Abstract Book

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Abstracts
Oral Presentations

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Prevention of HIV transmission in women and girls

Adolescent and young women’s acceptability and use of a proxy microbicide gel or pill in a mock trial in Tanzania

J. Headley1, J.N. Baumgartner2, S. Kaaya3, A. Kaale3, A. Minja3, H. Kalungula3, D. Bangapi3, E. Tolley1

1FHI 360, Social and Behavioral Health Sciences, Durham, USA; 2FHI 360, Social and Behavioral Health Sciences, Washington DC, USA; 3Muhimbili University of Health and Allied Sciences, Department of Psychiatry and Mental Health, Dar es Salaam, Tanzania

Background: Adolescents below the age of 18 are typically excluded from HIV prevention clinical trials; therefore, their acceptability and use of HIV prevention products is unknown. Given recent clinical trial successes of PrEP and microbicide products, it is increasingly important to understand the safety, acceptability, and effectiveness of these products among adolescents so as not to restrict their potential future access. We conducted a 6-month mock clinical trial in Dar es Salaam, Tanzania to assess the challenges of recruiting adolescents ages 15 to 17 versus young women ages 18 to 21 into a trial and to determine their acceptability of a proxy gel or pill.

Materials & Methods: A total of 135 sexually-active, HIV-negative, non-pregnant adolescents and young women were enrolled and followed at baseline, 2, 4 and 6 months. At month 4, participants could opt into a sub-study on a proxy product to simulate either the Truvada pill or microbicide gel that did not offer any HIV/STI protection. Nurse counselors provided gel arm participants with a box of Pre-Seed lubricant and counseled on its insertion and discretionary use. Pill arm participants received counseling on voluntary daily use of Vitacap multivitamins. At month 6, participants reported product use and perceptions. Acceptability was compared by age group.

Results: Of the 135 women enrolled in the mock trial, 56 participants (14 adolescents and 42 young women) were present, eligible, consented, and randomized to the proxy gel (n=24) or pill (n=32) arm. Of those 56, 77% (12 adolescents and 31 young women) returned to report on use and product perceptions (64% and 81% from the gel and pill arm, respectively). Due to a smaller-than-expected sub-study sample size, differences by age could not be reported. However, 81% of sub-study participants found gel or pill use to be easy or neutral. Pill users reported more difficulties in use than gel users. The top five 'likes' about the gel or pill, if they were to be found effective in HIV/STI prevention, were: offering some HIV protection (95%), offering some STI protection (74%), ease (67%), ability to use covertly (57%), and not interrupting sex (50%). The largest proportion of 'dislikes' reported was nothing (45%), followed by: appearance/smell (31%), remembering to use (19%), and inability to use covertly (12%). Most participants reported preferring to combine condoms with an effective gel or pill to protect themselves from HIV (55%), while the least preferred method of protection was using condoms only (14%).

Conclusions: Recruitment and retention challenges for the mock trial affected sub-study participation rates. However, while statistical comparisons between age groups were not possible, participants in both groups expressed general acceptability and positive perceptions of the proxy microbicide products. Protection against HIV, STIs, and perceived ease of use emerged as important positive attributes for the proxy products indicating that adolescents and young women are interested in and receptive to microbicide products. Future research with both adolescents and young women in prevention trials should be cognizant of the likes/dislikes of product properties as this may affect study retention and product adherence.

No conflict of interest
Abstract_2

Prevention of HIV transmission in women and girls

Characteristics associated with both adherence and sexual risk behaviors among women infected with HIV

M.M. Holstad\(^1\), S.A. Spangler\(^1\), S.M. Sharma\(^2\)

\(^1\)Emory University, School of Nursing, Atlanta, USA; \(^2\)Emory University School of Medicine, Dept of Psychiatry and Behavioral Sciences, Atlanta, USA

Introduction: Only an estimated 25% of all HIV-infected persons in the US are virally suppressed, which has important implications for individual health as well as for HIV transmission. Despite evidence for a strong indirect relationship between antiretroviral therapy (ART) adherence and sexual risk behavior, little is known about the characteristics of HIV-infected women who regularly practice or do not practice both of these behaviors. Understanding such characteristics is critical for designing interventions that improve HIV-related health outcomes; both high levels of adherence and low levels of risk behavior are needed to maintain optimal health in HIV-infected women and to prevent HIV transmission. The purpose of this study was to identify characteristics of women with different levels of ART adherence and sexual risk behavior. Specifically, we sought to examine characteristics of women with high levels of ART adherence who practice low-risk sexual behavior (HALR) as compared to women with low levels of ART adherence who practice high-risk sexual risk behavior (LAHR).

Materials & Methods: We analyzed data from the KHARMA (Keeping Healthy and Active with Risk Reduction and Medication Adherence) Project, a randomized clinical trial testing the efficacy of a group motivational interviewing intervention for ART adherence and risk reduction behaviors in HIV-infected women (n=207). For the current analysis, data were coded for adherence (90% vs. less using MEMS Track caps) and for sexual risk behavior (high-low split on a sexual risk index). The effects of selected characteristics on these outcomes were tested using a two-way ANOVA collapsed over time. Characteristics included HIV knowledge, HIV self-management, healthcare participation, HIV status disclosure, depression, stigma, difficult life circumstances, social support, spirituality, religious coping, ART adherence motivation, and safer sex motivation. Comparisons of different adherence and risk groups were performed using customized contrasts.

Results: The average age of the study participants was 44; most were African American, unmarried, unemployed, and with very low income. As compared to the LAHR group, the HALR group had significantly fewer difficult life circumstances \((t = 2.64, DF = 325, p = 0.009)\) and lower extrinsic motivation for adherence \((t = 3.80, DF = 783, p < 0.001)\), with significantly higher levels of intrinsic motivation for safer sex \((t = -2.36, DF = 785, p = 0.019)\) and perfect intrinsic motivation for safer sex \((t = 2.69, DF = 604, p = 0.007)\). These women also trended towards having higher levels of self-efficacy for ART adherence, higher levels of internal control for medical care, and lower levels of negative religious coping. No other characteristics tested were significant.

Conclusion: In addition to difficult life circumstances, motivation (intrinsic vs. extrinsic) was associated with combined practices of ART adherence and sexual risk behavior. Overall, women in the HALR group experienced greater internal control relative to these behaviors, while those in the LAHR group experienced greater external control. More research is needed to better understand motivation and control as determinants of adherence and sexual risk behavior, including the design of new interventions to shift this locus from external to internal among highly vulnerable groups of women.

No conflict of interest
Abstract_3

Treatment program for HIV infected women (design and implementation)

The inclusion (or exclusion) of women in HIV research: from clinical studies of ARVs and vaccines to cure strategies.

M. Curno1, S. Rossi1, Y. Hodges-Mameletzis1, R. Johnston2, M. Price3,4, S. Heidari1

1IAS, International AIDS Society, Geneva, Switzerland; 2amfAR, The Foundation for AIDS Research, New York, USA; 3IAVI, International AIDS Vaccine Initiative, New York, USA; 4UCSF, University of California San Francisco, Department of Epidemiology & Biostatistics, San Francisco, USA

Introduction: Health and medical intervention outcomes can differ between men and women, shaped by their biological and social differences. An important goal in clinical research is ensuring that affected populations are appropriately represented in order to provide evidence-based treatments. The aim of this systematic literature search was to determine the proportion of women participating in HIV clinical studies of antiretrovirals (ARV), preventive vaccines (VACC) and curative strategies (CURE) over time and to identify factors associated with female under-representation in HIV clinical trials.

Methods: Systematic searches in PubMed were conducted for each of the three areas of research. For ARV studies, articles describing clinical trials published during three time periods 1994-2011 were included. For VACC studies, articles published 2000-2012 that reported primary results from vaccine trials were included. For CURE studies, articles describing clinical studies published through 2012 were included. Studies seeking to enroll participants of only one sex were excluded. Data were extracted on the number of women, date of publication, sources of funding, country of study and trial phase.

Results: A total of 387 ARV, 53 VACC and 113 CURE studies were included in the analysis. Women represented a median of 19.2% ARV, 38.1% VACC and 11% CURE of the trial populations. There was an increase in female participation over time for ARV (p=0.0001) and VACC (p=0.03) studies, but no linear relationship between female participation and time for CURE studies. High-income countries were associated with fewer women in ART studies (p=0.0001) and CURE studies (p=0.01), and more women in VACC studies (p=0.055). Funding source did not have an effect on proportion of female participants in VACC and CURE studies, but did for ARV (p=0.03) with the highest proportion of women seen in private-non-commercially funded trials, while publicly funded trials had the lowest (median 16.7%, IQR 10-27%). Amongst the ARV trials 67 (17.3%) were funded, partially or wholly, by the NIH. Percent female participation in the NIH-funded studies was a median of 15.8%. Percent female participation was significantly lower in NIH-funded trials than overall non-NIH funded trials (p=0.02).

Conclusions: Although women represent half of the HIV-infected population worldwide, they continue to be underrepresented in HIV clinical studies. This underrepresentation can translate into less evidence-based intervention for women compared to men. Although federal policies have been established to address this gender gap, our study shows that publicly funded studies have even lower representation of women in ARV trials, indicating that the policies are neither enforced nor monitored. There is an urgent need to ensure that HIV clinical trials consider sex and gender dimensions in design and conduct of studies as a matter of routine.

No conflict of interest
Abstract_4

Epidemiology of HIV in women and girl

Clinical characteristics and quality of HIV care for women in the United States: Data from the Medical Monitoring Project, 2009

W. Short, L. Beer, A. Do, E. Frazier, J. Blair, H. Bradley, J. Skarbinski

1Jefferson Medical College, Medicine/infectious Disease
1015 Chestnut Street Suite 1020, Philadelphia, USA; 2Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention, Atlanta, USA

Background: Women comprise an estimated 25% of persons living with HIV infection in the United States, but there are no recent nationally representative estimates of the clinical characteristics of and quality of care received by these women. Establishing these estimates provides a national benchmark in order to characterize patterns of HIV care and monitor changes in care over time among HIV-infected women.

Material & Methods: The Medical Monitoring Project (MMP) is a nationally representative cross-sectional survey of HIV-infected adults ≥ 18 years of age receiving outpatient medical care in the United States and Puerto Rico. Using data collected via in-person interviews and medical record abstractions among women receiving HIV care in 2009, we assessed their clinical characteristics and quality of care in the year prior to interview.

Results: We obtained matched interview and medical record data for 1,139 HIV-infected women, who were estimated to represent 114,527 HIV-infected women who received outpatient medical care in 2009 in the United States and Puerto Rico. In all, 83% of women reported taking antiretroviral therapy (ART) and only 66% had a recent viral load test result that was undetectable or <200 copies/ml. A majority of women received at least two CD4 T-cell tests (87%), influenza immunization (76%), and were prescribed PCP prophylaxis (82%) when their CD4 T-cell count fell below 200 cells/ul. Most women reported receiving cervical cancer screening (77%). However, too few sexually active HIV-infected women received recommended screening for syphilis (49%), gonorrhea (28%), or chlamydia (30%). Only 50% of HIV-infected women reported receiving counseling from their healthcare provider about ways to prevent transmission of HIV and sexually transmitted infections (STIs). Among sexually active women, 67% of those aged 18-29 years compared to 53% of those aged ≥50 years reported receiving HIV and STI risk-reduction counseling.

Discussion: Because of differences between women and men in physiological and socioeconomic factors, treating women with HIV requires recognition by providers of these differences, as well as key standards of care that are unique to women. Despite the fact that the majority of women reported taking ART, only two-thirds were virally suppressed. Although most HIV-infected women in care received adequate CD4 T-cell monitoring, influenza immunization, and PCP prophylaxis, many women did not receive guideline-recommended STI screening and counseling. Too few sexually active HIV-infected women received HIV and STI risk-reduction counseling, especially older women. Efforts to improve adherence to clinical guidelines may help improve treatment of HIV-infected women in the United States.

No conflict of interest
Abstract_5

Treatment program for HIV infected women (design and implementation)

Acceptability of a proposed technology-assisted, group-based intervention promoting engagement in care and treatment for HIV-infected women

O. Blackstock¹, P. Shah², L. Haughton¹, C. Cunningham²

¹Montefiore Medical Center/Albert Einstein College of Medicine, Medicine, Bronx New York, USA; ²University of San Francisco School of Medicine, Medicine, San Francisco California, USA

Background: HIV-infected women in the US are disproportionately women of color and are impacted by poverty and its attendant consequences. Innovative strategies are needed to promote their engagement in all stages of the HIV treatment cascade. Leveraging technologies such as texting, the internet, and online social networking represents one such underutilized strategy. We conducted a qualitative study to understand HIV-infected women’s experiences with these technologies and their perceptions of the acceptability of a proposed technology-assisted, group-based intervention aimed at promoting engagement in HIV care and treatment.

Methods: We recruited English-proficient HIV-infected women at a community-based health center in the Bronx, New York. We conducted semi-structured interviews exploring participants’ experiences with texting, the internet, and online social networking as well as perceptions of integrating these technologies into a proposed group-based intervention that focuses on enhancing engagement in HIV care and treatment specifically among HIV-infected women. Interviews were audiotaped and professionally transcribed. Transcripts were analyzed using grounded theory and the constant comparative method.

Results: Of the 32 participants approached, 27 (84%) consented to participate. Mean age was 48.7±8.8 years old. Forty-five percent self-identified as African American/Black and 55.5% as Latina. Ninety-six percent owned a cellphone and 77.7% had internet access at home or on their cellphone. Most study participants had familiarity or direct personal experience with texting (92.6%), the internet (96.2%) or online social networking (92.6%). Overall, participants expressed interest in using technology (e.g., group texting or an online social networking group) as a complement to an in-person group-based component. They felt that such a component would have the added convenience of being able to readily communicate with others with HIV and would enhance participation by individuals who may be anxious in in-person groups. However, participants expressed concerns about technology use in the proposed intervention; these themes related to the quality of communication, expectation of misrepresentation on the part of others, privacy, and digital literacy. Participants frequently mentioned that the ‘routine’ nature of communicating via technology (particularly texting) precluded more in-depth discussion of important and sensitive matters. They expressed concern about the potential for their own words to be misinterpreted due to lack of clarity when using these technologies. The expectation of misrepresentation or dishonesty on the part of others – such as persons lying about their HIV status – was also raised. Themes that emerged relating to privacy included concern about the permanence of the written word and the inadvertent or intentional disclosure of HIV status. Participants also expressed concern about the ability of other women like themselves to use these types of technologies (i.e., digital literacy).

Conclusions: Overall, we found familiarity with these technologies to be high among HIV-infected women in the Bronx and a willingness to engage in a proposed technology-assisted, group-based intervention. However, potential barriers would need to be overcome to increase its acceptability. For example, training in the use of texting, the internet, and online social networking and strategies to maximize privacy could help address digital literacy and privacy concerns, respectively.

No conflict of interest
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Treatment program for HIV infected women (design and implementation)

The Oak Tree Clinic: a model of women-centered HIV care in British Columbia

M. Kestler1, E. Maan1, K. Friesen1, C. Moody1, S. Krell1, M. Murray1, A. Alimenti1, D. Money1, N. Pick1

1BC Women's Health Centre, Oak Tree Clinic, Vancouver BC, Canada

Introduction: There are significant gender differences in the way HIV and its treatment are experienced by those living with the disease. Studies show that women are less likely to begin and adhere to HIV treatment than their male counterparts. The reasons are complex and multifactorial, including the unique ways in which women are affected by HIV-related stigma, medication side effects, mental illness, substance use, and gender-based violence and poverty. Living with HIV also impacts a woman’s sexual health, pregnancy and role as a primary caregiver for family and children. While an increasing number of AIDS Service Organizations (ASO) provide gender-specific services, few HIV clinics in Canada are designed specifically for women. In focus groups and surveys, Canadian women living with HIV have expressed a strong desire for women-centered HIV care to improve their engagement in care and health outcomes.

Materials and Methods: The Oak Tree Clinic (OTC) is the provincial referral centre for HIV-infected women and children located at the BC Women's Hospital and Health Centre in Vancouver. An inter-disciplinary team provides for the holistic health needs of women and their families under a single roof.
- Adult, pediatric and obstetric/gynecological HIV specialists, nurse practitioners, nurses and pharmacists
- Psychiatrist and trauma/addictions counselor
- Clinic-based and outreach social workers and dietician

The OTC research program focuses on issues of concern to HIV-infected women and children including pregnancy, perinatal transmission, HPV and cervical cancer, HIV/HCV co-infection, bone health, neurocognition and strategies to improve engagement in care including mobile texting. As a University of British Columbia (BC)-affiliated teaching site, OTC is actively engaged in medical education.

Child care is provided during clinic visits as necessary. Monthly peer-support groups are held on-site and in collaboration with ASO partners in Vancouver.

Results: Since 1994, OTC has provided care for over 5000 patients, including 580 pregnant women and 81 HIV-infected children. As of 2012, 600 patients were actively engaged in care with a total of 2300 patient visits. Thirty-five percent of OTC patients are Aboriginal, 33% Caucasian and 32% African or South Asian immigrants. Forty-four percent have a history of IV drug use and 35% are HCV co-infected. Half of OTC patients live in the Vancouver area and half live in geographically diverse areas of BC. Since 1996, out of 487 mother-infant pairs, there has been no perinatal transmission for women engaged in care at OTC.

A study of harder-to-reach HIV-infected women in BC showed that women were significantly more likely to receive regular gynecological care, such as cervical cancer screening, if they were patients at OTC. A recent analysis exploring quality of HIV care in BC found that OTC patients had better scores than non-OTC patients. This agrees with data from the BC Centre for Excellence Drug Treatment Program showing that virologic suppression rates for women at OTC are 88%, compared to 67% for BC women overall.

Conclusions: A women-centered inter-disciplinary HIV clinic results in high quality care for challenging patient populations. The OTC provides a sustainable model for how this can be achieved.

No conflict of interest
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Treatment program for HIV infected women (design and implementation)

A conceptual model of trauma-informed primary care for women living with HIV

E. Machtinger1, N. Khanna2, Y. Cuca3, L. Kimberg4, M. Shumway5, M. Cloitre6, B. Green7, B. McCaw8, L. James9, G. Brown10, C. Engel11, J. Campbell12

1University of California San Francisco, Women’s HIV Program, San Francisco, USA; 2Positive Women’s Network, USA, Oakland, USA; 3University of California San Francisco, School of Nursing, San Francisco, USA; 4University of California San Francisco, Department of Medicine, San Francisco, USA; 5University of California San Francisco, Department of Psychiatry, San Francisco, USA; 6National Center for PTSD, Dissemination and Training Division, San Francisco, USA; 7Georgetown University, Medical School, Washington DC, USA; 8Kaiser Permanente, Family Violence Prevention Program, Oakland, USA; 9Futures Without Violence, Health Unit, San Francisco, USA; 10National Institutes of Health, Office of AIDS Research, Bethesda, USA; 11Uniformed Services University, Department of Psychiatry, Bethesda, USA; 12Johns Hopkins University, School of Nursing, Baltimore, USA

Background: It is increasingly recognized that trauma – childhood and adult physical, emotional, and sexual abuse, neglect, loss, and community violence – is associated with the leading causes of morbidity, mortality and disability in the United States. Both trauma and its consequences, including post-traumatic stress disorder (PTSD), are far more common among women living with HIV than among women in general, and are associated with increased risk of HIV acquisition and poor HIV-related health outcomes, including medication non-adherence, virologic failure and death. Multiple responses to trauma and its consequences have been described in the literature. However, there is a lack of guidance about the core components of a holistic and practical model of trauma-informed primary care for HIV-positive women. An increasing recognition of the impact of trauma on all aspects of the HIV epidemic led to the formation of the President's Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities. A key recommendation of its 2013 report is to develop, implement, and evaluate models that integrate trauma-informed care into services for women living with HIV. This study describes the development of a conceptual model of trauma-informed primary care (TIPC) for women living with HIV intended to facilitate implementation and evaluation studies.

