimates for tracking the epidemic in Mozambique. This HIV surveillance have been performing biannually since 1988. Until such time, the prevalence varies in the three regions of the country for still unclear reasons. The north of the country consistently has the lowest prevalence and southern highest. To better understand the challenges for risk factors of HIV prevalence in the country, it is essential to describe the socio-demographic and socio-economic, for this particular study. The aim of the study was to identify the socio-economic and demographic factors associated with the variations of HIV prevalence in pregnant women from 15 to 49 years old in the three regions of the country.

Material and Methods: A cross-sectional exploratory study was conducted in 2009 surveillance, involving pregnant women. This surveillance have place currently in 36 selected antenatal care (ANC) clinics, distributed in the 11 provinces of the country. The participants answered a standardized questionnaire on demographic information, socio-economic and health state. Were made bivariate and multivariate analyzes using hierarchical models implemented in the R statistical software (version 3.0.3). The adjusted odds ratios and confidence intervals to 95% were reported.

Results: In 2009 the prevalence in pregnant women aged 15 to 49 years old was 16.8%. Regional prevalence's were 9.1%, 17.7% and 22.2%, North, Central and South respectively. In the North, the students had a lower risk of HIV infection compared to domestic (OR: 0.6; p = 0.02). In the center the risk for HIV declines with age (OR: 2.17 to OR: 1.96; p <0.01). The highest level of education showed the highest risk (OR: 1.71; p = 0.01). Widows or separated had a high risk of HIV infection (OR: 4.16; p = 0.01) compared with never married. For professional category, the peasant had OR: 0:54; p = 0.01, for the domestic. In the South the risk for having HIV is four times higher in the age groups of 25-29 and 30-34 years, with OR: 4.53 and OR: 4.42 respectively p <0.01. The highest level of education was shown to have lower risk (OR: 0.71; p = 0.03). Widows or separated had OR: 0.75; P = 0.02. The peasant had OR: 0.56; p = 0.01.

Conclusion: The above results show that the factors studied did not have the same impact in the three regions of the country (North, Central and South), suggesting that the educational strategies in health and HIV prevention should be designed taking into account the factors risk of each region, in order to ensure the effectiveness of programs.

No conflict of interest

Abstract: 58

Epidemiology of HIV in women and girls

Use of guideline-recommended antiretroviral (ARV) regimens in a US HIV treatment-naïve population: a 5-year payer claims analysis focused on women

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Background: ARV therapy has greatly reduced HIV-related morbidity and mortality. The Department of Health and Human Services (DHHS) Panel has developed ARV Guidelines for Adults and Adolescents to provide practitioners with guidance based on knowledge of ARV drugs used to treat HIV in the US. The guidelines are periodically updated and made accessible as new evidence is available.

Objective: To investigate real-world use of ARV regimens listed in DHHS guidelines from 2010 to 2014 for a large insured US population of women (in reference to men) with HIV.

Methods: Adults aged ≥18 years with an HIV diagnosis and ARV pharmacy claim between 2010 to 2014 in the Optum Research and Impact National Benchmark Database were included. Those with HIV-2 diagnosis or prior ARV use were excluded. Baseline demographics and Quan-Charlson comorbidity index were described. Regimens consisted of ARVs filled <14 days of ARV initiation. For each year between 2010 and 2014, regimens received by the population were classified into 'Preferred/Recommended (P/R),' 'Alternative (A)' or Non-P/R/A regimens based on corresponding DHHS guidelines in the given year. In cases when guidelines were updated in a given year and a regimen's status changed in that year, the applicable guidelines were reviewed for that year and a hierarchical assignment (P/R as the highest, Non-P/R/A as the lowest) was employed for analytic purposes.

Results: This retrospective analysis included 1,387 treatment-naïve women (7,643 men): mean±standard deviation [SD] age=43.7±12.3 years for women (men=41.3±11.6 years); women resided nationwide with 55.1% in the South and 28.7% in the Northeast (men=47.0% and 27.0%, respectively). Approximately 25.5% of women (20.0% of men) had ≥1 comorbidity other than HIV/AIDS measured by the Quan-Charlson comorbidity index. Preferred/Recommended (P/R) regimens were most common over the 5 years ranging between 44.7% and 76.4% of total regimens for women (47.5% and 82.6% for men), while Alternative (A) regimens utilization ranged between 0.9% and 27.7% for women (2.6% and 36.4% for men). Non-P/R/A regimens ranged between 22.1% and 29.3% for women (14.8% and 20.3% for men). The most common regimens used (≥5% of patients) among women were efavirenz (31.1%), atazanavir/ritonavir (8.6%), rilpivirine (7.5%), darunavir/ritonavir (6.3%), raltegravir (5.8%) or elvitegravir/cobicistat (5.6%) in combination with tenofovir disoproxil fumarate/emtricitabine (40.1%, 5.1%, 8.2%, 6.9%, 6.8%, 9.3%, respectively for men).

