

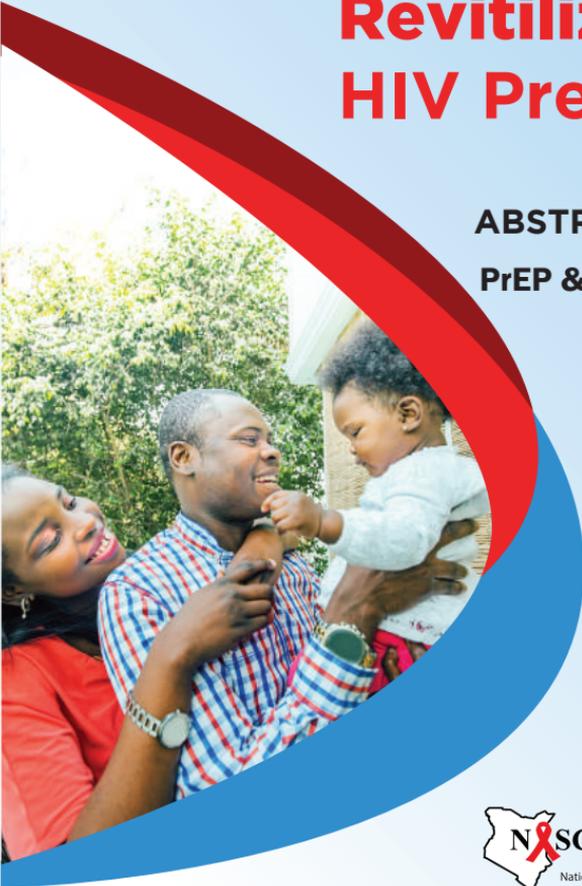


MINISTRY OF HEALTH

Revitalizing HIV Prevention

ABSTRACT BOOK

PrEP & HIV Self Test



JIPENDE
JIPrEP

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Introduction

Kenya has made strides in reducing new HIV infections and has also put in place strategies to increase HIV testing coverage among its population. The government through the Ministry of Health has been on the forefront in fighting HIV in Kenya while ensuring an enabling environment for donors and implementing partners to contribute to the national HIV response. More is still to be done to bring down the number of new HIV infections from approximately 71,000 in 2015 to zero by 2030. This requires all players to be innovative and strategic with interventions that encourage more people to know their HIV status for the correct prevention measure to be taken including uptake of new HIV prevention technologies. It is yet another defining moment for Kenya as the country launches Pre-Exposure Prophylaxis for HIV prevention and HIV Self Testing for more people to know their status. Kenya has had the privilege of hosting a number of clinical trials, pilot and demonstration projects for both PrEP and HIV Self Testing. Drawing from the experiences and lessons learnt in these projects, the Ministry of Health through NASCOP will be launching these two interventions and availing them to the public.

This abstract book brings together a wealth of information on the experiences, best practices and lessons learnt from some of the pilot and demonstration projects by implementing partners. The main aim is to scale up what has worked while finding solutions for what may not have worked well to support national implementation of PrEP and HIV Self-Testing.

HIV SELF TEST

Be Self Sure

Feasibility and acceptability of HIV self-testing among pre-exposure prophylaxis users in Kenya.

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INTRODUCTION: HIV testing is key to the delivery of pre-exposure prophylaxis (PrEP): testing HIV-uninfected at-risk persons is the first step for PrEP initiation and ongoing HIV testing is an essential part of PrEP delivery. Thus, novel and cost-effective HIV-testing approaches to streamline delivery of PrEP are urgently needed. Within a demonstration project of PrEP for HIV prevention among high-risk HIV serodiscordant couples in Kenya (the Partners Demonstration Project), we conducted a pilot evaluation of HIV self-testing.

METHODS: Clinic visits were scheduled quarterly and included in-clinic HIV testing using fingerstick rapid HIV tests and refills of PrEP prescriptions. HIV oral fluid self-test kits were provided for participants to use in the two-month interval between scheduled quarterly clinic visits. Acceptability of HIV self-testing was assessed using both quantitative and qualitative methods.

RESULTS: We found that 222 of 226 (98%) HIV-uninfected persons who were offered accepted self-testing. Nearly all (96.8%) reported that using the self-testing kit was easy. More than half (54.5%) reportedly did not share the HIV results from self-testing with anyone and almost all (98.7%) the participants did not share the HIV self-testing kits with anyone. Many participants reported that HIV self-testing was empowering and reduced anxiety associated with waiting between clinic HIV tests.