Materials & Methods: In August 2013, a two-day meeting was convened in Washington, DC to gather input from 24 leading policymakers, advocates, and trauma experts from the US government, military, academia, clinics, and community organizations, including 3 women living with HIV. Literature was reviewed and follow-up interviews were conducted with meeting participants and other experts to elucidate the core elements of the emerging model. The draft TIPC model was distributed to meeting and interview participants for comment and input.

Results: An evidence-based, consensus-driven, model of trauma-informed primary care for HIV-positive women has three core components: 1) a trauma-informed environment for both patients and providers that is calm, safe, and patient-centered; 2) routinized screening for current abuse including intimate partner violence (IPV), as well as the physical and mental health consequences of lifetime abuse including PTSD, complex PTSD, depression, and substance abuse; and 3) integrated interventions onsite and/or coordinated with community-based organizations that address current abuse and the impacts of lifetime abuse. The realization and sustainability of this model rests on a foundation of: a core set of trauma-informed values; clinic champions from each discipline; robust partnerships with community organizations; continuous monitoring, evaluation and feedback to providers; and an ongoing response to ‘vicarious trauma’ – the impact on the caregiver of working with traumatized individuals.

Conclusions: HIV programs for women offer an ideal milieu to develop a scalable model of trauma-informed primary care because of the high rates and poor outcomes of trauma in this...
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population and because these programs often have multidisciplinary care and a culture of innovation and evaluation. Once implemented and evaluated among women living with HIV, this model has the potential to improve health and well-being for other populations that have high rates and poor outcomes of current abuse and lifetime trauma.

No conflict of interest

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Treatment program for HIV infected women (design and implementation)

Factors associated with missed clinic visits at a tertiary care centre

L. Szadkowski¹, J. Raboud², S. Walmsley³

¹University Health Network, Toronto General Research Institute, Toronto, Canada ²University of Toronto, Dalla Lana School of Public Health, Toronto, Canada; ³University of Toronto, Department of Medicine, Toronto, Canada

Background: Retention in care is associated with improved rates of virologic suppression, clinical outcomes and mortality. It is important to understand patterns of missing visits and factors associated with missing clinic visits for all patients and for women specifically.

Materials & Methods: Patients attending the Toronto General Hospital (TGH) immunodeficiency clinic between April 2008 and August 2013 were studied. Inclusion criteria were: ≥1 kept visit, ≥2 scheduled visits, and ≥6 months of follow up. Measures of retention included (1) appointment adherence (percentage of kept to scheduled appointments), (2) number of missed visits per year of follow-up, (3) months between kept visits, (4) visit constancy (percentage of consecutive 4 month periods with ≥1 visit). Demographics, clinical variables, and measures of retention were compared across gender using the chi-square or Wilcoxon rank sum tests as appropriate. Generalized estimating equation (GEE) logistic regression models were used to examine factors associated with missing a visit.

Results: 1332 patients attended ≥1 appointment at the TGH Immunodeficiency Clinic and 1206 met inclusion criteria. Of those, 281 (23%) were women. The median years of follow-up and number of scheduled visits were 4.6 (Interquartile range, IQR 2.4, 5.0) and 16 (IQR 9, 20). Women were younger (39 vs. 46, p<.0001), more often black (64% vs. 16%, p<.0001) and more likely to have immigrated in the previous 10 years (32% vs. 10%, p<.0001) than men. Women had lower appointment adherence (87% vs. 92%, p<.0001) and missed more visits per year (0.57 vs. 0.26, p<.0001) than men. While women were more likely to miss a visit in a univariate GEE model (OR=1.32, p<.01), this effect was no longer significant (OR=1.00, p=0.99) after adjusting for age, race, intravenous drug use (IDU), immigration within 10 years of the visit, physician, years of HIV infection, viral load, CD4 count, and ARV use at the previous visit, whether the previous visit was missed, whether the patient had ever missed a visit, and the season of the visit. In a multivariate model that included women only and adjusted for race, immigration status, physician, years of HIV, viral load, and ARV status at the previous visit, the following factors were associated with missing a visit: younger age (OR=0.83 per 10 year increase in age, p<.01); IDU (OR=2.61, p<.001); having a CD4 count ≤200 cells/mm³ at the previous visit (OR=1.45, p=.04 compared to a CD4 count between 200 and 500 cells/mm³); having ever missed a visit (OR=1.51, p<.001); having kept the previous visit (OR=1.46, p=0.01); and having an appointment between December and February (OR=1.26, p=.01).

Conclusions: At a tertiary care clinic in the setting of universal health care, retention in care for patients with HIV was high. Women had similar retention as men, after adjusting for differences in age, race, and years of HIV infection. Among women, those who are younger, IDU, have a CD4 count ≤200 cells/mm³ or have previously missed a visit were at risk for missing a visit. The risk of missing a visit is higher in winter months.

No conflict of interest
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The role of contraception in transmission and progression in HIV infected women

Patterns and predictors of dual contraceptive use among sexually active treatment experienced women living with HIV in British Columbia, Canada

S. Patterson¹, W. Zhang², K. Salters³, Y. Chen³, G. Ogilvie³, R. Hogg², A. Kaida¹

¹Simon Fraser University, Faculty of Health Sciences, Burnaby, Canada; ²British Columbia Centre for Excellence in HIV/AIDS, St Paul's Hospital, Vancouver, Canada; ³British Columbia Centre for Disease Control, Clinical Prevention Services, Vancouver, Canada

Introduction: Current World Health Organization (WHO) guidelines recommend dual contraception for sexually active women living with HIV (WLWH) to prevent unwanted pregnancies and reduce HIV transmission. We sought to measure dual contraceptive prevalence and predictors among WLWH who have ever accessed antiretroviral therapy (ART).

Materials & Methods: The Longitudinal Investigation into Supportive and Ancillary health services (LISA) study is a cross-sectional survey of harder-to-reach HIV-positive individuals accessing ART in British Columbia, Canada. Interviewer-administered surveys collected information on socio-demographic, behavioral and healthcare factors, linked with clinical variables through the Drug Treatment Program at BC Centre for Excellence in HIV/AIDS. This analysis included sexually active, non-pregnant, pre-menopausal female LISA participants aged 19-49 years. The outcome variable of interest was self-reported contraceptive method used at interview (baseline). Dual contraceptive users reported concurrent use of barrier contraceptive methods and another modern contraceptive method. Multivariable logistic regression identified independent covariates associated with dual contraceptive use.

Results: The analytic sample included 104 female LISA participants, with a median age of 38 years (interquartile range (IQR) 33-42). At the time of interview, 14% (15/104) of women were employed and 25% (26/104) reported a history of intravenous drug use. Median time since HIV diagnosis was 9 years (IQR 6-12). While all women were ART-experienced, only 66% (69/104) were actively receiving ART at baseline. ART adherence (≥95%) was demonstrated by 39% (41/104) of women in the year before baseline, and 74% (77/104) had a history of treatment interruptions. Only 56% of women demonstrated ≥1 episode of viral suppression (viral load<50 copies/ml) in the year prior to baseline, and the recent median CD4 cell count was 340 cells/μL (IQR 190-550). Overall prevalence of contraceptive use was 76% (79/104). Mutually exclusive categories of contraceptive methods used included condoms (30%, 31/104), dual contraception (condoms plus hormonal/permanent method) (27%, 28/104), no method (24%, 25/104), permanent methods (tubal ligation/hysterectomy) (10%, 11/104), and hormonal methods (oral/injectable/nuvaring/intrauterine system) (9%, 9/104). The majority of dual contraceptive users (61%, 17/28) reported the use of condoms and permanent contraceptive methods. In the multivariate analysis, older sexually active women and those with higher parity demonstrated greater odds of using dual contraception (aOR 1.13 [95% CI: 1.03-1.24] and aOR 1.43 [95% CI 1.05-1.95] respectively).

Conclusions: Women in this cohort rely heavily on condom use exclusively. Only a quarter of women use WHO recommended dual contraception. Overall, dual contraceptive users are older with higher parity, and are largely comprised of women who use permanent contraceptive methods and condoms. In addition to low use of dual contraception, this ART-experienced cohort demonstrates suboptimal treatment outcomes. Supporting improved access and availability of women-centered care has the potential to improve both reproductive and HIV-related health outcomes for this cohort of WLWH.

No conflict of interest
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Prevention of HIV transmission in women and girls

An economic evaluation of conception strategies for heterosexual serodiscordant couples with HIV-positive male partners

M. Letchumanan1,3, P.C. Coyte1, M.R. Loutfy1,2,3,4
1Women's College Research Institute, Women's College Hospital, Toronto, Canada; 2Faculty of Medicine, University of Toronto, Toronto, Canada; 3Institute of Health Policy, Management and Evaluation, University of Toronto, Toronto, Canada; 4St. Michael's Hospital, Toronto, Canada

Introduction: To conduct an economic evaluation of three commonly used interventions that prevent sexual HIV transmission when heterosexual, HIV-discordant couples with positive male partners attempt conception (unprotected intercourse restricted to timed ovulation [UIRTO], sperm washing with intrauterine insemination [SWIUI], and unprotected intercourse restricted to timed ovulation with pre-exposure prophylaxis [UIRTO-PrEP]), and to inform policy decisions concerning the potential subsidization of pregnancy planning in Ontario, Canada, as there is currently no coverage for this setting.

Materials & Methods: We developed a cohort Markov chain to quantify the cost-effectiveness of three conception strategies for a 30-year old HIV-negative woman and an HIV-positive male, whose plasma viral load is suppressed with combination antiretroviral therapy. The model had a lifetime horizon and used the perspective of Ontario’s Ministry of Health and Long-term Care (MOHLTC). Effectiveness parameters were drawn from literature and costs were largely taken from MOHLTC’s Schedule of Benefits. A time-trade-off questionnaire was designed and administered to collect utility weights. Outcome measures were quality-adjusted life-years (QALYs) and incremental cost-effectiveness. Costs and benefits were discounted at an annual rate of 3%. Costs were reported in Canadian 2013 dollars and an exchange rate of 1 USD to 1.066 CND was applied where necessary. A Monte Carlo probabilistic sensitivity analysis was performed to determine mean incremental cost-effectiveness ratios (ICERs) with a 95% confidence interval. Deterministic sensitivity analysis explored the impact of varying annual discount rates (0, 5 and 7%).

Results: Our evaluation determined that UIRTO dominated U-PrEP and IUIWS. The base case ICERs of these analyses were -$2,920/QALY and -$46,593/QALY, respectively, when U-PrEP and IUIWS were compared to UIRTO. The results proved robust in a sensitivity analysis that modeled a range of HIV transmission risk during unconfirmed viral load status in the HIV-positive partner, yielding average ICERs of -$905/QALY [95% CI = -711.00, -1,100.00] and - $49,525.3/QALY [95% CI = -48,658.10, -50,392.50], respectively. IUIWS and UPrEP were both more costly than UIRTO. Base case findings determined that IUIWS incurred a greater cost increment for lesser benefits than U-PrEP. However, sensitivity analyses lead to 0.18 fewer QALYs yielded by U-PrEP than IUIWS.

Conclusions: According to our model, U-PrEP and IUIWS were not cost-effective relative to UIRTO for fertile HIV-negative women in Ontario who wish to conceive with an HIV-positive man whose plasma viral load is undetectable. Based on these findings, we cannot recommend UPrEP or IUIWS for subsidization by the MOHLTC. There were several limitations to our study as we did not consider infertility issues, alternate couple settings, changing reproductive capacity over time, and additional predictors of HIV transmission risk.

No conflict of interest
**Abstract_11**

*The role of contraception in transmission and progression in HIV infected women*

**Understanding current contraceptive choices and patterns among a cohort of HIV-positive women**

M. Sharma¹, S. Blitz², S. Walmsley², J. Raboud², D. Money³

¹University of Toronto, Infectious Diseases, Toronto, Canada; ²Toronto General Research Institute, Division of Experimental Therapeutics – Infection and Immunity, Toronto, Canada; ³University of British Columbia, Womens Health Research Institute, Vancouver, Canada

**Background:** Contraception and reproductive planning are of increasing concern to women living with HIV. Data suggests that hormonal methods of contraception (HC) may interact with HIV infection or treatment in clinically significant ways. A holistic understanding of all aspects of health for HIV-positive women is vital to optimize gender sensitive HIV care as well as guide clinical and research planning.

**Materials & Methods:** We assessed contraceptive choices among a cohort of Canadian women participating in the CTN236: HPV Vaccine in HIV trial, a multicenter, 27-month prospective, single arm open-label study designed to assess HPV vaccine effectiveness. For this substudy, data regarding contraceptive use were abstracted for sexually active, pre-menopausal women. Variables examined included demographics, use and type of ART, CD4 count, viral load, and hepatitis B co-infection, details on substance use and sexual history. Details on contraception use were collated and a descriptive summary was compiled.

**Results:** 377 girls and women had screening demographic data available. 168 women did not meet the inclusion criteria for this substudy: 24 (6.3%) were pre-menarchal, 36 (9.5%) had never had intercourse, 29 (7.7%) were post-menopausal, and 79 (21.0%) were not sexually active in the past year, leaving 209 women aged 15-57 for inclusion in the analysis. 87% reported a previous pregnancy. At least one method of current contraception use was reported by 89% of the cohort. The majority, 82.3% (173/209) reported condom use most or all of the time. 18.7% (39/209) were currently using HC (38% injectable, the majority (79.5% (31/39)) in combination with barrier protection. 156/209 (75%) of women reported HC use in the past. 48 women reported “other” contraceptive use: 89.8% (44/48) personal and 8.3%, (4/48) partner surgical sterilization. The median age of women using HC (with or without barrier protection) was 30, while that of women using no contraception or barrier protection alone was 38 and 37 years, respectively. Of the 31 women using combination HC and barrier methods, 14 (45%) were white, 9 (29%) were black, 4 (13%) were Aboriginal and 4 (13%) belonged to other ethnicities. 48% of women using barrier methods alone were black. Almost half (46%) of all HC users were currently smoking. Women using HC with or without barrier contraception had higher CD4 counts (510 cells/mm3 (310-730) and 520 cells/mm3 (221-755), respectively, than those using no contraception (330 cells/mm3 (250-687)). However, 82% of women using no contraception had a suppressed viral load compared to 50% of those using HC and 48% of those on combined barrier and HC. The majority of women had received prior ART, but 11% were not on therapy upon study entry. Of the 39 women reporting HC, 20 were on ART raising the potential for drug interactions.

**Conclusions:** Types of contraception use appeared to vary by age and ethnicity. Barrier protection rates were moderately high. Despite recommendations, dual contraception mode usage was low. Several concerning findings were noted, including high smoking rates and poor condom adherence among women on hormonal methods. This study highlights the importance of counseling and review of contraceptive choices among HIV-positive women.

*No conflict of interest*
Abstract 12

Epidemiology of HIV in women and girl

Perceived stress in pregnancy and postpartum of mothers living with HIV in Ontario, Canada

A. Ion¹, S. Greene¹, A. Carvalhal², F. Smaill³, M. Yudin⁴, M. Loutfy⁵

¹McMaster University, School of Social Work, Hamilton Ontario, Canada; ²St. Michael's Hospital, Psychiatry, Toronto Ontario, Canada; ³McMaster University, Pathology & Molecular Medicine, Hamilton Ontario, Canada; ⁴St. Michael's Hospital, Obstetrics Gynecology & Reproductive Infectious Diseases, Toronto Ontario, Canada; ⁵Women's College Hospital, Women's College Research Institute, Toronto Ontario, Canada

Background: Motherhood can be a stressful time for all women. A range of social determinants including younger age, lower socioeconomic status and non-resident immigration status can challenge women’s mental health and experiences of motherhood. These social determinants may exacerbate the experiences of mothers living with HIV who also contend with structural, social and psychological complexity of a chronic, stigmatizing illness. Mothers who perceive greater HIV-related stigma report higher levels of depression, anxiety and poor functioning on medical outcomes. The HIV Mothering Study sought to explore the psychosocial needs and experiences of women living with HIV in pregnancy and the first year of motherhood. This observational, mixed methods research initiative hypothesized that stress in mothers living with HIV would increase from pregnancy to postpartum and would be related to symptoms of depression and HIV-related stigma. This analysis describes predictors of perceived stress in pregnancy and early postpartum of mothers living with HIV across Ontario.

Methods: From March 2011 to December 2012, 77 pregnant women living with HIV in Ontario, Canada enrolled in the HIV Mothering Study at HIV and obstetrical care centers. Sociodemographic and clinical data were collected and participants completed scales measuring perceived stress, symptoms of depression and HIV-related stigma in their 3rd trimester and 3 months postpartum. The average Perceived Stress Scale score for the general female population is 24.96. Generalized estimating equation models were developed to assess change over time and correlates of perceived stress from pregnancy (n=69) to postpartum (n=62).

Results: HIV Mothering Study participants’ median age was 33 years (range 21 to 42). The majority identified an African country as their place of origin (57%; followed by 33% Canadian-born) and were on combination antiretroviral therapy in pregnancy (99%). Many women were not in a relationship in their 3rd trimester; 32% identified as single and 9% identified as separated/divorced. Mean perceived stress score decreased (t= -2.4, p=0.07) from pregnancy (mean=24.9, SD=7.1) to 3 months postpartum (mean=22.5, SD=8.2). In pregnancy, being single (z=2.25, p=0.03) and symptoms of depression (z=6.41, p<0.01) were significant covariates for perceived stress. At 3 months postpartum, perceived stress was significantly associated with being single (z=3.1, p=0.002), having more children (z=2.5, p=0.012), first time motherhood (z=3.13, p=0.002) and postpartum symptoms of depression (z=8.58, p<0.001). HIV-related stigma was not significantly associated with perceived stress in pregnancy and postpartum.

Conclusions: Mothers living with HIV across Ontario do not demonstrate higher perceived stress scores in pregnancy and early postpartum compared to the general female population. It is important to consider their social and emotional context including factors that may exacerbate stress in pregnancy and after the baby’s arrival, for example, if they exhibit symptoms of depression or are caring for multiple children. As being single is an important predictor of perceived stress in pregnancy and postpartum, it is important to explore why so many mothers living with HIV are single, the practical and emotional support provided by partners and how those mothers who are not in a relationship fulfill support needs to mitigate causes of stress.