Conclusions: Real-world use of ARV regimens according the DHHS guidelines was adopted for the majority of these women with HIV infection between 2010 and 2014. Despite the hierarchical assignment in the analysis that may have shifted regimens into P/R or A in a given year, approximately 22.1-29.3% of women and 14.8-20.3% of men received DHHS guideline Non-P/R/A regimens each year. Further analyses are needed to better understand these treatment patterns and outcomes by gender.

Conflict of interest: J.F., K.B., and A.S. are employees of Janssen Scientific Affairs, LLC. A.J.A. and J.M. are employees of Optum, which was contracted and paid by Janssen to execute this study.

Abstract: 59

Comorbidities in HIV infected women

Antiretrovirals and amenorrhea: a descriptive comparative cross-sectional study of HIV-1 positive women in Jos, Nigeria.

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Introduction: Women have borne much of the burden of HIV. This burden has been ameliorated by antiretrovirals (ARVs), but has not been without some adverse effects. Amenorrhea and other forms of menstrual disorders has been observed in many women on ARVs at sometimes worrisome level. This has become a problem as many women even consider stopping their ARVs due to the ensuing emotional stress. Unfortunately, no published studies have given answers to this phenomenon. This study was set up to elucidate this.

Materials and Methods: 200 women aged between 18 and 45 years were randomly studied on their routine clinic visits. An interviewer administered questionnaire was used to get their bio data, drug, menstrual and social histories. Lab results was pooled out from our APIN-PEPFAR data base and Urine pregnancy test and ultrasonographic scan was used to rule out pregnancy. Microsoft Excel and SPSS were used in analysis with confidence interval of 95%. Chi-square test was used to test significance.

Results: 160 women were finally analyzed as those using hormonal contraceptives were excluded. At least one form of menstrual irregularity occurred in 63.6% of the cohort. Amenorrhea occurred in 16.3% of the women. 100% of the women not on ARVs had no amenrrhea. But, 20.5% of participants on ARVs had amenorrhea while 79.5% of those on ARVs had no amenorrhea; P=0.01.
Various ARV categories patients were on include: Those on Protease inhibitor-based regimen like LOPINAVIR (LPV) and ATAZANAVIR (ATV) had 0.0% amenorrhea; P=0.14 and 0.33 respectively. Of the participants on an Efavirenz (EFV) –based regimen (EFV/TDF/FTC), 14.3% had amenorrhea as against 85.7% without amenorrhea; P=0.53. 100.0% of those on a NEVIRAPINE (NVP)-Based regimen (TDF/FTC/NVP) had amenorrhea, as against 0.0% without amenorrhea; P=0.005. 23.7% of participants on another NEVIRAPINE-Based regimen (AZT/3TC/NVP) had amenorrhea, as against 76.3% without amenorrhea; P=0.33. No significant difference using clinical indicators in cycle types (Ovulatory or anovulatory) in participants with amenorrhea or those without amenorrhea; P=0.74. Amenorrhea's rate increased as ARV experience lengthened: 10.3% within 1 to 2 years, 17.2% within 3 to 5 years, 72.45 after 5yeras; P= 0.17. Also, there was no significant relationship between baseline Cd4 counts (WHO Staging) {P=0.33} or Viral load {P=0.62} with presence or absence of amenorrhea.

Conclusion: Prevalence of amenorrhea (secondary) in our cohort was 16.3%; and this occurred only in those on ARVs. The prevalence of menstrual irregularity was 63.6%. These prevalences are a 5 to 10 fold rise compared to the known prevalences of amenorrhea and menstrual irregularities in the general population! The amenorrhea in our cohort was associated more with clinical features suggestive of ovulatory cycles. The commonest drugs associated are Nevirapine- and Efavirence- based regimens. Amenorrhea in women with HIV and on ARVs, tends to be commoner with longer ARV experience.

No conflict of interest

Abstract: 60

Comorbidities in HIV infected women

Trichomonas and HIV co-infection among drug using women on probation: A call for expanded screening

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Background: The United States has a large community corrections population, a growing number of whom are women. This population is at high risk for HIV and other STIs, but there is a lack of data on HIV and STI prevalence among women in the community corrections system. *T. vaginalis* infection is strongly associated with an increased risk of HIV acquisition and transmission, particularly among women, but there is a paucity of research on HIV and *T. vaginalis* co-infection among women in the community corrections system.