CONCLUSION: HIV self-testing was highly acceptable and may therefore be a feasible strategy to efficiently permit routine HIV testing between PrEP refills.

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LVCT Health studies on HIV self-testing usability, counseling and linkage

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Background

HIV self-testing (HIVST) is a potentially beneficial strategy to reach persons at risk of HIV infection. Uptake of HIVST is however low due to lack of information, stigma and low perception of risk. Being a new strategy, little is known about the usability of HIVST and effective strategies for optimizing counseling and linkage. LVCT Health has conducted two studies to provide evidence on these two questions.

Description

The first exploratory study aimed to determine the usability of five late stage HIVST prototypes (4 blood sample (finger prick) and 1 oral-swab) among 50 lay users in Nairobi County in 2013. Data on usability (time taken, ease of following instructions, sample collection process) was collected through live video recording. In-depth interviews (IDIs) were conducted to explore participants' experience as they used the HIVST prototypes. Key informant interviews were conducted with persons living with HIV, policymakers, laboratory practitioners and HIV researchers.

The second pre-posttest study was conducted in 2014 to determine the most efficient strategies for counselling HIVST users and linking them to care. 1,608 participants, including self-reported sex workers and men who have sex with men were asked to choose between oral HIVST and standard HIV testing and counselling (HTC) in seven HTC sites in Nairobi, Kisumu and Machakos. Unsupervised oral HIVST was offered to participants in a private room within the HTC sites. Participants could opt to take up confirmatory tests and post-test counselling was conducted after the HIVST.

Key lessons learned

The first study found that oral HIVST kits were easier to use compared to a blood sample kits. The average test time for using the oral HIVST kits was 14 minutes. Most users preferred using HIVST kits in the privacy of their homes and were willing to purchase kits at a maximum of KSh 500 (Approx. USD 5) in pharmacies. Participants indicated that HIVST kits should be provided free-of-charge in health facilities. One key lesson is that HIVST kits should incorporate pictorial instructions in English and Swahili.

In the second study, 80% of participants had never heard of HIVST but trusted the kits to give accurate HIV results. Only 24.4% (395/1608) took up HIVST and less than 30% indicated intention to seek post-test counselling. Actual uptake of post-test counselling was at 12.6%. Women and MSM were more likely to seek post HIV test counselling and HTC sites were most preferred for post-test counselling. 28% of participants those who used the oral HIVST kits took up confirmatory tests in HTC sites.

Conclusions/Next steps

Participants found it easier to use oral HIVST kits compared to the blood sample kits. Uptake of oral HIVST was higher among home testers, repeat testers, female sex workers and MSM. Since less than 30% took up unsupervised oral HIVST in HTC sites, these may not be ideal distribution points for unsupervised HIV self-testing. Community-based distribution systems may be more efficient for accessing HIVST compared to HTC sites. Early linkage to counselling and uptake of a confirmatory test were relatively low overall.

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Pre-Exposure Prophylaxis

JIPENDE
JI PrEP

Introducing Pre Exposure Prophylaxis (PrEP) in Combination Prevention in Kenya (IPCP-KENYA)

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Background: Although the efficacy of oral PrEP for HIV prevention has been demonstrated in clinical trials, there are lingering questions about uptake, adherence and scale up in real-life healthcare settings. Introducing PrEP in Combination Prevention in Kenya (IPCP-Kenya) is a two-staged project that aims to provide evidence on the deliverability of PrEP

Description: In 2013, a *feasibility study* was conducted to determine the willingness to take daily oral PrEP for HIV prevention among young women (YW), men who have sex with men (MSM) and female sex workers (FSW) in Nairobi, Kisumu, Homa bay and Nakuru Counties in Kenya. The feasibility study also assessed characteristics of potential candidates for PrEP, such as self-perceptions of HIV risk, barriers and motivators to PrEP adherence. Policy makers and health workers were also interviewed to explore their perceptions on PrEP and how it may be delivered. This study also modelled the cost of delivering PrEP to key populations using the activity based costing approach.