No conflict of interest
Abstract_13

The role of contraception in transmission and progression in HIV infected women

High proportion of unintended pregnancies and limited contraceptive use among HIV-positive women in rural Zambia

S. Okawa1, M. Changala2, N. Ishikawa3, H. Kapyata2, S. Muvuma2, K. Komada4, S. Miyano3, M. Jimba1, C. Msiska2, S. Gardner5

1University of Tokyo, Community and Global Health, Tokyo, Japan; 2Ministry of Health, Chongwe District Medical Office, Chongwe, Zambia; 3National Center for Global Health and Medicine, Bureau of International Medical Cooperations, Tokyo, Japan; 4Japan International Cooperation Agency, SHIMA project, Lusaka, Zambia; 5Ministry of Health, Clinical Care and Diagnostic Services, Lusaka, Zambia

Background: Preventing unintended pregnancies is one of the priority interventions towards eliminating mother-to-child transmission of HIV. Contraceptive use is the most effective approach to avoid unintended pregnancies, which subsequently reduce the number of infants at risk of HIV infection. However, a limited number of studies have examined unintended pregnancies and contraceptive use among HIV-positive women in Zambia. This study was aimed at assessing the proportions of unintended pregnancy and contraceptive use among HIV-positive pregnant women, and identifying their associated factors in rural Zambia.

Methods: We conducted a prospective cohort study from July 2011 to March 2013 in eleven health centers in Chongwe district. A total of 371 HIV-positive pregnant women who accessed prevention of mother-to-child transmission of HIV (PMTCT) services participated in the study. Face-to-face interviews were conducted and participants were asked about their background characteristics, pregnancy intention, contraceptive use, and reasons for not using contraceptives. We performed univariate analysis to select independent variables with p-value less than 0.2. Then, we conducted multiple logistic regression analysis to examine the associations between background characteristics of women and unintended pregnancies among all participants. We also conducted logistic regression analysis to identify factors associated with non-contraceptive use among those who had unintended pregnancies.

Results: Of 371 HIV positive women, 48.8% already knew their HIV status before the current pregnancy, 46.4% were over 30 years old, 33.2% had educational experience of eight years, 83.2% were married, 38.4% had more than four children, and 63.1% were not engaged in paid work. In terms of their partners, 37.2% were HIV positive and 44.8% were engaged in paid work. It was found that 88.5% of women have disclosed their HIV status to their partners, and 18.6% have experienced domestic abuse. Fifty percent of women reported unintended pregnancies. Of those who reported unintended pregnancies, 101 (54.0%) did not use any contraceptive. In multiple logistic regression analysis, unintended pregnancy was associated with maternal age older than 30 years (AOR: 1.78, 95%CI: 1.12-2.84), unmarried status (AOR: 3.72, 95%CI: 1.48-9.33), and non-permanent job status of the partner (AOR: 1.63, 95%CI: 1.03-2.57). On the other hand, non-contraceptive use among women who had unintended pregnancy was marginally associated with unmarried status (AOR: 2.01, 95%CI: 0.99-4.09). The major reasons for not using contraceptives were (multiple answers): 'did not want to use (45.9%)'; 'did not ask health workers (42.9%)'; 'did not know any contraceptives (31.6%)'; and 'partner did not want to use contraceptives (23.5%)'. Meanwhile, religious belief (6.1%) and traditional contraceptive practices (6.1%) were not common reasons for non-use of contraceptives.

Conclusion: High proportion of unintended pregnancies and low use of contraceptives were observed among HIV-positive pregnant women in this setting. There is an urgent need to strengthen contraceptive coverage among HIV-positive women and their partners without pregnancy intentions. Family planning services which are provided at antiretroviral therapy clinic and PMTCT services during postnatal period may significantly contribute to reduce unintended pregnancies among HIV-positive women who do not have pregnancy intentions.

No conflict of interest
Abstract_14

Epidemiology of HIV in women and girl

Increasing Numbers of Young Pregnant Women with HIV in a South African district

G. Fatti1, A. Jason2, E. Mothibi3, A. Grimwood4

1Kheth’Impilo, Research, Cape Town, South Africa; 2Kheth’Impilo, Maternal and Child Health, Cape Town, South Africa; 3Kheth’Impilo, Clinical Services, Cape Town, South Africa; 4Kheth’Impilo, CEO, Cape Town, South Africa

Background: HIV prevalence amongst pregnant women aged 15-24 is considered a proxy measure for HIV incidence, as this age group is less affected by AIDS mortality and HIV infections are likely to be recent. We investigated trend over time in the age distribution of HIV-positive pregnant women presenting in the Nelson Mandela Bay Metropolitan (NMBM) district of the Eastern Cape, South Africa.

Methods: A cohort study of HIV-positive pregnant women and their infants using routine clinical data was performed at three sentinel surveillance antenatal facilities in sub district B of NMBM between January 2009 and June 2012. Individual-level electronic clinical data was collected. The age distribution of all HIV-positive pregnant women by year of presentation were analysed. Trend over time was assessed using the Cochrane-Armitage test.

Results: 1455 women were included, of whom 111 (7.5%), 225 (15.3%), 754 (51.2%) and 383 (26%) presented in 2009, 2010, 2011 and 2012, respectively. The proportion of HIV-positive women aged 15-24 years increased by almost 50% between 2009 and 2012, from 27.9% (95% CI: 19.8-37.2%) to 41.1% (95% CI: 36.0%-46.2%) (P-trend = 0.0003). The proportion of HIV-positive women aged 18-21 years increased over two-fold from 8.1% (95% CI: 3.8%-14.8%) in 2009 to 18.1% (95% CI: 14.3%-22.4%) in 2012 (P-trend = 0.0015). The proportion of adolescents aged < 18 years increased from 3.6% (95% CI: 0.1%-7.1%) to 6.1% (95% CI: 3.7-8.6%) during this period (P-trend = 0.084).

Conclusions: Increasing proportions of younger women with HIV are presenting at facilities in this district. This may be due to increasing HIV incidence in this age group, increased pregnancy amongst youth, or a combination of both. Factors driving this phenomenon should be investigated, and intensified HIV prevention and planned pregnancy efforts should be directed toward youth in this area.

No conflict of interest
Abstract 15

Cervical cancer: HPV screening, treatment, vaccines

Lower immune response in HIV positive girls to the qHPV vaccine

D. Money1, E. Moses2, S. Dobson3, S. Blitz4, J. Brophy5, G. Ogilvie6, A. Bitnun7, L. Samson8, N. Lapointe9, S. Walmsley9

1University of British Columbia, Obstetrics, Gynecology, Vancouver, Canada; 2University of Toronto, Public Health, Toronto, Canada; 3University of British Columbia, Pediatrics, Vancouver, Canada; 4University Health Network, Biostatistics, Toronto, Canada; 5Children's Hospital Eastern Ontario, Pediatrics, Ottawa, Canada; 6University of British Columbia, Obstetrics, Gynecology, Vancouver, Canada; 7University of Toronto, Pediatrics, Toronto, Canada; 8University of Montreal, Pediatrics, Montreal, Canada; 9University of Toronto, Medicine, Toronto, Canada

Background: The qHPV vaccine is approved for use in HIV negative adolescents and is highly immunogenic. There is limited information on the adequacy of the immune response in HIV+ adolescents.

Methods: HIV positive girls and women were enrolled in a study of the safety and immunogenicity of the qHPV vaccine in HIV positive persons. Sub-analysis of 9-13 year old girls was assessed from participants given 3 doses of the qHPV vaccine at months 0, 2 and 6. Geometric mean antibody titers pre vaccine and at months 7, 12, 18 and 24, were evaluated by the Merck cLIA assay to HPV 6,11,16,18. Results were compared to the 3 dose arm of a 2 dose/ 3 dose study in HIV- girls age 9-13 given qHPV vaccine.

Results: 26 girls under age 9-13 were enrolled of a total of 407 subjects. All but one girl was seronegative to all types in the quadrivalent vaccine (6,11,16,18) and completed vaccine schedule per protocol. For HIV+ study participants, mean age was 11, 4% white, 70% black and 24% other. Mean time since HIV diagnosis was 9 years. Median (IQR) baseline CD4 was 710 (554-940), and 62% had a suppressed viral load. CD4 Nadir 470 (230-610) and 76% were on HAART. All girls seroconverted at month 7. A statistically significant difference in age was observed between HIV+ and HIV- girls, using a generalized linear model age adjusted GMTs were calculated for each group.

No conflict of interest

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Abstract 16

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

Single-tablet regimen rilpivirine / emtricitabine / tenofovir DF is safe and well-tolerated to efavirenz / emtricitabine / tenofovir DF in art-naïve females

C. Creticos1, C. McDonald2, S. Segal-Maurer3, I. Brar4, B. Wade5, C. Brinson6, W. Gamer7, D. Porter8, T. Fralich9, J. DeMorin9, O. Lugo-Torres9, E. Elbert9

1Howard Brown Health Center, Infectious Disease, Chicago, USA; 2Tarrant County Infectious Diseases, Infectious Disease, Fort Worth, USA; 3New York Hospital Queens, Medicine, Flushing, USA; 4Henry Ford Hospital, Medicine, Detroit, USA; 5Center for Prevention/Treatment, Infectious Disease, Pensacola, USA; 6Red River Family Practice, Medicine, Austin, USA; 7Gilead Sciences, Biostat, Foster City, USA; 8Gilead Sciences, Virology, Foster City, USA; 9Gilead Sciences, Medical Affairs, Foster City, USA

Introduction: Women are a significant proportion of the HIV-infected population yet have been difficult to enroll in clinical trials for a variety of reasons. STaR is the first study to directly compare the safety and efficacy of two once daily single-tablet regimens (STRs), Rilpivirine / Emtricitabine / Tenofovir DF (RPV/FTC/TDF) and Efavirenz / Emtricitabine / Tenofovir DF (EFV/FTC/TDF).

Material and Methods: STaR is an open-label, randomized 1:1, 96-week study in treatment-naïve HIV-1 infected subjects. The primary endpoint was the proportion of subjects with HIV-1 RNA <50 copies/mL at Week 48 (12% non-inferiority margin; Snapshot analysis). Additional analyses were performed to assess safety and efficacy outcomes in females.

Results: Overall for the primary endpoint, RPV/FTC/TDF (n=394) was non-inferior to EFV/FTC/TDF (n=392; 86% vs 82%) by Snapshot analysis for HIV RNA <50 copies/mL (difference 4.1%, 95% CI [-1.1%, 9.2%]) at Week 48 and also at Week 96 (78% vs 72%; difference 5.5%, 95% CI [-0.6%, 11.5%]). In the female subgroup (RPV/FTC/TDF [n=28], EFV/FTC/TDF [n=28]), the proportion of subjects with HIV-1 RNA <50 copies/mL at Week 48 was 79% in the RPV/FTC/TDF arm vs 61% in the EFV/FTC/TDF arm (difference 17.4%, 95% CI [-8.8%, 43.6%]) and at Week 96, 68% vs 57%, respectively (difference 12%, 95% CI [-15.5%, 39.5%]). The rate of all Grades treatment-emergent adverse events in >10% of subjects in either arm for the female subpopulation by Preferred Term for RPV/FTC/TDF and EFV/FTC/TDF (n, %; respectively) were upper abdominal pain (3, 11%; 1, 4%), nausea (2, 7%; 4, 14%), vomiting (1, 4%; 3, 11%), folliculitis (3, 11%; 0), bronchitis (1, 4%; 4, 14%), upper respiratory tract infection (5, 18%; 5, 18%), urinary tract infection (3, 11%; 2, 7%), muscle spasms (0; 3, 11%), pain in extremity (1, 4%; 3, 11%), somnolence (1, 4%; 4, 14%), headache (3, 11%; 3, 11%), dizziness (3, 11%; 8, 29%), insomnia (2, 7%; 5, 18%) and rash (1, 4%; 8, 29%). There were 5 discontinuations due to an adverse event in the female population. Of these, 2 (7%) were in the RPV/FTC/TDF arm and 3 (11%) in the EFV/FTC/TDF arm, and all occurred before Week 48.

Conclusions: In the female population, RPV/FTC/TDF is safe, well-tolerated and effective. Treatment-naïve HIV-1-infected females had no apparent differences in virologic success (HIV-1 RNA <50 copies/mL) for RPV/FTC/TDF and EFV/FTC/TDF through 96 weeks. RPV/FTC/TDF demonstrated low adverse event rates through Week 96. Discontinuations due to adverse events were also low, with all events occurring prior to Week 48.

Financial relationship(s): Dr. Catherine Creticos :Gilead, Viiv Healthcare and Pfizer. Dr. Cheryl McDonald: Gilead, Viiv, BMS, Merck and Boehringer Ingelheim. Dr. Sorana Segal-Maurer: Gilead, Janssen, Forest Pharmaceuticals, Cubist Pharmaceuticals and Pfizer. Dr. Indira Brar: Gilead, Merck and Viiv. Dr. Barbara Wade: Gilead. Dr. Cynthia Brinson: Gilead, Astra Zeneca, Bristol Myers Squib, Shinnogi, Glaxo Smith Kline, Viiv Healthcare, Novo Nordisc, Jansen, Johnson and Johnson

Drs. William Garner, Danielle Porter, Todd Fralich, Jennifer DeMorin, Olga Lugo-Torres, and Elizabeth Elbert are full time employees of Gilead Sciences, Inc.
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Abstract_17

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

The efficacy and safety of raltegravir in women

K. Squires¹, L.G. Bekker², C. Katlama³, Y. Yazdanpanah⁴, A. Rodgers⁵, K. Strohmaier⁶, P. Sklar⁷, R. Leavitt⁷, H. Teppler²

¹ Jefferson Medical College of Thomas Jefferson University, Dept of Medicine, Philadelphia, USA; ²University of Cape Town, Desmond Tutu HIV Foundation, Cape Town, South Africa; ³Hopital Pitie Salpetriere, Dept of Infectious Diseases, Paris, France; ⁴Hopital Bichat-Claude Bernard, Dept of Infectious & Tropical Diseases, Paris, France; ⁵Merck & Co. Inc., Biostatistics, Whitehouse Station NJ, USA; ⁶Merck & Co. Inc., Global Scientific & Medical Publications, Whitehouse Station NJ, USA; ⁷Merck & Co. Inc., Clinical Research, Whitehouse Station NJ, USA

Introduction: Clinical trials of raltegravir have generally shown similar efficacy for men and women, although the number of female participants in any given study has been relatively small. To confirm these findings, we conducted a pooled subgroup analysis of the efficacy and safety of raltegravir in women as compared with men, using combined data from the STARTMRK and QDMRK studies.

Methods: STARTMRK and QDMRK were double-blind, randomized, controlled trials of raltegravir in treatment-naïve patients with HIV-1 infection. This exploratory subgroup analysis by sex included data collected through week 48 exclusively from patients in the raltegravir 400-mg bid arms of these studies. The proportion of patients with HIV RNA <50 copies/mL and the mean change from baseline in CD4 cell counts were summarized by sex using the observed failure approach; safety measurements included the proportion of patients with adverse events (AEs) and changes in laboratory parameters. Due to the exploratory nature of these analyses, no formal statistical comparisons were performed.

Results: Of the 669 patients who received raltegravir 400 mg bid, 525 (78%) were male (mean age 38.0 years, SD 9.4) and 144 (22%) were female (mean age 38.5 years, SD 11.3). The female cohort had a lower proportion of white patients (37% vs 64%) and a higher proportion of black patients (29% vs 9%) and Asian patients (20% vs 8%) than the male cohort. At baseline, plasma vRNA was >100,000 copies/mL in 40% of women vs 47% of men (mean [SD]: 4.8 [0.6] vs 4.9 [0.6] log₁₀ copies/mL, respectively). Baseline CD4 cell count was ≤200 cells/µL in 33% of women vs 39% of men (mean [SD]: 226 [135] vs 261 [121] cells/µL, respectively). Clade B viral subtype was less common in women (44%) than in men (85%). Overall, 89% of women and 91% of men completed 48 weeks of treatment. Other than pregnancy (3% vs 0%), most reasons for discontinuation were similar between cohorts. At week 48, HIV RNA <50 copies/mL was achieved in 93% of women (126/135) and 91% of men (458/505); difference: -3.0, 95% CI (-7.4, 3.0). The mean change in CD4 cell count from baseline to week 48 was 189 cells/µL in women and 194 cells/µL in men; difference: 5.3, 95% CI (-21, 31). Clinical AEs were reported by 85% of women and 88% of men, considered drug-related by the investigator in 35% and 32%, respectively, and led to treatment discontinuation in 2% of each cohort. Serious AEs were less common in women (2%) than in men (9%). Laboratory AEs occurred in 7% of women vs 9% of men and were considered drug-related in 3% of each cohort. Changes in laboratory parameters were similar between cohorts: grade 2/3 increase in LDL-cholesterol occurred in 5% of women vs 6% of men; grade 2/3 increase in total cholesterol, 6% vs 5%; grade 2/3 increase in serum triglycerides, 0% vs 1%.

Conclusions: The results of this exploratory analysis suggest that the efficacy and safety of raltegravir are similar in men and women with previously untreated HIV-1 infection.

Financial relationship(s): served on Advisory Boards and as a consultant for Merck.
Abstract_18

**ARV therapy for women -- efficacy, toxicity, pharmacokinetics**

**Improved Virological Outcomes Amongst Women Starting Efavirenz for First-Line Antiretroviral Treatment In South Africa**

G. Fatti¹, A. Grimwood²

¹Kheth’Impilo, Research, Cape Town, South Africa; ²Kheth’Impilo, CEO, Cape Town, South Africa

**Background:** Efavirenz (EFV) and nevirapine (NVP) are commonly available non-nucleoside reverse transcriptase inhibitors (NNRTI) for first-line antiretroviral treatment (ART) in low-income settings. NVP has increased adverse effects and reduced efficacy when administered with rifampicin for concomitant tuberculosis, while EFV is more costly and has been purported to be linked with congenital abnormalities when administered during the first trimester. This study compared virological outcomes amongst women starting EFV and NVP in a multicentre cohort in routine settings in South Africa.

**Methods:** A multicentre cohort study was performed at public ART facilities in four South African provinces, using routinely collected clinical data. ART-naïve adults starting ART were included and followed till a maximum of 5 years after starting ART. The outcomes were virological suppression (< 400 copies/ml) after starting ART, cumulative incidence of virological rebound (viral load > 400 copies/ml after initial virological suppression), cumulative incidence of confirmed virological failure (two consecutive viral loads > 1000 copies/ml, and proportions of patients switching to a second-line regimen during the study period. Data were analysed using multivariable generalised estimating equation population-averaged models, Kaplan-Meier and Cox analyses, and log-linear regression.

**Results:** A total of 53,447 women were included, of whom 33,946 (63.5%) started EFV and 19,531 (36.5%) started NVP. 7.6% of women were pregnant when starting ART, of whom 82.9% were initiated on NVP. After starting ART, virological suppression was higher in the EFV cohort (85.3% vs. 79.0%) at any timepoint. After adjustment for confounding and time on ART, women starting EFV had a 65% improvement in virological suppression over 5 years; adjusted odds ratio (AOR) 1.66 (95% CI: 1.58-1.74; P<0.0001). Pregnant women also had improved virological suppression on EFV; AOR 1.38 (95% CI: 1.10-1.72). The cumulative incidence of confirmed virological failure was lower in the EFV cohort; 13.7% vs. 21.6% (adjusted hazard ratio [aHR] 0.66 [95% CI: 0.57-0.77]) after 36 months. The incidence of virological rebound after initial viral suppression was lower in the EFV cohort; 6.9% vs. 9.4% (aHR 0.79 [95% CI: 0.66-0.95]) after 12 months of ART. The proportion of women who switched to a second-line regimen was substantially lower in the EFV cohort; 1.3% vs. 4.2% (relative risk=0.31 [95% CI: 0.28-0.36; P<0.0001]).