Materials & Methods: This study examined HIV/STI prevalence and diagnosis history among 337 drug involved women in community corrections programs in New York City. Women received biological tests for HIV, *T. vaginalis, C. trachomatis,* and *N. gonorrhoeae.* Women were also asked whether they had ever been previously diagnosed with these infections, and whether they had been diagnosed with these infections in the last three months.

Results: Forty-five women (13.4%) were HIV positive. Nearly a quarter (N=77, 23.1%) of women tested positive for *T. vaginalis*. Women with HIV had significantly higher rates of *T. vaginalis* infection than women without HIV (36.4% vs. 21.3%, p=.027). There were no significant differences in rates of *C. trachomatis* and *N. gonorrhoeae* infection between women who were HIV positive and women who were HIV negative. Only 19.5% (N=15) of those infected with *T. vaginalis* said they had previously been diagnosed with Trichomonas. Of those previously diagnosed, only 13.3% (N=2) had been diagnosed within the past three months.

Conclusion: Given the high prevalence of *T. vaginalis* among this sample of women, particularly among HIV positive women, and low rates of previous diagnosis, screening for *T. vaginalis* among women in community corrections programs may have a substantial impact on reducing HIV acquisition and transmission among this high risk population and their sexual partners.

No conflict of interest

Abstract: 61

Assessment of Liver Disease in HIV-1 Positive Antiretroviral (ARV) Naive Women Using Transient Elastogram (Fibroscan) in Jos Nigeria

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Background: Liver disease is of utmost importance among people living with HIV/AIDS. Most of the drugs used in management of these patients have effects in the liver. Women are not left out and often it is difficult to tell a patient who has liver disease. This study is geared towards using more convenient ways of identification of degree of fibrosis using transient elastogram. Unfortunately, there is paucity of data on women who are ARV naïve and commencing ARV on these patients in Sub-Africa can a big challenge.

Material & Methods: It was a descriptive observational cross-sectional study of 114 women. An interviewer administered questionnaire was used to get information from the patients and each had a transient elastography (Fibroscan) done to obtain their Liver Stiffness Measurements (LSM). Laboratory results were pulled out from the APIN/PEPFAR data base.

Results: A total of 114 women aged between 21 to 61 years were studied over the period of 18 months. 50.9% had tertiary level of education. 77.2 % were Christians and 21.7 % were Muslims. About 63% were both Civil servants and Business women. 12.5% were either full time house wife or unemployed.

17.5% of the patient was reactive to Hepatitis B surface Antigen (HBVsAg Positive). None of the women had Hepatitis C, and 82.5% were negative for both Hepatitis B and C at the time of this study. Using the LSM, 82.5% had NO significant Fibrosis (LSM< 7.0Kpa), 12.3% Had significant fibrosis (LSM 7.0 to 12.5 Kpa). While just 2 patients (1.8%) had Cirrhosis(LSM> 12.5 KPa). Only 4 (3.5%) smoke tobacco and 26 (22.8%) take at most, moderate quantity of alcohol. Majority of the patients were in WHO stages I, II % III. Only 8.8 percent came stage IV disease.

Teachers, Sport women, Students and Business women had the highest prevalence (70%) of Hepatitis B; P=0.12.

The only two(2) patients with cirrhosis also were HBVSAg Positive. Strangely, about 10 patients (71.4%) of those with No Hepatitis B or C infection had significant fibrosis; P=0.13.

Thirty one(31) percent of patients with Hepatitis B had abnormal ALT level (>19.0 IU/L) as against 13.6% without Hepatitis B; P= 0.26. No significant difference was found between the use of herbal medication and LSM scores; P= 0.56.

Correlating ALT levels and LSM score was significant as 80.0% of patients with significant fibrosis had ALT values greater than 19 IU/L as against just 41.9% with No significant fibrosis. P=0.10. LSM score did not differ significantly with WHO staging, smoking tobacco and Alcohol consumption.
Hepatitis B vaccination status was significant when correlated with LSM scores as those who had No vaccination had more significant fibrosis and cirrhosis compared with those who had incomplete vaccination; P= 0.03. Unfortunately, in the whole cohort, no woman had complete 3 doses of the Hepatitis B vaccination.

Conclusion: The prevalence of HIV/ Hepatitis B Co-infection in the women was as high as 17.5 %. No HIV/Hepatitis C co-infection was seen in all 114 patients. About 14.0% had significant fibrosis or cirrhosis.
The greatest risk factors identified in these women include: No or incomplete vaccination against hepatitis B, Outdoor occupations and elevated ALT levels.

No conflict of interest

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