The *IPCP Demonstration Project* is an on-going prospective cohort study (October 2015-December 2017) that seeks to demonstrate what's needed to effectively deliver PrEP to YW, FSW and MSM in Nairobi, Kisumu and Homa bay Counties. This project also seeks to: validate tools for HIV risk identification, document adverse events associated with PrEP and test strategies and messaging to promote PrEP uptake and adherence. Qualitative data on attitudes, perceptions and reasons for participant behaviour will be explored using interviews, focus group discussions and quantitative data on demographics, behaviour and clinical evaluations are being collected using case report forms. Drug level testing is being done to confirm reported adherence. The study planned to enrol 2,100 participants

Key lessons learned: The *feasibility study* found high levels of willingness to take daily oral PrEP among MSM (83%), FSW (88%) and YW (85%). Willingness to take PrEP was motivated by the desire to remain HIV negative to protect their partners from infection. Potential users identified poor history of completing medication doses, general dislike of medicines, drug and alcohol abuse, fear of side effects, cost and social stigma as potential barriers for PrEP uptake. Health care workers and policy makers were supportive of PrEP but were concerned about the additional resource burden on the health system and potential increase of drug resistance to first-line anti-retroviral drugs.

The *IPCP Demonstration Project* closed recruitment at 1,632 participants (78% of target). Preliminary data indicate that PrEP uptake is about 64% (FSW), 60% (YW) and 67% (MSM). Social stigma is a major barrier to uptake. The decision to take PrEP may be influenced by sexual partners, peer educators, community leaders and people living with HIV. Key outputs for this project are: validated tools for identification of HIV risk and strategies to optimize uptake and adherence to oral HIV PrEP among YW, MSM and FSW. This study will model the impact of PrEP as part of HIV combination prevention

Conclusions/Next steps: Key populations in this study demonstrated willingness to take oral PrEP. For PrEP to be delivered effectively, opinion leaders should also be targeted in demand creation and messaging.

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Project Name: An implementation project to scale-up delivery of antiretroviral-based HIV-1 prevention among Kenyan HIV-1 serodiscordant couples

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Background:

The Kenyan Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Kenya launched on July 16, 2016 recommends use of PrEP as one of several HIV prevention strategies for attaining zero new infections in Serodiscordant couples (where one partner is HIV infected and the other uninfected). The Serodiscordant couple PrEP demonstration studies showed 96% protection. 'Test and Treat' recommend initiation of antiretroviral treatment to all HIV+ve regardless of CD4 count or viral load hence PrEP would be used by the HIV-ve to allow time for viral suppression for those who are adherent. The PrEP couples scale up study seeks to roll out PrEP for serodiscordant couples even as Test and treat strategies are simultaneously rolled out in 12 public HIV-1 care centers in Homabay, Migori Kisumu and Siaya counties.

Description: PrEP is given to the HIV-ve partner in a serodiscordant relationship as a bridge and stopped six months after viral suppression is achieved for the HIV+ve partner. The recommended regimen for PrEP is: TDF 300 mg and Emtricitabine 200 mg once daily (given as a FDC). We will conduct monitoring and evaluation activities during follow up of the cohort to identify implementation barriers, facilitators, characterize costs, and provide best practices for further scale-up. Three days training conducted.

Key lessons learned: This scale up selects 12 high volume HIV-1 care sites in the four counties to understand PrEP rollout to serodiscordant couples. PrEP initiation at the selected sites is implemented as randomly assigned by County Health Management Team (CHMT). A total of 200 Health care providers (HCP) from six facilities have been trained on delivering PrEP and ART for HIV prevention at the HIV-1 care centers and an additional 700 HCP reached through Continuous medical education (CME). From March 2017 six of 12 sites have begun to deliver PrEP to serodiscordant couples.

Successes: The team has been able to create demand for PrEP within the target group by training HCP, sensitizing the community through media to mobilize couples for HIV testing, increasing PrEP awareness and uptake. Through trainings and radio shows we have dispelled myths and misconceptions within the community and health facilities. CMEs target 1200 HCP which include nursing students, non- health care workers.

Additional on job training has provided quality checks, HCP attitude change and use of the reporting tools to the National AIDS and STIs Control Programme (NAS COP) such as drug management, capture indicators for newly initiated on ART and PrEP, number tested for HIV, partner testing and serodiscordant couples served. Treatment as Prevention (Tasp)/PrEP work together as a strong strategy in HIV prevention

Challenges This has included but not been limited to addressing HCP concerns around increased work load. PrEP stock outs, unclear PrEP messages in the community that could create confusion, they also worry on risk compensation. Health care workers not having knowledge on PrEP.

Conclusions/Next steps: Develop clear PrEP messaging to improve community awareness on PrEP and increase PrEP uptake.

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Project Name: Prevention options for Young women Evaluation research Formative work

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Background: The World Health Organization (WHO) guidelines on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV (September 2015) recommends daily oral PrEP be offered as an additional prevention method for those at substantial risk of acquiring HIV. Studies on PrEP have shown that people who took Truvada or Tenofovir daily as prescribed had over 90% chances of getting HIV when exposed. Poor adherence reduces PrEP effectiveness. We sort to assess key factors that would influence young women's decision to take up and adhere to oral PrEP by key informants.