**Conclusions:** Virological outcomes of women receiving EFV were significantly better than for those who received NVP for first-line ART in routine settings in South Africa. These results support other studies for using EFV as the preferred NNRTI in low-income settings.

*No conflict of interest*
Abstract 19

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

HAART discontinuation in women: Results from the Chilean Aids Cohort

P. Vasquez1, C. Beltran1, P. Zitko1, A. Carrasco1, for the Chilean AIDS Cohort

1Hospital San Juan de Dios, Infectiologia, Santiago, Chile

Background: There is conflicting evidence on HAART failure rates in women in clinical trials. These studies have been criticized for few women enrollment. Cohort studies suggest lesser adherence to HAART among women. More research in this issue with larger number of women on HAART is urgently needed to determine factors associated with failure and lack of adherence. Previous studies from the Chilean Aids Cohort demonstrated higher risk of failure in women. Objective: To determine whether women have more risk than men for HAART discontinuation, as a marker of adherence, a possible explanation for higher failure rates among women in some studies. To determine factors associated with abandonment for the design of intervention strategies.

Method: Chilean AIDS cohort of more than 11,000 patients in follow up (1,513 women) of which + / - 8,500 have been followed for 12 months and 7,850 for 24 months or more. We identified HAART discontinuation cases (excluding ART suspensions after PMTCT) and we studied abandon rates and factors associated to with descriptive statistics at 12 and 24 months, by year of starting ART, sex, age group, CD4 and CDC stage. Logistic regression determined the risk of discontinuation associated by gender in univariate and adjusted analysis. We explored the causes of abandonment. All results are reported with their respective 95% CI.

Results: A higher discontinuation rate at 12 months in women: 5.4% (4.3 to 6.6) vs 1.9% among men (1.6 to 2.2). At 24 months OR 0.70 (0.61 to 0.81) lower in men by univariate analysis and 0.74 (0.63 to 0.87) by multivariate analysis. Factors associated with abandonment by multivariate analysis to 24 months in this Cohort: use of ATV or ATV/r 0.61 (0.48 to 0.78) and NVP and LPV/r by univariate analysis, year of HAART initiation and baseline viral load. Among women reasons for discontinuation were: Lack of adherence 66.4% (61.1 to 71.8) with no other specification, toxicity 12.5% (8.8 to 16.3) and lost of follow up after PMTCT completion 12.5% (8.8 to 16.3).

Conclusions: In Chile, a middle income country, women have significantly higher risk of HAART discontinuation in this cohort study with a large number of women. Toxicity and type of ARV used are related to the risk of HAART discontinuation. The end of PMTCT protocol is a risk factor for HAART and care abandonment. Further studies are required to analyze in depth lack of adherence in women.

No conflict of interest
Abstract_20

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

Gender disparities in treatment based outcomes persist in the era of modern ART


1Royal Free Hospital London NHS Foundation Trust, Thoracic Medicine, London, United Kingdom; 2Royal Free Hospital London NHS Foundation Trust, HIV Medicine, London, United Kingdom; 3University College London, Infection and Population Health, London, United Kingdom

Introduction: We evaluated whether gender based inequality in treatment outcomes existed in the era of modern ART. Previous UK studies such as UK CHIC had demonstrated that regimen changes, treatment discontinuation and virological failure in women than men.

Methods: All ART-naive HIV positive individuals who attended the Royal Free Hospital, London, UK who started combination ART (≥3 antiretrovirals) from 2006 onwards were included. Individuals were required to have at least one documented viral load after starting ART. Percentage experiencing failure of virological control (1st of 2 consecutive VLs>200 cps/ml >6 months post ART) and treatment modification were estimated using standard survival methods.

Results: Of 1131 individuals, 29% (327) were women, 58% (563) were identified as being men who have sex with men (MSM) and 19% (241) as non-MSM men. Women and non-MSM men started ART at a more advanced stage, with a median CD4 at ART initiation of 219 and 218 cells/mm³ respectively compared to 298 in MSM. Women and non-MSM men were also more likely to be of black African ethnicity and to have a previous AIDS diagnosis.

Time to achieve virological suppression (viral load<50 copies/ml) was similar in all groups with 88.8% of MSM, 83.4% of non-MSM men and 84.7% of women achieving control by one year (p=0.19; log rank test). By 18 months, 2.6% of MSM, 6.2% of non-MSM men and 9.8% of women had experienced virological failure (P<0.0001). After adjustment for potential confounders, non-MSM men had more than three times the rate of virological failure (adjusted hazard ratio [aHR]=3.69; 95% CI 1.76-7.74) and women more than 4 times the rate (4.63; 2.26-9.48; p=0.0001) compared to MSM.

By 1 year post-ART initiation, 42.6% of the women had changed a component of their treatment regimen compared to 35.5% of non-MSM men and 26.9% of the MSMs (p<0.0001) 16.6% of women altered their ART regimen due to drug toxicity compared with 9.6% of MSM and 12.09% of non-MSM men.

In the first 12 months of ART, 5.0% of MSM, 12.0% of non-MSM men and 15.4% of women had completely discontinued their ART regimen for at least two weeks (P<0.0001, log rank test; Figure 2b). We found that, after adjustment for potential confounders, that non-MSM men had more than twice the rate (aHR=2.28; 1.35-3.83) and women had more than three times the rate (aHR=3.45; 2.20-5.40; p<0.0001) of complete ART discontinuation compared to MSM.

Conclusion: In our cohort women are more likely than both MSM men and non-MSM men to change or discontinue their ART regimen and also to experience virological failure. A greater proportion of women changed their ART regimen as a result of drug toxicity compared to men. Overall these differences seem to be associated with poorer outcomes in terms of more failure to control viral load. The challenge is to better understand the reasons behind these differences to achieve better outcomes for women in the future.

No conflict of interest
**Abstract_21**

**ARV therapy for women -- efficacy, toxicity, pharmacokinetics**

**Systematic review of clinical outcomes of infants born to women receiving lopinavir/ritonavir-based antiretroviral therapy (ART) during pregnancy**

M. Martinez¹, M. Pasley¹, D. Arikan², A. Nilius¹

¹AbbVie, Global Pharmaceutical Research and Development, North Chicago Illinois, USA; ²AbbVie, Global Pharmacovigilance, North Chicago Illinois, USA

**Introduction:** Lopinavir/ritonavir (LPV/r) plus two nucleoside reverse transcriptase inhibitors is recommended by the 2012 DHHS Perinatal Guidelines to treat HIV-1 infection in pregnant women and reduce risk of mother-to-child transmission (MTCT). Increased risk of adverse infant outcomes, such as infant mortality, preterm birth, and low birth weight, have been reported for infants born to HIV-infected women and have been associated with class of ART intervention during pregnancy. This systematic review assessed published data on MTCT and adverse clinical outcomes in infants born to HIV-infected pregnant women treated with LPV/r-based regimens.

**Materials and Methods:** PubMed/EMBASE databases and HIV congresses were searched for studies published through January 2013 or March 2013, respectively. Outcomes of infants born to HIV-infected mothers receiving LPV/r during pregnancy were a primary or secondary objective of included studies. Data from included studies were tabulated. The AbbVie Global Safety Database was also searched for the infant outcome of prematurity through December 2011.

**Results:** Twenty-seven publications / presentations describing 17 studies were identified. These studies assessed outcomes of infants born to 4331 women receiving LPV/r during pregnancy: 2263 received LPV/r 800/200 mg/day, 101 received >800/200 mg/day, and 1967 received an unknown LPV/r dose. Infant outcomes reported for the studies are in the table. Post-marketing safety data estimated a prematurity reporting rate of 0.66/10,000 patient treatment years for LPV/r.

In the 10 studies reporting MTCT, rates ranged from 0-2.8%. In the 4 studies reporting infant mortality, rates ranged from 0-5.8%. In the 13 studies reporting preterm birth, rates ranged from 8.7-25.0%; in the 6 studies reporting very preterm birth, rates ranged from 0.4-5.0%. In the 9 studies reporting low birth weight, rates ranged from 11.5-20.3%. In the 6 studies reporting on very low birth weight, rates ranged from 0.3-3.0%.

**Conclusions:** In this systematic review on outcomes of infants exposed to LPV/r in utero, MTCT rates were low. Preterm birth rates in the included studies reflected the rate for the geographical area in which the study was conducted; these data and post-marketing safety data suggest that in utero exposure to LPV/r may not increase risk of preterm birth. Infants born to women who received LPV/r 800/200 mg/day and those born to women who received >800/200 mg/day had similar rates of preterm birth, low birth weight, and MTCT.

**Conflict of interest**
financial relationship(s): All authors are AbbVie employees and may hold AbbVie stock or options.
Abstract_22

Epidemiology of HIV in women and girl

Morbidity among HIV exposed uninfected children compared to children not exposed to HIV – a danish nationwide study

E.Moseholm-Larsen¹, S.B. Nordly², V. Rosenfeldt³, N. Weis³, M. Helleberg⁴, T.L. Katzenstein⁴

¹North Zealand Hospital, Department of Lung and Infectious Disease, Hillerød, Denmark; ²Hvidovre Hospital, Department of Pediatrics, Hvidovre, Denmark; ³Hvidovre Hospital, Department of Infectious Disease, Hvidovre, Denmark; ⁴Rigshospitalet, Department of Infectious Disease, Copenhagen, Denmark

Background: Since the introduction of antiretroviral drugs for the prevention of mother-to-child transmission (PMTCT) of HIV, the number of children infected during labour and childbirth has decreased to <1% in Denmark and most Western countries. With the availability of antiretroviral drugs increasing globally, the number of HIV exposed, uninfected children will increase significantly. Previous studies have shown that HIV exposed, uninfected children can have a decreased stem cell function and decreased production of thymic cells. The clinical implications of these early immunological changes are unknown, and few studies, especially from developed countries, have examined morbidity in HIV exposed, uninfected children. The objective of this study is to examine rates, diagnoses and lengths of hospital admission and use of antibiotics among Danish HIV exposed, uninfected children. The preliminary results, presenting the birth related characteristics of the cohort, are presented here.

Method: Information on all births in Denmark in the period January 1st 2000 – December 31st 2010 was collected from the national registries at Statistics Denmark. Demographic, maternal and child characteristics were summarized and compared between HIV infected mothers and HIV uninfected mothers using Pearson χ²-test or unpaired T-test, as appropriate. These results will, at a later stage, be linked to the National Patient Registry and the National Pharmaceutical Registry with the purpose of determining the rates, diagnosis and lengths of hospital admissions and use of antibiotics among Danish HIV exposed, uninfected children.

Results: A total of 712,428 children were born in Denmark between January 1st 2000 and December 31st 2010; of these 268 children were born by HIV-infected mothers. HIV-infected mothers were less likely to be married (26% vs. 30%), slightly older (mean 32 years, 95% CI 31,4-32,7 vs. 31 years, 95% CI 30,7-30,9), and their infants had a shorter gestational age (mean 267 days, 95% CI 264-269 vs. 278 days, 95% CI 277-278), were more likely to be delivered by Caesarean section (65% vs. 21%) and had a lower birth weight (mean 3035g, 95% CI 2951-3121 vs. 3478g, 95% CI 3477-3480). There was no difference between smoking habits during pregnancy, number of completed pregnancies, multiple births or Apgar score at 5 minutes.

Conclusion: These results are the first from a study investigating morbidity among HIV exposed uninfected children compared with children born by uninfected mothers in Denmark. Information on birth related outcomes of HIV infected women in Denmark can create a basis for understanding the needs of these women in relation to pregnancy and childbirth, in addition to factors potentially associated with morbidity during childhood. These preliminary results show that HIV exposed uninfected children were more likely to have a shorter gestational age and lower birth weight compared to children not exposed to HIV, and this could potentially be associated with childhood morbidity. This study intends to investigate this further. If there is an increased morbidity among HIV exposed uninfected children, there may be a need for a closer follow-up of these children.

No conflict of interest
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Abstracts
Poster Presentations
Abstract_23

Prevention of HIV transmission in women and girls

How prepared are the overseas workers’ wives for HIV: an experience from Bangladesh

S. Chowdhury¹, S.H. Talukder¹, U. Kulsum²

¹Eminence, Communicable Diseases, Dhaka, Bangladesh; ²National Development Programme, Communicable Diseases, Dhaka, Bangladesh

Introduction: Mobility is a key structural factor that has been linked to increased HIV incidence and vulnerability globally. Bangladeshi overseas workers suffer problems found among other internal and international migrant groups including socioeconomic and power inequalities, limited social capital, loneliness, and coping with different cultural norms relating to sex. Although the overseas workers are greater in proportion of reported HIV positive cases in Bangladesh, due to various reasons, this group is still out of the national HIV/AIDS surveillance system. HIV transmission from international migrant workers who have returned and are HIV positive has been mostly restricted to their spouses. This study investigates the preparedness of the migrant workers wives by assessing their knowledge, attitude and practice on HIV transmission, prevention and treatment.

Methods: The general knowledge, attitudes, and practices were assessed through qualitative method while a quantitative survey was also done to attain information on women’s age, education, income and expenditure. 133 wives of overseas workers whose heads are used to be migrant workers were interviewed through focus group discussion (FGD) and in depth interview (IDI).

Results: Majority of the husbands (76.2%) of our respondents had been staying abroad for one to three years. These husbands had been working mostly in Dubai (23.8%), Saudi Arabia (19%), Malaysia (14.3%) and Singapore (11.1%). Only 23 out of 133 women were aware that HIV is transmitted by the sharing of infected needles, receiving blood from an infected person and from infected mother-to-child. 99 respondents believed that HIV is transmitted through insect bites. Only 10 women expressed willingness to use condom if their husbands get infected. Rest of them (n=123) said they will not use condom with their HIV positive husbands if he prohibits doing so. 11 women reported having sexual partner besides their husbands and none of them have ever used condom with their partners. Condom use is considered a family planning method (n=131) only rather than a tool for HIV prevention (n=2). Only 22 respondents have shown an interest to test for HIV, provided that it is done at a center far from their households. Print media is more accessible to the broader women community as they are not generally allowed to watch or hear subjects on TV or radio that deals with sexual topics. Women have very low control over their sexual relationship and are not in a position to make decisions about safer sex practice. For similar reasons, testing for HIV is of less importance to them, even for those who know about their husband’s pre- or extramarital sexual relationship.

Conclusion: Practice of low condom use, fear of social discrimination, conservative family structure and marital disharmony poses great risk to the wives of overseas workers. Therefore, besides emphasizing national prevention interventions on most at risk population (MARP), empowering wives of migrant workers in terms of sexual decision making and communicating comprehensive HIV knowledge through community volunteer/peer group should be in place immediately. The VCT services should be available to these women to support in understanding their test result and its implications.

No conflict of interest
Abstract_24

Prevention of HIV transmission in women and girls

Retention to Care of HIV Positive Postpartum Females in Kumasi, Ghana

R. Reece¹, A. Rana¹, A. Kwara¹, B. Norman², T. Flanigan¹

¹Brown University, Infectious Diseases, Providence, USA; ²Komfo Anokye Teaching Hospital, Infectious Diseases, Kumasi, Ghana

Introduction: Universal access to antiretrovirals (ART) during pregnancy is recognized as the standard of care globally for prevention of mother to child transmission (PMTCT). However, it is more than just access to medications but engagement and retention in care that leads to successful treatment and viral suppression.

Methods: We performed a retrospective chart review of all postpartum patients referred to Komfo Anokye Teaching Hospital (KATH) HIV clinic, in Kumasi Ghana, between January 1 2010 and December 31 2011. Patients were classified into three groups: optimal follow-up (1 visit every 6 months), sub-optimal follow-up (1 visit every 12 months) and loss to follow-up (LTFU no visits in 12 month period). Charts were abstracted for demographic and medical variables of interest (such as age, CD4 count, time of HIV diagnosis, marital status, family planning, education, employment, etc). Univariate and multivariate logistic regression analyses were used to identify factors associated with optimal follow-up. All covariates in the multivariate model with p <0.05 were considered significant.

Results: 207 HIV positive postpartum women were referred to KATH during the study period. Of 207 patients, 141 (68%) medical charts were available for review. Of the 141 women, 56% were diagnosed at pregnancy and the mean CD4 count was 518 cells/µL. Overall, 93% had disclosed their HIV status to family or friends. 89% of women had completed adherence counseling (at least 3 visits) but only 35% reported mode of family planning. Overall, optimal follow-up was 66% with sub-optimal 16% and LTFU 18%. The rate of LTFU among women diagnosed at pregnancy was 22% compared to 13% for those with known HIV diagnosis (P=.078). Multi-variate analysis showed that adherence counseling (OR 5.0, CI 1.6 – 15.7; P=.006) and family planning (OR 2.3, CI 1.0 – 5.3; P=.041) were predictive of optimal follow-up.

Conclusion: In this cross sectional study, only two-thirds of postpartum women remained engaged in care at one year of follow-up. Investigating barriers to adherence counseling and family planning during pregnancy may impact postpartum engagement in care among HIV-infected women in Kumasi.

No conflict of interest

Abstract_25

Prevention of HIV transmission in women and girls

Gender based violence and risk of HIV infection among women attending voluntary counseling and testing services in Dire Dawa, Ethiopia.

T. Woldeyes¹, T. Legesse²

¹Horizon pharmacy, pharmacy, jimma, Ethiopia; ²concern, public health, addis ababa, Ethiopia

The global deadly disease HIV/AIDS has now entered its third decade. Investigations have discovered that gender roles influence the level of an individual’s risk to HIV infection. However HIV strategies assume an idealized world in which everyone is equal to make empowered choices, and can opt to abstain from sex, stay faithful or use condoms consistently. In reality, women face a range of HIV-related risks and vulnerabilities that men do not, many of which
are embedded in social relations and economic realities of their societies.
In sub Saharan Africa Women and girls are affected disproportionately with HIV/AIDS. Gender based violence (GBV) on the other hand affect one out of every three women worldwide. Similarly Ethiopia is a country having the highest prevalence of GBV in Africa.
The General Objective of the study was to assess the relationship between gender-based violence and HIV infection among women attending four VCT service in Dire Dawa from January 1 to February 30/2012.
Study Design employed was a comparative Cross-sectional survey with qualitative in-depth interview. Analysis were done using SPSS version 12.0.1. Ethical approval was obtained from Jimma University research and publication office. And at the study setting, women were given their consent to participate on the study. Unlinked anonymous methods were employed to link up the socio-demographic variables with sero-status results.
The result of the study showed 17.5 % women were tested HIV-positive and 72.3% of women report psychological violence in their life time with 48.4%in the past one year. 45.6% report physical violence in their life time, while 24.4% reported physical violence in the past one year. With respect to sexual violence 56.6% and 37.7% women report sexual violence in their life time and in the past one year respectively. Sexual violence in the last one year and sero positive status were significantly associated, adjusted OR (95%CI) 2.333(1.449, 3.755). Besides women who do not use condoms were having an increased risk of HIV infection adjusted OR (95%CI) 3.173 (1.703, 5.192). Childhood sexual assault, forced first intercourse, and adult sexual assault by non-partners were not associated with HIV serostatus.

Overall, this study confirms that women who have experienced intimate partner violence are at increased risk of HIV infection. Therefore public health policies, institutions, and programs must pay more attention to violence against women not only as a public health problem, but also as a key component of the HIV/AIDS pandemic.

No conflict of interest

Abstract_26

Prevention of HIV transmission in women and girls

The factors associated with having multiple sex partners among urban African American women in Atlanta, Georgia

H. Klein1, C.E. Sterk1, K.W. Elifson1

1Emory University, Behavioral Sciences and Health Education, Atlanta Georgia, USA

Introduction: In urban areas of the United States, women of color, especially African Americans, account for a disproportionately-high number of new HIV infections. Many factors have been identified as contributing to the greater-than-average rates of HIV infections among African American women, including (among others) substance use/abuse, childhood maltreatment experiences, psychological functioning, sociodemographic characteristics, and relationship dynamics that make it difficult for women to safeguard their sexual health. In this study, we examine one specific behavior—namely, having multiple sex partners—that has been linked to having an elevated risk for contracting or transmitting HIV, and identify the factors associated with involvement in this risk practice.

Materials & Methods: The data were collected in Atlanta, Georgia between 2009 and 2011 as part of the People and Places study. This study entailed conducting interviews with 1,864 African American adults (820 of whom were women) residing in 80 specific census block groups selected on the basis of various socioeconomic characteristics, such as the density of persons (a) living below the poverty line, (b) who had not completed high school, (c) living in female-headed households, (d) who were unemployed or no longer in the labor force, among others.

Results: 17.7% of the women reported having had more than one sex partner during the month prior to interview. Multivariate logistic regression analysis revealed eight factors that were
associated with women's risk of recently having had multiple sex partners: (a) being married or 'involved' in a romantic-type relationship (OR=0.26, p<.001), (b) perceived importance of one’s racial/ethnic identity (OR=0.80, p<.05), (c) level of assertiveness (OR=0.16, p<.01), (d) level of self-esteem (OR=0.57, p<.01), (e) recent frequency of alcohol use (OR=1.01, p<.01), (f) whether or not the person had become intoxicated recently (OR=3.00, p<.001), (g) age of first illegal drug use (OR=0.99, p<.001), and (h) whether or not the woman resided with a user of illegal drugs (OR=1.67, p<.05). Together, these factors accounted for 27.5% of the variance.

Conclusions: Having more than one recent sex partner was not uncommon in this population of urban, socioeconomically-challenged, African American women, and was reported by approximately 1 woman in 6. In previous studies, this behavior has been linked to an increased risk of contracting or transmitting HIV. In this study, numerous factors were found to underlie the practice of having multiple sex partners; and these factors indicate some specific directions for prevention or intervention. For example, intervention programs might wish to include components to boost women's assertiveness skills and/or their levels of self-esteem, as low assertiveness and low self-esteem were associated with a greater likelihood of having multiple sex partners. As another example, substance abuse prevention, intervention, and/or treatment appear to be necessary, as four of the eight multivariate predictors were in this domain. HIV intervention programs might also benefit by providing targeted outreach to single or 'uncoupled' women, as they were found to be more likely to have more than one recent sex partner.

No conflict of interest

Abstract_27

Prevention of HIV transmission in women and girls

Drug resistance among women attending antenatal in Ghana

E. Mensah¹, J. Amoah², P. Enyan³


Background: Initial evidence from resource-limited countries using the WHO HIV drug resistance (HIVDR) threshold survey suggests that transmission of drug-resistance strains is likely to be limited. However, as access to ART is expanded, increased emergence of HIVDR is feared as a potential consequence. We have performed a surveillance survey of transmitted HIVDR among recently infected persons in the geographic setting of Accra, Ghana.

Methods: As part of a cross-sectional survey, 2 large voluntary counseling and testing centers in Accra enrolled 50 newly HIV-diagnosed, antiretroviral drug-naive adults aged 18 to 25 years. Virus from plasma samples with >1,000 HIV RNA copies/mL (Roche Amplicor v1.5) were sequenced in the pol gene. Transmitted drug resistance-associated mutations (TDRM) were identified according to the WHO 2009 Surveillance DRM list, using Stanford CPR tool (v 5.0 beta). Phylogenetic relationships of the newly characterized viruses were estimated by comparison with HIV-1 reference sequences from the Los Alamos database, by using the ClustalW alignment program implemented.

Results: Subtypes were predominantly D (39/70, 55.7%), A (29/70, 41.4%), and C (2/70; 2, 9%). Seven nucleotide sequences harbored a major TDRM (3 NNRTI, 3 NRTI, and 1 PI-associated mutation); HIVDR point prevalence was 10.0% (95%CI 4.1% to 19.5%). The identified TDRM were D67G (1.3%), L210W (2.6%); G190A (1.3%); G190S (1.3%); K101E (1.3%), and N88D (1.3%) for PI.
Conclusions: In Accra the capital city of Ghana, we found a rate of transmitted HIVDR, which, according to the WHO threshold survey method, falls into the moderate (5 to 15%) category. This is a considerable increase compared to the rate of <5% estimated in the 2006-7 survey among women attending an antenatal clinic in Mamobi. As ART programs expand throughout Africa, incident infections should be monitored for the presence of transmitted drug resistance in order to guide ART regimen policies.

No conflict of interest

Abstract_28

Prevention of HIV transmission in women and girls

ARV-based prevention for women: a review of factors influencing choice, adherence and potential success of product formulations

E. Tolley1, B. Friedland2, M. Gafos3, R. Amico4, L. Van Damme5, C. Woodsong6, K. MacQueen1, L. Mansoor7, S. McCormack8

1FHI 360, Social and Behavioral Health Sciences, Durham NC, USA; 2The Population Council, HIV & AIDS Program, New York NY, USA; 3Medical Research Council, MRC Clinical Trials Unit, London, United Kingdom; 4University of Connecticut, Center for Health Intervention and Prevention, Storrs CT, USA; 5The Bill and Melinda Gates Foundation, Global Health Program, Seattle WA, USA; 6International Partnership for Microbicides, Social and Behavioral Science, Chapel Hill NC, USA; 7CAPRISA, Clinical Trials Unit, Durban, South Africa; 8Medical Research Council, Department of Clinical Epidemiology, London, United Kingdom

Introduction: Achieving high product adherence has been a challenge for some microbicide and PrEP trials. Low demonstrated adherence in recent trials has led to questions about whether these products are well-suited for certain groups of women. However, the relationship between study product use within blinded clinical trials, and use of a proven HIV prevention product within service delivery settings, is less clear. We explore this relationship and consider implications for future microbicide uptake and adherence.

Methods: A multidisciplinary team of social, behavioral and clinical researchers examined the published and unpublished data from microbicide clinical trials to examine how adherence behavior is shaped by a framework of factors, including product attributes, clinical trial design and procedures, characteristics of the study population, socio-cultural context, and health care structures. We examined how these factors might affect microbicide uptake and adherence in a post-introduction environment, by drawing on literature from the fields of HIV treatment and prevention, as well as contraception.

Results: As a bio-behavioral strategy, microbicide use is influenced by the relationship between the study product and the person, communities, and systems surrounding its use. How individual users perceive microbicides is influenced by the attributes of the study product, including insertion timing, dosage, mode of application, formulation, and real or perceived side effects. Product characteristics, including the simplicity or flexibility of the regimen, are likely to influence uptake and use of microbicides in similar ways in everyday service delivery settings. The clinical trial context, including the protocol, ethical processes, and site procedures, contextualize the way in which adherence is framed in clinical trials; the balance between the benefit of adherence for the study versus the individual are managed, and how the social contract of study participation is negotiated. Post-trial, client-centered approaches need to build motivation and positive attitudes towards product-related adherence, and identify and reduce barriers that undermine adherence. Initially microbicide trials mainly recruited female sex workers in Africa, but as the epidemic became more generalized, recruited women from the general population. The characteristics of the study population inform women's HIV risk, their perception of risk, their motivations to participate in trials, as well as their ability to adhere to and sustain use of products, within or outside of trials. Socio-cultural norms relating to
sexual behavior, vaginal practices, sexual pleasure and gender dynamics impact women’s use of microbicides. Beyond clinical trial settings, social and cultural factors may exert an even stronger influence on microbicide acceptability and on adherence. The characteristics of healthcare systems and policy-level decisions about introduction, access points and cost, negatively and positively impacted the introduction of technologies such as antiretrovirals, prevention of mother-to-child transmission and female condoms. Microbicide introduction is likely to face both similar and different challenges.

**Conclusions:** This review considers how to best position microbicides so that women in different contexts of risk can access and use them, and which service delivery settings are most suitable for women in different socio-cultural settings. These factors will shape microbicide adherence and its impact on the epidemic.

*No conflict of interest*

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**Abstract_29**

Prevention of HIV transmission in women and girls

A systematic review of stigma-reducing interventions for diasporic black, african and caribbean women living with HIV


¹Women’s College Research Institute, Women and HIV Research Program, Toronto ON, Canada; ²Women’s Health in Women’s Hands Community Health Centre, Research Department, Toronto ON, Canada; ³University of Toronto, Factor-Inwentash Faculty of Social Work, Toronto ON, Canada; ⁴University of Toronto, Dalla Lana School of Public Health, Toronto ON, Canada; ⁵McMaster University, School of Social Work, Toronto ON, Canada

**Introduction:** Diasporic Black, African and Caribbean (DBAC) populations are highly impacted by, and experience major struggles dealing with HIV. Despite the growing number of DBAC women living with HIV (WLWH) in Canada, little current research has been conducted to determine the social and structural factors driving these health inequities; these include poorer access to and quality of care and reduced overall health. There exists significant literature documenting the association between health, well-being, and quality of life of DBAC WLWH and intersecting forms of stigma. However, there remains a gap in knowledge pertaining to effective HIV-related stigma-reducing interventions to improve health that also attend to diversities across race, gender, sexuality, and culture for such populations as DBACC WLWH. Therefore, the objective of this systematic review was to identify evidence-based practice interventions that have been proven or are promising in terms of effectiveness in reducing the multiple forms of stigma experienced by DBAC WLWH.

**Materials & Methods:** The Cochrane methodology for systematic reviews was used to develop a search strategy in consultation with a librarian scientist to identify relevant studies. Multiple electronic databases were searched including: the Cochrane Library, Cochrane Central Register of Controlled Trials, Clinicaltrials.gov, EMBASE, PsycInfo, Social Science Abstracts, MEDLINE and nine others. There were no time, geographic or language restrictions considered in the search strategy. Two reviewers independently assessed the studies for potential relevance and conducted the Cochrane grading of RCTs to assess risk of bias and the Newcastle-Ottawa scale to assess the quality of non-randomized studies. Eligible papers employed an intervention design with DBAC WLWH as the target population and had a primary outcome of stigma reduction.

**Results:** Of 18,219 unique records identified in the original search, 5 articles were selected for full inclusion; 3 of the selected studies were small scale randomized controlled trials and the remaining 2 studies had a quasi-experimental design. They included two emotional writing disclosure (EWD) interventions, and one each involving self-care symptom management, a coping intervention and a didactic workshop. A
quantitative synthesis could not be justified due to the heterogeneity of the studies. As such, a qualitative synthesis was conducted. One study in particular, ‘the Unity Workshop’ which was adapted from an evidence based toolkit by the International Centre for Research on Women (ICRW) was shown to be particularly effective in reducing stigma and is also highly culturally informed.

Conclusions: Although the systematic review did not identify a singular intervention that combined multiple forms of stigma including race, class, gender and sexual orientation, it was successful in identifying an HIV stigma-reducing intervention that can be used to inform our larger research goal, which is to develop a controlled trial to assess the effectiveness of a stigma-reducing intervention that will be tailored to Diasporic Black, African, and Caribbean WLWH in Canada.

No conflict of interest

Abstract_30

Prevention of HIV transmission in women and girls

Are we providing enough care and support on the topic of infant feeding to women living with HIV in high resource countries?

M. Loutfy1, M. Ringlein2, L. Kennedy3, J. MacGillivray4, M. Muchenje5, S. Greene6, N. Steiri7, L. Samson8, A. Bitnum9, A. Ión9, G. MacDougall9, W. Tharao9, L. Serghides10, M. Yudin4, on behalf of the Ontario HIV Infant Feeding Group

1Women’s College Research Institute Women’s College Hospital, Women & HIV Research Program, Toronto ON, Canada; 2The Teresa Group, Toronto ON, Canada;
3Women’s College Research Institute Women’s College Hospital, Toronto ON, Canada; 4St. Michael’s Hospital, Obstetrics & Gynaecology, Toronto ON, Canada; 5Women’s Health in Women’s Hands, Toronto ON, Canada; 6McMaster University, Social Work, Hamilton ON, Canada; 7Children’s Hospital of Eastern Ontario, Infectious Diseases, Ottawa ON, Canada; 8The Hospital for Sick Children, Infectious Diseases, Toronto ON, Canada; 9McMaster University, Hamilton ON, Canada; 10University Health Network, Toronto ON, Canada

Background: Infant feeding in the context of HIV infection is a controversial topic. In resource-rich countries, guidelines recommend exclusive formula feeding and breast feeding is contraindicated. Recent changes in guidelines and practices in some European countries have allowed breastfeeding in rare circumstances. The WHO Guidelines contribute to the controversy and confusion by having different recommendations for resource-rich and resource-poor countries, and by not taking into account that resource-poor settings exist in some developed countries and vice versa. Many HIV-positive mothers in resource-rich countries are wondering if breastfeeding is an option for them if they are on antiretroviral therapy. Increasingly, women are advocating for opportunities to learn about the true risk of transmission, and are expressing the desire to experience the benefits of breastfeeding that their counterparts throughout the world are experiencing.

Methods: In June 2012, community advocates attending the Annual Interdisciplinary HIV Pregnancy Research Group (IHPREG) Conference, expressed an urgent need for transparency on the topic of HIV and infant feeding in Ontario, Canada. Community advocates indicated confusion over discrepancies in International HIV Infant Feeding Guidelines, particularly in the postmigration context of many HIV-positive women in Ontario. A discussion emerged on the potential for this confusion to result in women in Ontario (high-resource setting) choosing to breastfeed privately, given the cloak of secrecy that exists around the topic. This unprecedented dialogue resulted in the formation of the Ontario HIV Infant Feeding Working Group, which is a partnership between IHPREG and the Teresa Group, an AIDS Service Organization supporting women and families affected by HIV.

Results: The Ontario HIV Infant Feeding Working Group began in October 2012 with more than twenty members. Three preliminary meetings were held, and in September 2013 the first Community Consultation was held in Toronto, Ontario. The purpose of this meeting...
was to focus on community knowledge transition and the creation of future research opportunities. The sharing of diverse perspectives has highlighted important findings that the group intends to focus on in the future: (1) Confusion exists related to the WHO Guidelines that is exacerbated by the lack of knowledge among community members on the actual transmission risk associated with breastfeeding; (2) Clinicians and service providers have erroneously assumed that recommendations regarding infant feeding provide sufficient information to women. Expanded support for HIV-positive women regarding Canadian guidelines for HIV and infant feeding is needed. (3) Research in resource-limited settings may not be transferable or acceptable in a Canadian context. The development of a research agenda for resource-rich settings is required.

**Conclusion:** We are at the beginning stages of evaluating breastfeeding as an option in Canada for HIV-positive mothers. The dialogue must continue across disciplines, communities, and provinces to ensure all voices are being acknowledged as research programs are developed. Community members are eager to forge equal partnerships to ensure knowledge is developed and exchanged that will meet the needs of HIV-positive mothers. The experience of forming this working group can inform other areas of practice, as the honest nature of this dialogue has been eye opening for all those involved.

No conflict of interest

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**Abstract_31**

*Prevention of HIV transmission in women and girls*

*Empowerment of rural antenatal women in HIV/AIDS pandemic*

_M. Kamala_¹, S.M. Jacob¹, S. Parameshwari¹, D. Anitha¹, A. Ganesan², G. Thatchinamoorthy²

¹Tamilnadu Dr MGR Medical University, Experimental Medicine, Chennai, India

**Introduction:** Globally women are at risk for HIV infection than any other group. Women constitute 50% of the HIV/AIDS infected worldwide. The PMTCT (Prevention of Mother to Child Transmission) program was initiated at the Namakkal Government Hospital (GH) in the year 2000. Gender related inequalities threaten the right to over all good health and add to HIV vulnerability. Empowering women and equitable relations between men and women at national, local and household levels are urgently required to contain and reverse the AIDS epidemic. This study assessed the knowledge, attitude and empowerment of rural antenatal women in HIV/AIDS.

**Materials & Methods:** 1639 antenatal women were recruited into the study at Namakkal Government Hospital. They were counseled and tested after obtaining informed consent. Participation in the study was voluntary and informed consent was obtained either by signature or thumb impression. Assessment on Knowledge, Attitude, Demographics and empowerment were analysed using standardized questionnaire. Confidentiality was maintained. The study involved the University, PMTCT project and the Hospital staff. Statistical analysis was done using SPSS software.

**Results:** 87 % of antenatal women were out patients. The age of these women ranged from 15 to 40 yrs. 36.9%, 40.1% & 23 % were 1st, 2nd and multi gravida respectively. 63 % were illiterate & 77.4 % were homemakers. 98.9 % were married. 71.2 % & 83.5% of these women knew about HIV & AIDS respectively. 69.7 % were aware of HIV transmission. 58.2 % had the information how it is not transmitted. 66.1 % had knowledge on MTCT while 51.2 % knew about PMTCT prophylaxis. 70% were unaware of condom usage. 96.4% did not have high risk behavior. 69.1% had regular menstrual history. 54.1 % had no abortions. 6.6% and 33.1% had one and two abortions. Regarding breast feeding 34.8% did not breast feed whereas 2.4% (3 months) 5.9% (6 months) 4.3% (9 months) 16.5% (up to 1 year) 26.1(till 2 years) 2.5% (till 3 years) breast fed their infants. 2.19 % (36) of women were HIV positive and 97.8 % tested negative. 90% of the spouses did not get tested. 98% faced gender inequalities. 80% were unaware of their rights as women. 80 % felt that...
women need empowerment in the society and household.

Conclusions: The knowledge and attitude of HIV/AIDS is high among the antenatal women in rural areas. The negative women were counselled to remain negative. The spouses were motivated to go in for couple counselling and get tested for HIV. The PMTCT program is a success in rural hospital in South India. Even though the knowledge and attitude is high the empowerment of women is low. The imbalance in power between women and men in gender relations curtails women's sexual autonomy thereby increasing their risk and vulnerability in the HIV/AIDS pandemic. In HIV positive women the most violent forms of stigma and discrimination can be seen. It is tragic to the women who play a key role in ensuring economic and food security for their families. Gender-related barriers prevent women from accessing HIV prevention, treatment and care facilities.

No conflict of interest

Abstract_32

Prevention of HIV transmission in women and girls

Communicating microbicides with women in mind: developing materials that position microbicides for women in Kenya

E. Tolley1, E. Ryan2, A. Pack3, E. Bockh4, C. Mackenzie5, S. Sidibe6, G. Githuka7

1FHI 360, Social and Behavioral Health Sciences, Durham NC, USA; 2FHI 360, Social Marketing & Communication, Washington D.C., USA; 3FHI 360, Social & Behavioral Health Sciences, Durham NC, USA; 4FHI 360, Global Health Population & Nutrition, Washington D.C., USA; 5FHI 360, Kenya Country Office, Nairobi, Kenya; 6Centers for Disease Control & Prevention, HIV Prevention Branch - Youth Prevention, Atlanta, USA; 7National AIDS & STD Control Programme (NASCOP), Most at Risk Populations, Nairobi, Kenya

Background: The field of HIV prevention has made important strides forward over the last several years. Nevertheless, continuing high rates of HIV, especially among young African women, despite widespread availability of condoms, suggest the need to carefully consider how to position new products so that women can use them. Existing research on acceptability and use of microbicides and other SRH products suggests that women’s social and sexual contexts – for example, whether they are involved in sex work, or are adolescents, women in stable relationships and women in sero-discordant couples, shape their willingness and ability to use technologies. We conducted a three-phase project in Kenya, in collaboration with local policy makers, program implementers and advocacy groups to develop and test audience-specific messages and materials that could be used to generate demand for and appropriate use of microbicides, should such products become available in the future.

Methods: In this paper, we present findings from our phase 1 literature review and policy consultation related to potential priority audiences and then discuss how these findings influenced the development of messages and materials in phase 2. Specifically, we examine similarities and differences in barriers to HIV prevention for different profiles of at-risk women in Kenya, including female sex workers (FSWs), adolescents, women in stable relationships and women in sero-discordant couples.

Results: In Kenya, incident HIV infections are highest among those in stable partnerships. However, women in such relationships find condom use challenging, because they connotate a lack of trust. Such women may be married or cohabitating, adolescents or FSWs with boyfriends or husbands. Microbicide introduction must avoid stigmatizing gel use within longer-term relationships, while promoting the benefit of increased intimacy and protection. Women in other contexts are often able to negotiate condom use, though face challenges with consistent use. They include FSWs who use condoms with clients, some adolescents in the initial stages of a sexual relationship, and HIV...
sero-discordant couples who may or may not wish to conceive a child. Microbicide introduction must avoid promoting the substitution of microbicides for more effective condom use in such contexts.

Conclusions: Microbicide introduction strategies face several challenges. They must position microbicide use as possible, even desirable, within longer-term relationships, while reinforcing the idea of gel as a ‘back-up’ or added protection for those already using condoms in more casual contexts. Accomplishing these multiple goals requires careful message development and testing prior to introduction of new products. Working with a Kenyan design firm, this project has developed and pre-tested a suite of materials for mass media (posters, TV and radio spots) and for interpersonal channels (provider and community flip charts). Two sets of mass media materials position microbicides as 1) a new HIV prevention method, or 2) a new product that promotes intimacy while providing HIV protection. More content-rich interpersonal materials can be adapted to a range of contexts. These materials will be further assessed during phase 3 (November 2013-January 2014) to determine how message framing affects interest in microbicide use, stigmatizing attitudes, and condom use.

No conflict of interest

Abstract_33

Prevention of HIV transmission in women and girls

The development of the green tea catechin epigallocatechin gallate as an HIV-1 microbicide

M. O’Byrne, E. Siwak, W. Shearer, C. Nance

1Baylor College of Medicine and Texas Children’s Hospital, Pediatrics, Houston, USA; 2Baylor College of Medicine, Virology, Houston, USA

Introduction: The majority of new cases of HIV-1 infection are the result of heterosexual transmission and currently half of all individuals infected with HIV-1 are women. Since many new infections will occur in low income countries among female populations that have limited sexual autonomy, the availability of an effective method for women to protect against HIV-1 infection is critical. Topical microbicides, designed to be applied to the vaginal mucosal tissue to prevent HIV-1 infection, are potential preventive methods. One class of agents is the HIV-1 entry inhibitors. Our laboratory previously demonstrated that the green tea catechin, epigallocatechin gallate (EGCG), inhibits attachment of gp120 to the CD4 receptor on T cells and prevents HIV-1 entry. We present evidence to show EGCG to be safe and effective as a potential HIV-1 microbicide.

Methods: Cervicovaginal cultures (explants) derived from normal human ectocervical cells in simulated vaginal fluid (SVF) and simulated seminal fluid (SSF) were used to simulate an in vivo mucosal environment. Cultures were exposed to EGCG (0 - 100uM) or control catechin and subjected to pH transition with pH adjusted RPMI or simulated fluids with SVF at pH 4.2 and SSF at pH 7.7. Simulated fluids were tested separately or combined 1:4 (SVF: SSF) in the presence or absence of EGCG. Viability was measured using a MTT assay. Cultures were exposed to HIV-1 BaL and HIV-1 89.6, and infectivity determined by an HIV-1 p24 EIA kit. Human CD4+ T cells isolated from PBMCs from HIV-1 uninfected donors were cultured in RPMI or simulated fluids. Also, to mimic the in vivo mucosal environment, simulated fluids were combined in a 1:4 ratio (SVF: SSF). CD4+T cells were activated with 1mg/ml phytohemagglutinin (PHA) prior to EGCG exposure (50uM). Statistical comparisons were made with Student’s t distribution.

Results: In explants, no cytotoxicity was observed upon exposure to EGCG (0 - 100uM) at 1 and 24 hours for all EGCG concentrations tested (viability ≥ 93%; p>0.05). No cytotoxicity was observed at pH transition from pH 4.2 (SVF) to pH 7.0 (SVF: SSF) in the presence of 50 uM EGCG (viability ≥98%; p>0.05). EGCG (50uM) did decrease viability in explants exposed to pH adjusted RPMI (pH 4.2) (24%; p=0.04). HIV-1 p24 levels were detected in the basal culture
supernatants from both HIV-1 viral strains (HIV-1<br>\( \text{BaL} = 87 \text{ pg/ml}; \text{HIV-1} \_89.6 = 19 \text{ pg/ml} \)). CD4+ T cells showed no significant decrease in viability within fluid groups in the presence of 50uM EGCG (3%; \( p>0.05 \)). EGCG (50uM) down-regulated CCR5 (CD195) expression (53%; \( p<0.05 \)).

**Conclusion:** We have shown that EGCG is not cytotoxic on human cervicovaginal cultures at concentrations up to 100uM and in an environment of pH transition using SVF and SSF. We have also shown that 50uM EGCG is not cytotoxic in human PBMCs. Thus as a potential HIV-1 microbicide, EGCG would be a safe and well tolerated component.

**No conflict of interest**

**Abstract_34**

**Prevention of HIV transmission in women and girls**

**Understanding the relationship between HIV status and Aboriginal women’s life stressors**

A. Benoit\(^1\), D. O’Brien Teengs\(^2\), K. Beaver\(^3\), J. Cotnam\(^4\), J. Raboud\(^5\), A. Zoccole\(^6\), L. Balfour\(^7\), S. Greene\(^8\), R. Masching\(^9\), M. Loutfy\(^10\)

1Women's College Research Institute, Women's College Hospital University of Toronto, Toronto ON, Canada ;
2Women & HIV Research Program, Women's College Research Institute, Whitby ON, Canada ;
Women’s College Research Institute, Whitby ON, Canada ;
Women's & HIV Research Program, Women's College Research Institute, Toronto ON, Canada ;
Women’s & HIV Research Program, Women's College Research Institute, Thunder Bay ON, Canada ;
University of Toronto Dalla Lana School of Public Health, Biostatistic, Toronto ON, Canada ;
2-Spirited People of the 1st Nations, Support and care services, Toronto ON, Canada ;
Ottawa Hospital University of Ottawa, Psychology, Ottawa ON, Canada ;
McMaster University, School of Social Work, Hamilton ON, Canada ;
Canadian Aboriginal AIDS Network, Research and policy, Halifax NS, Canada ;
Women's College Hospital University of Toronto, Women's College Research Institute, Toronto ON, Canada

**Background:** Chronic stress has a detrimental impact on physical and psychological health and wellbeing and is prevalent in the lives of some Aboriginal women living with and affected by HIV. Chronic health concerns such as HIV and mental health for Aboriginal women requires innovative continuity of care solutions to engage women in HIV prevention and their physical and psychological wellbeing and management. Furthermore, the Indigenous perspective of health which includes balance and wholism has been shown to be important in health care and must be incorporated. The objectives of this study are: 1) to characterize stressors, 2) to measure stress levels and 3) to determine whether stress management approaches have been adopted by Aboriginal women living with and affected by HIV.

**Materials & Methods:** The quantitative findings of this study are from a cross-sectional mixed-methods study with 84 participants. Participants meeting the inclusion criteria self-identified as: 1) a woman, 2) Aboriginal, and were 3) greater or equal to 18 years old. Both HIV-positive and HIV-negative women including women at risk were recruited into the study. Quantitative data was collected using a socio-demographic questionnaire and a variety of questionnaires measuring stress, depression, post-traumatic stress disorder (PTSD), well-being and social support. Baseline demographic and psychological health characteristics were presented as frequencies and proportions for categorical variables and medians and interquartile ranges (IQR) for continuous variables.

**Results:** The median age for 58 HIV-negative women was 37 years old [IQR: 28-46] and 40 years old [IQR: 36-48] for 24 women living with HIV. Other cohort characteristics were that for both HIV-negative and -positive Aboriginal women, 78% had an annual income of less than $20,000 and approximately 67% reported being single. Among women with children, 73% of HIV-negative women had children under 18 years old in contrast to 33% of women living with HIV, and 29% and 19%, respectively, reported living with their children. Co-morbidities excluding HIV were reported by 80% of HIV-negative women and 84% of HIV-positive women. Severe depressive symptoms were reported by 60% of HIV-negative women and 70% of HIV-positive...
women. Among HIV-negative women, very high perceived stress levels were reported by 62% in contrast to 42% of HIV-positive women. Severe levels of PTSD were reported by 86% of HIV-negative women and by 83% of HIV-positive study participants. Importantly, 70% of HIV-negative women and 80% of HIV-positive women made lifestyle changes and were practicing approaches to manage stress.

Conclusions: High stress, depression and PTSD levels were measured for Aboriginal women. Culture was identified as important in reducing stress levels, in their healing journey in general and for supporting continuity of care. Future interventions for improving overall health and wellbeing must include culture and an HIV prevention component as both HIV-negative and HIV-positive Aboriginal experience many similar life stressors. Next steps consist of identifying covariates of stress, depression and wellbeing through regression analysis. Additional work will include analysis of the qualitative data on life stressors and stress management which will strengthen and add a different perspective to life stressors experienced by Aboriginal women.

No conflict of interest

Abstract_35

Prevention of HIV transmission in women and girls

Pre-conception considerations for a large cohort study of HIV-positive individuals desiring a child in Ontario, Canada: a feasibility pilot study

V.L. Kennedy1, M.R. Loutfy1, D. Regier2, on behalf of the Ontario HIV Preconception Cohort Study Team

1Women's College Research Institute, Women and HIV Research Program, Toronto ON, Canada; 2Canadian Centre for Applied Research in Cancer Control, Department of Health Economics, Vancouver, Canada

Introduction: Due to advances in treatment for and prevention of vertical and horizontal HIV-transmission, individuals and couples affected by HIV are increasingly considering pregnancy. As such, the demand for conception counselling in the context of HIV has increased. A broader understanding of the factors that contribute to the decision-making process related to conception, current gaps in services related to conception, and clinical issues and outcomes related to conception is required. However, no large scale cohort of HIV-affected individuals or couples has been developed.

Materials and Methods: HIV-positive individuals (with or without their partners) who were considering pregnancy were recruited from 15 sites across Ontario from February 2012-April 2013. Participants attended two visits and completed five surveys on sociodemographics, pre-conception considerations and medical history. Feasibility of recruitment and appropriateness of study instruments for a larger study were also determined. Survey data were entered twice and verified prior to analysis. Statistical analyses included summary statistics of demographic and outcome variables using frequencies and proportions for categorical variables, and median and interquartile range (IQR) for continuous variables. Univariate analyses were carried out for awareness of and access to fertility services.

Results: Fifty-nine HIV-positive primary participants and nineteen partner participants were recruited. Fifty-two (68%) of the HIV-positive primary participants were female with a median age of 36 (IQR 33-40) for all participants. The majority reported being in a relationship/married (84%), had an annual household income of < $40,000 CAN (52%), lived in Toronto (58%) and expected to parent two or more children in the future (66%). The current analysis focused on the results of the preconception considerations survey. The outcomes of this analysis suggest that awareness of and access to fertility services in the context of HIV are improving. 52% rated the availability of supports for healthy conception for HIV-positive people moderate-high and 67% thought the availability of information was moderate-high. However, 57% and 52% of participants agreed that there is a lack of expertise in the preconception and pregnancy
care of HIV-positive people in Ontario, respectively. We were able to recruit successfully from 15 of 21 sites as they were able to get ethics approval, start recruiting and enroll 1 or more participant in < 12 months.

**Conclusions:** This pilot study supports the feasibility of a large HIV preconception cohort study. This study seemed particularly appealing to HIV-positive women in relationships. Increasing participants deemed the availability of supports for healthy conception for HIV-positive people as moderate-high and 67% thought the availability of information was moderate-high. A full-scale cohort of more than 250 participants is intended to expand the findings of this pilot study.

**No conflict of interest**

### Abstract_36

**Treatment program for HIV infected women (design and implementation)**

**Implementing Prevention of Mother to Child Transmission of HIV in a resource limited setting; A case of Jinja District, Uganda**

E. Asiimwe¹, J.K.B. Matovu², N. Dyogo³

¹Makerere University College of Health Sciences, School of Public Health CDC Fellowship, Kampala, Uganda; ²Makerere University College of Health Sciences, School of Public Health, Kampala, Uganda; ³Jinja District Local Government, Directorate of Health, Jinja, Uganda

**Background:** Provision of Antiretroviral Therapy (ART) to pregnant mothers has proved to significantly reduce transmission of HIV from HIV positive mothers to their unborn children. Uganda had 96,700 HIV-positive pregnant women in 2011, majority of whom might have transmitted HIV to their babies in absence of HIV prevention interventions. Prevention of Mother to Child Transmission (PMTCT) of HIV programs were initiated in Uganda in the year 2000, since then policy guidelines have evolved. Currently the Ministry of Health's scale-up plan for PMTCT (2010-2015) emphasizes that all pregnant women be offered HIV Counseling and Testing (HCT); those found HIV positive be provided with ART for life. Health services in a district are provided from Health Centre II (HC), HCIII, HC IV and hospital. This paper discusses implementation of the PMTCT program in Jinja District, Eastern Uganda in relation to policy guidelines.

**Methods:** We reviewed national PMTCT policies to establish guidance for implementation of PMTCT in a district health system. We also reviewed the Jinja district Health Management Information Systems annual reports from 2008/09 to 2011/12 and extracted data on ANC visits, deliveries in health facilities, HIV testing for pregnant mothers, provision of ART for prophylaxis and treatment for HIV positive pregnant mothers and babies. Extracted data were entered into access database and analyzed for proportions and trends by Health Centre level using Microsoft excel.

**Results:** PMTCT policies recommend that ANC, deliveries and provision of ART to HIV positive mothers and their babies be conducted from HCIIIs, HCIVs, and district hospitals while HClIs should mainly conduct counseling parents for HIV testing and infants' feeding. Analysis of district PMTCT data revealed that ANC attendance for pregnant women was highest at HCII with 49%, lowest at HCIII with 21% and HCIV with 30%. Deliveries in health centers; HCII delivered 52%, HCIII & IV 19% and 29% respectively. Trends analysis for the period 2008/9 – 20011/12 showed that capacity to test for HIV increased; HCII from 0% to 58% and HCIV from 96% to 100% whereas HCIII declined from 90% to 86%. Provision of ART for prophylaxis increased in HCII from 0% to 72% and HCIV from 98% to 100%, HCIII registered a decline from 91% to 80%. Provision of ART for treatment registered slow progress at all levels; HCII improved from 0% in 2008/9 to 10% in 2011/12, HCIII from 4% to 6% and HCIV from 17% to 28%. Babies born to HIV+ mothers provided ART at birth; HCII increased from 40%
in 2008/9 to 58% 2011/12, HCIV from 97% to 100% while HCIII declined from 91% to 84%.

Conclusions: Contrary to policy recommends on ANC and delivery, overwhelming numbers; about half of the Districts pregnant women turn up and are provided service at HCII. Yet at HCII, HIV testing and provision of ART services is lowest suggesting a big missed opportunity for universal comprehensive access to PMTCT. Therefore there is need to devise means to ensure access of PMTCT services for the pregnant women in resource limited districts who deliver at HCII.

No conflict of interest

Abstract_38

Treatment program for HIV infected women (design and implementation)

Women and HIV across the continuum of care

D. Averitt1, J. Auerbach2, J. Kates3, W.R.I. Women’s Research Initiative on HIV/AIDS1

1Women’s Research Initiative on HIV/AIDS, Brooklyn, USA; 2University of California San Francisco, Center for AIDS Prevention Studies, San Francisco, USA; 3Henry J. Kaiser Family Foundation, Global Health and HIV Policy, Washington DC, USA

Background: Great strides have been made in HIV care in the United States, but despite these efforts, only a quarter of women living with HIV have undetectable virus. The Women’s Research Initiative on HIV/AIDS (WRI) used the continuum of care as a framework to identify challenges and opportunities at each point across the HIV disease spectrum (testing, linkage to care, engagement in care, adherence), as well as recommendations to improve outcomes.

Materials and Methods: The WRI was established to elevate, enhance and expedite HIV treatment and prevention research on women and girls and identify gaps in clinical care and research. Its membership includes national HIV/AIDS thought leaders representing clinical care, research, academia, advocacy, the government, the pharmaceutical industry and women living with HIV. The WRI reviewed original data, knowledge and experience on the barriers and opportunities to treatment success for HIV-positive women. The group utilized a transdisciplinary lens to holistically examine the multitude of factors affecting women getting tested for HIV, being linked into care, being engaged in their care, adhering to treatment and achieving optimal health and well-being outcomes.

Results: With the recognition that the continuum of care is a dynamic process, rather than a linear one, the WRI identified a number of recommendations to impact and improve women’s outcomes at each point across the HIV disease spectrum, including: 1. Tailor provider trainings required by the Affordable Care Act (ACA) to address stigma, the need for routine testing, shared decision-making/patient-centered care and collaborative problem solving; 2. Ensure that providers at community health centers are well-informed about issues related to women and HIV; 3. Leverage women’s health centers as expert resource in community outreach and service provision; 4. Leverage peer educators and/or system navigators to assist individuals newly diagnosed with HIV in getting linked to care, engaging women in their long-term care and providing adherence support; 5. Ensure provision of culturally competent care and high-quality case management; 6. Leverage knowledge gained from successful models of care, both disease-specific (diabetes and obstetrics) and institution-specific (the VA system, Kaiser Permanente); 7. Build upon evaluative requirements of ACA to ensure providers are addressing HIV among female patients (testing, treatment, adherence, etc.); 8. Develop novel evaluation metrics around non-adherence; 9. Conduct research into effective adherence interventions; 10. Establish better understanding of pill taking over the long term; and 11. Develop improved patient support and patient empowerment tools.

Conclusions: The continuum of care is an important tool, allowing for the identification of vital intervention points along the treatment
spectrum. The WRI identified a number of opportunities across the continuum of care to improve outcomes among women. In order to be successful, these efforts will require a cohesive, transdisciplinary and inter-sectoral response encompassing efforts across a diversity of fields including: basic science, patient care, behavioral sciences, policy, advocacy and education.

No conflict of interest

Abstract_39

Treatment program for HIV infected women (design and implementation)

Bridging the gap: an interdisciplinary outreach collaborative approach to HIV care at Alouette Correctional Centre for women

N. Pick¹, K. Friesen¹, C. Quaia¹, M. Kestler², S. Krell², C. Moody¹, L. Mervyn¹, D. Feder¹, B. Pickering¹, M. Murray¹

¹BC Women's Health Centre, Oak Tree Clinic, Vancouver BC, Canada

Introduction: In Canadian prisons, HIV seroprevalence levels are up to 10 times higher than in the general population (1.0 to 8.8%). HIV prevalence among women prisoners generally exceeds that of male prisoners. In 2011, 11% of the Canadian prison population were women, and 41% of sentenced females were aboriginal. Interruptions in antiretroviral therapy (ART) occur commonly during and post incarceration. However the period of incarceration also presents healthcare providers with an opportunity to offer HIV treatment and harm reduction strategies. Alouette Correctional Centre for Women (ACCW) in BC holds all three levels of security (324 inmate capacity) with a median length of stay of six months. Recently, the number of identified HIV positive women has increased, potentially due to point of care testing and the amalgamation of correctional facilities.

Historically, ACCW has referred HIV positive women (one at a time) to the Oak Tree Clinic, the provincial HIV referral centre for women and children with HIV, located at the BC Women's Hospital in Vancouver, requiring a huge allocation of recourse to facilitate one visit in HIV clinic.

Methods: In September 2008, OTC initiated a monthly outreach program comprised of an interdisciplinary team (Physician, Nurse, Pharmacist, and Outreach Social Worker) that provide specialized HIV care on-site and complements the primary health care provided by ACCW. This outreach program provided a unique opportunity for OTC to educate the various health care providers at ACCW on HIV care and treatment, and engage women in HIV care while in ACCW.

Results: The outreach program has improved access to HIV care for women through ACCW staff education about HIV treatment, HAART and stigma/confidentiality. As a result, point of care testing is now available and encouraged for all women upon admission to ACCW. Since 2008, 50 HIV positive women were identified and all have received HIV care on-site for a total of 94 visits. Women are linked to an HIV care provider upon release, and given a month supply of HAART, instead of the previous 3-7 days policy present prior to our outreach initiative. When relevant, HCV co infection was addressed as well.

The next phase of this outreach program will focus on support for women after release, including innovative approaches, such as using texting with cell phones, to ensure improved engagement in longitudinal HIV care.

Conclusion: The OTC outreach initiative has improved HIV care for women while in ACCW. Although advanced, challenges remain to maintain the continuity of therapy upon release.

No conflict of interest
Abstract_40

The role of contraception in transmission and progression in HIV infected women

Family planning use and associated factors among people living with HIV, who are on follow up care in health centers of Addis Ababa, Ethiopia

T. Mekonnen1, B. Mengesha2

1Ethiopian Orthodox Church- Development And Inter Church Aid Commission, Development, Addis Ababa, Ethiopia;
2World Wide Orphan- AIDS Health care Foundation(WWO-AHF), Medical, Addis Ababa, Ethiopia

Introduction: Ethiopia belongs to the heavily affected countries of Sub-Saharan Africa by HIV/AIDS. Besides the dominant heterosexual transmission, vertical virus transmission from mother to child accounts for more than 90% of pediatric AIDS.

Strengthening family planning (FP) programs and providing reproductive health counseling to HIV-infected peoples are best approaches of; preventing unintended pregnancies among People Living with HIV (PLHIV), and reducing the risk of new HIV infections among infants. Thus information regarding FP use and associated factors among PLHIV will be important in understanding the different factors affecting the utilization of FP services.

Material and Methods: An institution based cross-sectional study design was employed from October 2010 to May 2011 in selected health centers of Addis Ababa city administration. The study subjects were selected PLHIV who are on follow up care in Anti Retro viral treatment (ART) units of the selected health centres. A multi stage sampling procedure was used to select study participants. There are 10 sub-cities in AddisAbaba and one health centre (HC) was selected randomly from each sub-city. 628 study subjects living with HIV were selected using systematic random sampling technique from ART unit clients of these 10 HCs. Data were collected using pre tested, interviewer administered questionnaire, and it was double entered and cleaned using EPI info version 3.5.1, and analyzed using SPSS Version 16.0 computer software.

Results: Of the respondents, 68.9% and 31.1% were females and males respectively with age range of 19-53 years. 266(43.5%, with 95% CI of 39.6% and 47.5%) of the participants were found to be using at least one method of FP, of which 238(89.4%) were using condom and 68(25.5%) were using injectables. Abstinence from sexual intercourse 197(54.2%) and desire for child 94(27.2%) were the major reasons mentioned for not using FP. Only 295(48.3%) of the respondents had discussion about FP and child bearing with their service providers.

The study also revealed that those who had high school and above level of education were two times more likely to use FP than those who had no formal education. [AOR: 2.65, 95%CI: 1.42, 4.95]. Compared to those study subjects who had no children, those who had one and above found to have a twofold increase to use FP. Respondents with above one year duration since HIV diagnosis were three times more likely to use FP compared to those with less than six month duration [AOR: 3.27, 95%CI: 1.53, 6.99]. Those who are singles and non married partners also found to have a two and fourfold increase in using FP compared to married ones respectively. [AOR: 2.75, 95%CI: 1.29, 5.85 and AOR: 4.23, 95%CI: 1.76, 10.14 respectively].

Conclusions: Above half of the respondents were not using FP during the study time, of which nearly half are sexually active. And most of the non users had no discussion about FP and child bearing with their service providers. So, adequate counseling and discussion regarding issues like FP, child bearing and sexuality with fully integrated FP service in the ART units may help in maximizing the uptake of FP methods by PLHIV.

No conflict of interest
Abstract_41

The role of contraception in transmission and progression in HIV infected women

Pregnancy and Contraception: The Perspective of HIV-Positive and Negative Women

C. Oraka¹, S.C. Ani²

¹Nnamdi Azikiwe University Teaching Hospital, Medicine & Surgery, Nnewi, Nigeria

Objective: To understand pregnancy intentions and contraception knowledge and use among HIV-positive and negative women in the prevention of mother-to-child transmission (PMTCT) program in the teaching hospital.

Design: A cross-sectional survey of 236 HIV-positive and 162 HIV-negative postpartum women interviewed within 18 months of their expected delivery date in a public-sector health facility providing PMTCT services.

Methods: Bi-variant analyses explored fertility intentions, and family planning knowledge and use by HIV status. Multivariate analysis identified socio-demographic and service delivery-related predictors of reporting a desire for additional children and modern family planning use.

Results: HIV-positive women were less likely to report wanting additional children than HIV-negative women (8 vs. 49%, P < 0.001), and although a majority of women reported discussing family planning with a health worker during their last pregnancy (HIV-positive 79% vs. HIV-negative 69%, P = 0.0), modern family planning use remained low in both groups (HIV-positive 43% vs. HIV-negative 12%, P < 0.001). Condoms were the most commonly used method among HIV positive women (31%), whereas withdrawal was most frequently reported among HIV-negative women (19%). In multivariate analysis, HIV-negative women were 16 times more likely to report wanting additional children and nearly 85% less likely to use modern family planning. Women who reported making two or less antenatal care visits were 77% less likely to use modern family planning.

Conclusion: Our results highlight success in provision of family planning counseling in PMTCT services. As family planning use was low among HIV-positive and negative women, further efforts are needed to improve uptake of modern methods, including dual protection, in the PMTCT settings.

No conflict of interest

Abstract_42

The role of contraception in transmission and progression in HIV infected women

Knowledge and barriers to family planning services among HIV infected women in Tamilnadu, India

M. Periasamy¹, K. Periasamy², B. Charles³

¹AIDS PREVENTION AND CONTROL PROJECT, CARE SUPPORT AND TREATMENT, Chennai, India
²Positive womens network, Advocacy, Chennai, India
³AIDS PREVENTION AND CONTROL PROJECT, Programs, Chennai, India

Introduction: A woman’s state of physical, mental and social well being is inextricably linked with her sexual and reproductive health. This is even more crucial in case of women living with HIV as the infection potentially affects all the dimensions of women’s sexual and reproductive health. A quantitative survey was conducted in high prevalence districts of Tamilnadu in South India, with active collaboration of a non-Governmental body – Positive Women’s Network among women living with HIV/AIDS. The research was technically supported by AIDS Prevention and Control (APAC) project funded by USAID India.

Materials & Methods: This was a cross sectional study conducted among 986 HIV infected women across 13 districts in Tamil
Nadu with an objective to assess the magnitude of knowledge, attitude and behaviour of HIV infected women on sexual & Reproductive health (SRH) needs as well as to identify the challenges faced by women in health care delivery systems while accessing SRH services. Stratified sampling technique was used to arrive at the sample size. Married women above 18 years were selected for the study. A questionnaire was administered through trained HIV infected women volunteers. Information pertaining to Socio-demographic details, Antenatal and Postnatal care Services , Mother to child transmission, Immunization, Contraception and family planning, Menstrual health and hygiene, Sexual health rights and barriers to access to health care were collected.

**Results:** 69.3 % (n=683) of the study participants were literate. Knowledge on contraception: 47.3% (n=466) of the study participants did not know about any method of contraception which could avoid unwanted pregnancy. 49.5 % (n=488) of the participants have not used condom for contraception. Moreover these women felt that condoms are only used for prevention of HIV & STI. Decision making for family planning: 86.8% (n=856) of the participants agreed that there should be spacing of minimum of three years between children. About 41.1% (n=405) of the participants reported that they did not have the freedom to decide on spacing of child birth. Only 20.89% (n=206) had taken decision on this issue independently.

**Conclusion:** The study clearly indicated that there is lack in knowledge among HIV infected women about dual protection of condoms. In continuation women don’t have the freedom to decide on the spacing of children. Women living with HIV should be assisted in choosing a contraceptive method that is most suited to their situation and needs, including disease stage, treatment situation, lifestyle and personal desires. Each woman is best placed to interpret the risks and benefits of available methods and she must make the final selection of a contraceptive method. Integrated comprehensive information, training and counseling needs should be fulfilled through effective communication mechanism to WLHA & their spouses.

*No conflict of interest*

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**Abstract 43**

The role of contraception in transmission and progression in HIV infected women

Modern contraceptive utilization and associated factors among female ART attendees in health facilities of Gimbie town, West Ethiopia

G. Girma1, A. Polisi2, A. Polisi2, E. Gebrehanna3

1Haramaya University, Public health, Harar, Ethiopia; 2Filtu Hospital, HIV care and support, Filtu, Ethiopia; 3Addis Continental Institute of Public Health, Reproductive health, Addis Ababa, Ethiopia

**Introduction:** According to the recent Ethiopian DHS (Demographic and Health Survey) contraceptive prevalence remains low (29%). More than 90% of pediatric AIDS results from the transmission of the virus through HIV positive pregnant mothers to their children. Little has been known about the prevalence and factors associated with contraceptive use among HIV positive women under antiretroviral treatment (ART). Hence the objective of this study was to assess modern contraceptive use and associated factors among females on ART in health facilities of Gimbie town, west Ethiopia.

**Methods:** A facility based cross-sectional study was conducted. Systematic random sampling method was used to select study subjects. Data was collected using a structured questionnaire. Data was entered using Epi info and analyzed by SPSS software. Binary logistic regression and multivariate analysis were employed to see association between different variables.

**Results:** Three hundred ninety five women on ART have participated in the study. More than half, 224 (56.7%) of the respondents were using modern contraceptive where 67(30%) of the contraceptive users use dual methods. On multivariate analysis having information on modern contraception is positively associated with modern contraceptive use with (AOR=6.324, 95% CI (1.671, 24.067)).
Respondents who have family size <=4 have 50% less contraceptive use than those who have family size >4 (AOR=0.507, 95% CI (0.267, 0.963).

**Conclusion:** Although contraceptive use among HIV positive women is better than the general population use of dual methods, long acting and permanent method of contraceptives were found to be low.

No conflict of interest

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**Abstract 45**

**Epidemiology of HIV in women and girl**

**Barriers to postpartum HIV-care among low-income women — a mixed-methods study**

T. Bell¹, M. Buchberg², F. Fletcher³, D. Vidrine⁴, X. Yu⁵, J. Levison⁶, M. Peters⁷, R. Hardwicke²

¹University of Texas Health Science Center, Internal Medicine, Houston, USA; ²University of Illinois at Chicago School of Public Health, Community Health Sciences, Chicago, USA; ³MD Anderson Cancer Center, Behavioral Science, Houston, USA; ⁴Baylor College of Medicine, Center for AIDS Research, Houston, USA; ⁵Baylor College of Medicine, Obstetrics and Gynecology, Houston, USA; ⁶Harris Health System, Thomas Street Health Center, Houston, USA

**Background:** Postpartum adherence to HIV care among low-income women is sub-optimal, particularly in the southern United States. HIV-infected women are more likely to adhere to care during pregnancy as compared to postpartum. Thus, identifying the barriers and challenges these HIV-infected women face is needed to design interventions that will improve postpartum adherence rates.

**Materials & Methods:** Thirty five HIV-infected, pregnant women were recruited from two county clinics in Houston, Texas that provide HIV-specific obstetric care. Patients entered the study in the second or third trimester of pregnancy and completed self-report surveys to assess demographic, psychosocial and behavioral characteristics. Participants were asked to participate in surveys and semi-structured interviews designed to qualitatively explore barriers to care postpartum. Electronic medical records (EMRs) were used to classify participants as adherent or non-adherent to postpartum care with their obstetrician (OB) and primary care provider (PCP). Participants were adherent to OB care if they attended one appointment within three months of delivery and adherent to PCP care if they attended a PCP appointment within six months of delivery. Chi-square tests and two-sample t-tests were used to identify variables associated with adherence to care. Qualitative interviews were evaluated for re-emergent themes using NVivo software.

**Results:** The mean age (SD) of participants was 28.2 (6.2) years. The sample was predominantly African American (77%) and economically disadvantaged with 86% reporting use of public assistance. Mean (SD) CD4 cell count and HIV viral load at baseline were 498 (265) cells/µL and 18,930 (48,585) copies/mL respectively. Postpartum OB appointments were attended by 25 (71%) of participants, while only 20 (57%) attended a PCP appointment. A higher number of prior pregnancies (p=0.03) and a lower CD4 at delivery (p=0.04) were significantly associated with poor OB follow-up. High viral load at baseline was significantly associated with poor PCP follow-up (p=0.03). Depression (p=0.05) and low interpersonal social support (p=0.05) were marginally associated with poor OB adherence. High internalized stigma was marginally associated with poor PCP follow-up (p=0.07).

Individual, interpersonal and institutional level factors were identified as barriers to care among the 22 women that participated in the structured interviews, postpartum. Individual level factors included knowledge about the benefits of adherence to care, competing responsibilities, and feelings of being labeled at HIV-specific facilities. Interpersonal level factors included relationships with healthcare providers and lack of support networks due to fear of disclosure. Institutional level factors included transportation access and experiences of institutionalized stigma.
Conclusions: Interventions targeting postpartum adherence need to focus on both HIV disease education and psychosocial support. This population may not experience health consequences of HIV disease with less immunosuppression. Stigma remains a problem on multiple levels in this minority indigent population in the South. Potential future interventions that will beneficial for this population include support groups, motivational interviewing, and other efforts to lessen stigma and depression and increase knowledge about HIV disease management.

No conflict of interest

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Epidemiology of HIV in women and girl

Female gender is a risk factor for late antiretroviral therapy initiation in North Rhine Westphalia, Germany: Data from the RESINA study group

U.E.H. Haars1, F. Huettig1, B.E.O. Jensen1, R. Kaiser2, E. Schuelter2, P.E. Verde3, D. Haeussinger1

1Heinrich-Heine-University, Department of Gastroenterology Hepatology and Infectious Diseases, Dusseldorf, Germany; 2University of Cologne, Institute of Virology, Cologne, Germany; 3Heinrich-Heine-University, Coordination Centre of Clinical Trials, Dusseldorf, Germany

Introduction: Late presentation for HIV Diagnosis and ART initiation is associated with increased early mortality rates, clinical progression and ongoing transmission of HIV. The term Late Presentation with many different definitions is commonly used to describe either late diagnosis or late Initiation of ART. Typical risk factors for late presentation have been described in most countries, including origin from countries with high HIV prevalence, older age, low socio-economic status and male heterosexuality.

Results: From 2001 to 2012, 2848 persons have been enrolled in the RESINA study cohort prior to ART Initiation; 2292 (80%) were male, 556 female (19%), 11 (1%) unspecified. CD4 Count before ART initiation was available in 376 (68%) of all female patients.

CD4 cell counts in women of African origin were nearly identical to those of Caucasian origin when initiating ART (44%, n=70, versus 41%, n=71, had CD4 Counts < 200/µl, p= 0.5776). 81% of the Caucasian participants were German, the remaining 19% were primarily of eastern European origin.

Asians presented with significantly lower CD4 Counts (82%, n=31, versus 44%/41% < 200/µl, p < 0.001) compared to African and Caucasian women, and 42% of them (n=16/31) had CD4 Cell counts < 50/µl.

Conclusions: As immigration from a high prevalence country poses a well-known risk factor for late diagnosis of HIV, the number late presenters for ART initiation of African origin was not unexpected. Caucasians however, mainly German women, had nearly identical CD4 cell counts before initiation of ART, reflecting the fact that late diagnosis and ART initiation of our female study participants wasn’t primarily dependent on ethnic group but on female gender.

The alarmingly high percentage of Asian women initiating ART considerably late with CD4 cell
counts below 50/µl, highlights a special need for
the development of strategies to address this
problem. These results emphasize the necessity
for the implementation of strategies to diagnose
and treat HIV positive women in Germany earlier,
independent of their ethnicity.

No conflict of interest

Abstract_47

Epidemiology of HIV in women and girl

Low levels of perinatal and postpartum depression in mothers living with HIV in Ontario, Canada: a prospective study

A. Carvalhal1, A. Ion2, S. Greene2, F. Smaill3, M. Yudin4, M. Loutfy5

1St. Michael's Hospital, Medical Psychiatry, Toronto Ontario, Canada; 2McMaster University, School of Social Work, Hamilton Ontario, Canada; 3McMaster University, Pathology & Molecular Medicine, Hamilton Ontario, Canada; 4St. Michael's Hospital, Obstetrics Gynecology & Reproductive Infectious Diseases, Toronto Ontario, Canada; 5Women's College Hospital, Women's College Research Institute, Toronto Ontario, Canada

Introduction: Women living with HIV are at increased risk for depression and other psychiatric disorders. In pregnancy and postpartum, HIV-positive women face particular stressors that are compounded by an HIV diagnosis. The HIV Mothering Study is a prospective, observational, mixed-methods research initiative that sought to explore the psychosocial needs and experiences of women living with HIV across Ontario in pregnancy and the first year of motherhood. The present study describes symptoms of depression and other psychosocial concerns in pregnancy and 3 months postpartum.

Methods: From March 2011 to December 2012, 77 pregnant women living with HIV in Ontario, Canada enrolled in the HIV Mothering Study at HIV and obstetrical care centers. Sociodemographic and clinical data were collected and participants completed the Edinburgh Postnatal Depression Scale (EPDS), the Berger HIV Stigma Scale and the Everyday Discrimination Scale (Racism) in their 3rd trimester and 3 months postpartum. Scores ≥12 on the EPDS are indicative of perinatal depressive illness. Sociodemographic and clinical data was summarized in aggregate format. Generalized estimating equation models were developed to assess change over time and correlates of depressive symptoms from pregnancy (n=71) to postpartum (n=62).

Results: HIV Mothering Study participants’ median age was 33 years (range 21 to 42). The majority of participants had immigrated to Canada (52% African-born) and relied on social assistance as their main source of income (78%). Many had been previously diagnosed with a mental illness including depression (33%), post-traumatic stress disorder (6%) or another psychiatric disorder (16%). Mean EPDS scores decreased from pregnancy (10.2, SD=6.0) to postpartum (8.8, SD=6.2); these scores were below the threshold for depressive illness and the decrease was not statistically significant. In 3rd trimester and 3 months postpartum, 45% and 24% of participants had EPDS scores ≥12, respectively. In pregnancy, greater perceived stress (z=6.1, p<0.001), greater perceived HIV stigma (z=4.2, p<0.001) and Children's Aid Society involvement (z=1.8, p=0.08) were important covariates for symptoms of depression. At 3 months postpartum, higher EPDS scores were associated with higher EPDS scores in pregnancy (z= 3.1, p=0.002) and higher parity (z=1.8, p=0.08).

Conclusions: Mothers living with HIV in Ontario exhibit a decrease in severity of depressive symptoms from pregnancy to postpartum. HIV stigma is a significant covariate of depressive symptoms in pregnancy; if women feel stigmatized they may experience barriers to accessing and receiving care in pregnancy. As depressive symptoms in pregnancy are an important predictor of depression postpartum, we must consider how individualized and coordinated care that responds to women’s HIV,
obstetrical and mental health needs can be effectively delivered to prevent isolation and exacerbation of psychiatric disorders.

No conflict of interest

Abstract_48

Aging and co-morbidity of the HIV infected women

High prevalence of HSV-2 in HIV seropositive women in Tamil Nadu, India.

S.M. Jacob1, G. Thatchinamoorthy1, K. Sivasangeetha1, D. Anitha1, S. Mary1, A. Ganesan1

1Tamilnadu Dr MGR Medical University, Department of Experimental Medicine, Chennai, India

Introduction: Viral infection with Herpes Simplex Virus (HSV) is one of the commonest opportunistic infection in HIV seropositive patients. Many studies have confirmed that genital herpes caused by HSV-2 has been associated with twofold to threefold increased risk of HIV acquisition. Limited published data exists on the prevalence of HSV-2 in HIV seropositive patients in India. It is known that acute or reactivated HSV-2 infection may stimulate HIV replication leading to the progression of HIV disease. This study was designed to determine the seroprevalence of HSV-2 in HIV positive patients.

Materials and Methods: This was a prospective, cross sectional study conducted for six months from July 2012 to January 2013. Blood was collected from HIV positive patients visiting Department of Experimental Medicine laboratory for various investigations. After obtaining written informed consent, HIV positive patients were enrolled into the study. Two ml of whole blood was collected under aseptic precautions and sera was separated and stored at -20°C until further testing. Demographics such as age and gender were recorded. Serology test was performed using HSV-2 IgG ELISA test kit from Calbiotech, USA. Statistical analysis of the data was done using Chi-Squared Test and Spearman’s rank correlation coefficient.

Results: Two hundred and seventy three HIV positive patients were enrolled into this study. There were 183 (67%) men, 88 (32.2%) women and one transgender. Average age of the individuals was 38.8 years (range: 18-76 years). Overall 50% (137/273) of HIV positive individuals were positive for HSV-2 IgG antibodies. Seroprevalence of HSV-2 among HIV positive men was 47% (86/183) (p = 0.01) and 57% (51/89) (p = 0.01) among HIV positive women. The transgender person was HIV positive and negative for HSV-2 IgG antibodies. The highest HSV-2 seropositivity was detected among the age group of 36 to 45 years. Chi-squared analysis showed that there is a statistically significant association between HSV-2 and HIV infection ($\chi^2=55.900$, $P=0.0076$). CD4 counts were available for 100 HIV positive patients who were ART naive. The median CD4 counts were 563.50 cells/mm$^3$. Using Spearman’s rank correlation, there a significant negative association between HSV-2 seropositivity and CD4 counts ($p<0.05$).

Conclusions: HSV-2 prevalence was significantly higher in HIV positive women than in men. This suggests a higher risk of acquisition of HSV-2 infection among women. These findings have relevant public health implications. The implementation of continuous interventions for STIs and HIV will bring down the prevalence and spread of both HSV-2 and HIV.

No conflict of interest

Abstract_50

Cervical cancer: HPV screening, treatment, vaccins

Cervical cancer screening as part of routine medical care in HIV-positive women

D. Mohammed1, M. Kokkola1, S. Garcia1, R. Sison1, J. Dazley1, N. Rae2, J. Slim2
Introduction: Cervical cancer is five times more likely to develop in HIV-positive women than in the general population. Routine screening can identify and facilitate treatment of cervical cancer before it enters a late stage of disease. The goal for the performance of routine screening is 90% in HIV positive women but national reports are at 63%. This study will report the progress of our clinical site in fulfilling this objective.

Methods: This retrospective study compared the performance of routine cervical screening from February – September, in two time periods, 2011 and 2013. In 2011, screenings were conducted by a co-located gynecologist. Patients were referred by medical providers or recruited by staff. An incentive of $25 was provided to patients for completion of routine screening. Follow up was done by a designated nurse. In 2013, screening and follow up was performed as part of routine HIV care by medical providers. Patients could also schedule appointments with a designated provider. Ongoing coordination of services was done by a designated medical assistant. Pap smears were performed using the ThinPrep Pap Test. Chisquare was used to evaluate the proportion of women with completed PAP smears in 2011 and 2013.

Results: A total of 1059 women ≥ 18 years with at least one medical visit from October-September, in the study period, were included in this evaluation, 545 in 2011 and 514 in 2013. When compared to 2011, in 2013 there were higher proportions of women 18-34 years (7.4% vs. 6.1%) and ≥ 55 years (33.1% vs. 26.1%), p-value < 0.05. Race/ethnicity was similar in both time periods. Women who did or did not have cervical cancer screening were similar in age and race/ethnicity. The proportion of women who had routine cervical screening in 2013 was 55% higher than in 2011 for the same time period, 291(60.8%) vs. 188 (39.3%), p-value ≤ 0.05. Race/ethnicity was similar in both time periods. Women who did or did not have cervical cancer screening were similar in age and race/ethnicity. The proportion of women who had routine cervical screening in 2013 was 55% higher than in 2011 for the same time period, 291(60.8%) vs. 188 (39.3%), p-value ≤ 0.05. Compared to 2011, in 2013 there were more likely to be aged 18-34 (8.9% vs. 5.9%) or ≥ 55 (33.9% vs. 22.9%), p-value ≤ 0.05. Abnormal results were noted in 26% of screened women in 2013, (ASCUS: 13% and LGSIL/HGSIL: 13%). Human Papilloma Virus was positive in 100 (34.4%) women. HIV viral load suppression at ≤ 200 copies was present in 71.4% of women and 90% had CD4 counts > 200 cells.

Conclusions: An increase in the proportion of women with cervical cancer screening was accomplished (from 39.3% to 60.8%) when providing this service as a routine part of medical care compared to the previous time period when services were provided in a co-located manner. Continual cervical screening is needed to achieve a goal of 90% over a 12 month period. Involvement of all clinic staff was key to the improvement in cervical screening rates.

No conflict of interest

Abstract_51

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

The utility of customized birth-weight centile calculators for HIV exposed infants

M. Giles1, G. Cross2, K. Blyth1, F. O'Keefe1, O. Vujovic1, P. Bryant2, T. Connell3, E. Wallace4, F. Cullinane5

1The Alfred Hospital, Infectious Diseases Unit, Melbourne, Australia; 2Monash Health, Infectious Diseases Unit, Melbourne, Australia; 3The Royal Children's Hospital, Infectious Diseases Unit, Melbourne, Australia; 4Monash Health, Obstetrics, Melbourne, Australia; 5The Royal Women's Hospital, Obstetrics, Melbourne, Australia

Introduction: Foetal growth restriction is a major cause of perinatal morbidity and mortality. Early data conflict regarding whether receipt of highly active anti-retroviral therapy (HAART) during pregnancy is associated with low birth weight infants. The aim of this study was to determine the rate of small for gestational age (SGA) infants born to HIV positive, HAART exposed mothers from a multi-ethnic population using standard birth-weight centile charts and a customized birth-weight centile calculator adjusted for maternal characteristics.
Methods: Women receiving HAART from two institutions in Melbourne were eligible for inclusion. Singleton pregnancies delivered after 37 weeks were included. Infant weight was plotted on standard population birth-weight centile charts. A customized birth-weight centile calculator, (Gestation network, Perinatal Institute, UK) which adjusted for maternal height, weight, ethnic origin, parity and foetal sex, was used to determine if infants were SGA (<10th centile) at birth.

Results: Between 2008 and Aug 2013, 82 HIV positive women delivered 102 infants in Victoria, Australia. There were four sets of twins. Six infants had missing gestational age data. Of the remaining 68, 11 were born at a gestational age <37 weeks and four others had missing birth-weight data. According to standardized birth-weight centile charts, 13/73 (18%) infants were SGA compared with 6/45 (13%) when a customized birth-weight centile calculator was applied. This difference was more obvious when comparing those who were at or below the 15th centile. Infants born to African women who were <165cm had the greatest discrepancy between standardized birth weight centile and customized birth weight centile.

Conclusion: Assessment of birth-weight centile by standardized birth-weight charts returns a high rate (18%) of SGA in HAART exposed infants. A customized growth calculator, taking into consideration maternal weight, height, ethnicity and parity, provides a more conservative rate (13%) of SGA infants, particularly to women of African origin.

No conflict of interest

Abstract_52

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

Comparison of socio-demographic and clinical profile of HIV-infected men and women in the clinical setting

C. Miralles1, C. Pazos1, L. Lavajo1, S. Rodriguez1

1C. Hospitalario Universitario de Vigo, Internal Medicine (HIV), Vigo, Spain

Objectives: Despite that women account for 25% of the HIV-infected population, females are often underrepresented in antiretroviral clinical trials. In this setting virological failure and treatment discontinuation rates may be higher in women, however there is lack of information in the real world scenario. The objective of this study is to describe the socio-demographic and clinical characteristics of the HIV-infected population within our cohort and make a comparison between the men and women evolution.

Methods: Observational retrospective study within 'Complejo Hospitalario de Vigo', Spain, that follows-up 1,000 HIV-infected patients. Patients were collected from the Pharmacy records in 2:1 basis (2 women: 1 men) according to the order they had collected antiretroviral (ARV) medication in the last 4 years (January 2009-December 2012). The epidemiological and clinical characteristics were obtained from the patients records. All patients signed written informed consent.

Results: The study population was 544 patients (272 men and 272 women). There were no statistical differences between women and men regarding HIV infection, viral load, immunological status and CDC stage both at diagnosis and at the current situation. However it was observed that women were diagnosed earlier than men when the practice risk was heterosexual (33 vs 37.8 years; p< 0.001), while the trend in the intravenous drug user was the opposite, p=0.065. Treatment switching was remarkably higher in women than men (p=0.012). Regarding ARV therapy it was observed that more women were treated with a PI-based regimen.

Conclusion: Intrinsic women characteristics may lead to more treatment switching than men. This fact emphasizes the idea of tailoring the best treatment for each patient, choosing carefully potent and tolerable ARV for women, as they are in risk of suffering more treatment
changes. In this scenario, PI-based regimen could play an important role.

No conflict of interest

Abstract_53

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

The ATASAFE women cohort: Outcome of Atazanavir/r use after 2 years

C. Michalik¹, A. Skaletz-Rorowski², A. Potthoff³, C. Stephan⁴, P. Khaykin⁵, H. Jaeger⁶, A. Plettenberg⁷, S. Esser⁸, B. Haastert⁷, N. Brockmeyer⁸, A. Haberl⁹

¹University of Cologne, Center for Clinical Trials, Köln, Germany; ²University of Bochum, Dermatology Allergology and Venerology, Bochum, Germany; ³JW Goethe University of Frankfurt, HIVCenter, Frankfurt, Germany; ⁴MVZ Karlsplatz Munich, HIV Research and Clinical Care Center, Munich, Germany; ⁵Ifi Institute Hamburg, Institute for interdisciplinary medicine, Hamburg, Germany; ⁶University Hospital Essen, Clinic for Dermatology and Venerology, Essen, Germany; ⁷mediStatistica, Statistics, Neuenrade, Germany; ⁸University of Bochum, Competence Network for HIV/AIDS, Bochum, Germany

Introduction: HIV-positive women are often under-represented in clinical trials and cohort studies; thus, gender-specific treatment-response data are limited. The German ATASAFE Cohort aims to analyse long-term efficacy and safety data of ritonavir-boosted atazanavir (ATV/r) in HIV-infected women.

Methods: ATASAFE is a multicentre, retro-/prospective, non-interventional cohort study of KompNet HIV/AIDS and HIVCENTER (Frankfurt) databases over 4 years. Inclusion criteria were female, HIV-1 diagnosis, age ≥18 years, ≥3-month ART on ATV/r + NRTI backbone. 140 women were documented for VL (viral load) and CD4 biannually during their routine check-up. A 2-year interim analysis was conducted after ATV/r initiation. Immunological status time-course analysis was conducted in subpopulations of women who had paired baseline and 2-year values for CD4 and VL. Missing CD4 and HIV-1 RNA values for the 2-year interim analysis were imputed using the LOCF method from values from 1 year forward. Discontinuations were included and analysed ITT. A paired t-test was performed for the CD4 change baseline vs. 2 years and the McNemar's symmetry test for the viral load below detection limit.

Results: The interim analysis provided a complete data set of n=92 women, for CD4 and VL with n=9 imputed, respectively. At baseline (initiation of ATV/r), ATV/r was most frequently combined with TDF/FTC as backbone (61.8%), mean age was 39.0 years and 55.1 % were Caucasian. Main route of transmission was heterosexual contact (45.7%), secondly intravenous drug use (22.8%). The majority of women were CDC status B (44.6%) at last observation. At baseline, 27% (n=25) of the women were treatment-naïve and 73% (n=67) treatment-experienced. Prior to ATV/r-containing ART the mean duration of documented ART exposure of pre-treated women was 5.5 years (2 unknown). 3 women discontinued ATV/r treatment during the first 2 years (mean: 0.7 years, range: 0.6-0.9) for unknown reasons, however 2 of them had a VL below detection limit (<400 c/ml). The proportion of women with viral load below detection limit increased significantly (p-value <0.0001) by 50.0% (baseline n=42, after 2 years n=88) for the overall population (N=92). After 2 years of ATV/r treatment, 96.0% of naive patients' viral loads were below detection. The mean CD4-cell count increased significantly (p-value <0.0001) by 203 cells/μl for both groups (N=92) over 2 years, regardless of pre-treatment or ATV/r as first line therapy.

Conclusion: This cohort analysis confirms clinical data showing a good efficacy and safety profile of ATV/r based HAART. The low discontinuation rate over 2 years confirms the durability and sustainability of ATV/r based regimens in real-life. The ATASAFE cohort is an important evidentiary addition to ATV/r-treatment in women. The study aims to close the gap of gender specific long term data. This ATASAFE study population is reflective of the real life situation of HIV+ women in Germany and
therefore will improve the gender specific clinical care in people living with HIV.

No conflict of interest

Abstract_54

ARV therapy for women -- efficacy, toxicity, pharmacokinetics

HIV+ Women who are receiving ARV treatment base on LOPINAVIR/ RITONAVIR (LPV/r). Spanish multicenter cross sectional study.

M. Galindo¹, C. Miralles², S. Pérez-elías³, P. Arazo⁴

¹Hospital clínico universitario, Internal medicine. Unit of infectious diseases, Valencia, Spain; ²Hospital Xeral cíes, Unit of infectious diseases, Vigo, Spain; ³Hospital Ramón y cajal, Infectious diseases, Madrid, Spain; ⁴Hospital miguel servet, Infectious diseases, Zaragoza, Spain

Background: HIV+ women have differential facts against HIV+ men, reason why they require special attention, mainly in stages like childbearing age and maturity. LPV/r is an effective and safety drug that is used in a high proportion of HIV+ women along the different stages of their life.

Objective: To know the clinical characteristics of HIV + women who are receiving ART based on LPV/r nowadays in our clinical practice.

Materials and Methods: The project includes 56 hospitals throughout Spain organized into four different groups with four different patients profiles, and women is one of them. We will present the baseline characteristics of the patients included in this women group until September 2013, corresponding to 20 hospitals with ARV treatment based on LPV/r at the time of inclusion in the study. Quantitative variables were analyzed as median and 25-75 percentile, mean and SD, and qualitative variables as percentages.

Results: According to 228 women included 160 (70.2 %) were Caucasian and the rest from other ethnic with a mean IMC of 29.2 (±1.62) . The mean age was 42.8 years (±9.9) with a mean duration of HIV diagnosis of 12.7 years (±7.3). 82 women were smokers (36%) and women with alcoholic habit were 7.5% (17 cases). HIV transmission was sexual in 154 women (67.5%) and UDIS in 69 (30.3%) being coinfected 31.6% (72 women). They had suffered AIDS in 64 cases (28%), being the average duration of antiretroviral therapy 9.9 years (± 6.1). The 24.9 % (48 cases) were in first line therapy, 18.7% (36 cases) in second line, and 78.4 % (109 cases) ≥3rd line. 38 women were menopausal (17.7%). From 150 who were of childbearing age, 94 (62.6 %) used some form of contraception. The CD4 nadir cell count was 219/mm3 (±170) being the values at the last visit 652/mm3 (± 473) and in the 90.7% (205 cases) were >200/mm3 . The viral load was <50 copies/ml in 80.01%. Mean values of total cholesterol were 197.3 mg/dl (±64.9), HDL-C 55.7 m/dl (±17.2), LDL-C 115 mg/dl (±38.5), triglycerides 152.4 mg/dl (±83.5) and GFRe (CKD-EPI) 96.9 ml/min (±21.3). The average duration of LPV/r was 4.23 years (±3.3) and in the 35 women who discontinued LPV/r 1.73 years (±2.17). The reasons for discontinuing LPV/r were: pregnancy (8 women), patient desire and adverse events (6 cases respectively), optimization of ART 4 cases, only in one case was discontinued because of virological failure. Of the 208 women who are currently with LPV/r 79.2% in the BID and 20.6% in QD. 51.9% receive triple therapy, 38.46% monotherapy, 6.7% dualtherapy and 6% remaining other combinations.

Conclusions: Women treated with LPV/r in Spain have a profile of mature age, pre menopause, so we must to pay attention to typical problems regarding childbearing age conception/contraception, and to the control of symptoms associated with menopause and its prevalent comorbidities (osteoporosis, cardiovascular risk, dyslipidemia, polypharmacy, HPV). We found a high efficacy, tolerability and durability in women treated with LPV / r.

Conflict of interest financial relationship(s): Bms, abvie, gilead, janssen, viiv grants and advisories, and participation as speaker in meetings held by these companies
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