Description: Qualitative data was sort from health care providers working at the public family planning clinic and other key informants (KIs) working with young women between August 2016 to September 2016. The target population included 6 health care workers and 9 other key informants working with young women in Kisumu, which included local health professionals, religious leaders, outreach workers, youth group leaders, NGO workers, traditional healers, sex worker organization leaders and women group's leaders. They were identified by the study staff using local networks to document perspectives on factors influencing young women's decisions to take up and adhere to PrEP as a HIV prevention strategy. Textual data coding as a primary qualitative analytical approach was used to summarize, extract meaning and condense the data using Nvivo.

Key lessons learned: KIs thoughts were that Young women would likely be interested in taking PrEP because it is private, safe and they can stop taking it when they feel they are no longer at risk. Concern was expressed over possible disinhibition with regards to sexual high risk behavior including non-condom use, or even using PrEP to advertise their HIV negative status.

Non-adherence to PrEP was attributed to any one or a combination of the following factors : The burden of daily pill taking, forgetfulness, fear related to side effects, concerns of 'drug resistance', consequences of family and / or partner (s) finding out, myths and misconceptions that by taking PrEP they are used as "guinea pig", fear of the unknown, stigma of taking a pill openly, being judged by the health providers that they could be promiscuous, difficulty in taking the pills when not sick, and the burden of testing for HIV every three months and access to PrEP.

Conclusions/Next steps: Health care workers should focus on clarification of the myths associated with PrEP, encourage and explain benefits of condom use (other STD and pregnancy prevention) , encourage the YWAG to consider ways of making taking the pill part of or linked to a daily routine, and how train to empower YAAG to communicate with partner(s) or parents about PrEP. There is also need to address deeply embedded bias and judgments among providers with regards to sexuality especially among YWAG. Peer PrEP peers educators/ ambassadors should may be an innovative method for both outreach in addition to the creation of youth-friendly spaces for PrEP delivery and discussions to reduce barriers to PrEP uptake.

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Pre-exposure Prophylaxis Use by Breastfeeding HIV-Uninfected Women: A Prospective Short-Term Study of Antiretroviral Excretion in Breast Milk and Infant Absorption.

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BACKGROUND:

As pre-exposure prophylaxis (PrEP) becomes more widely used in heterosexual populations, an important consideration is its safety in infants who are breastfed by women taking PrEP. We investigated whether tenofovir and emtricitabine are excreted into breast milk and then absorbed by the breastfeeding infant in clinically significant concentrations when used as PrEP by lactating women.

METHODS AND FINDINGS:

We conducted a prospective short-term, open-label study of daily oral emtricitabine-tenofovir disoproxil fumarate PrEP among 50 HIV-uninfected breastfeeding African mother-infant pairs between 1-24 wk postpartum. PrEP was administered to women through daily directly observed therapy (DOT) for ten consecutive days and then discontinued thereafter. Non-fasting peak and trough samples of maternal plasma and breast milk were obtained at drug concentration steady states on days 7 and 10, and a single infant plasma sample was obtained on day 7. Peak blood and breast milk samples were obtained 1-2 h after the maternal DOT PrEP dose, while maternal trough samples were obtained at the end of the PrEP dosing interval (i.e., 23 to 24 h) after maternal DOT PrEP dose. Tenofovir and emtricitabine concentrations were quantified using liquid chromatography-tandem mass spectrometry (LC-MS/MS) assays. Of the 50 mother-infant pairs enrolled, 48% were ≤ 12 wk and 52% were 13-24 wk postpartum, and median maternal age was 25 y (interquartile range [IQR] 22-28). During study follow-up, the median (IQR) daily reported frequency of infant breastfeeding was 15 times (12 to 18) overall, 16 (14 to 19) for the ≤ 12 weeks, and 14 (12 to 17) for the 13-24 wk infant age groups. Overall, median (IQR) time-averaged peak concentrations in breast milk were 3.2 ng/mL (2.3 to 4.7) for tenofovir and 212.5 ng/mL (140.0 to 405.0) for emtricitabine. Similarly, median (IQR) time-averaged trough concentrations in breast milk were 3.3 ng/mL (2.3 to 4.4) for tenofovir and 183.0 ng/mL (113.0 to 250.0) for emtricitabine, reflecting

trough-to-peak breast milk concentration ratios of 1.0 for tenofovir and 0.8 for emtricitabine, respectively. In infant plasma, tenofovir was unquantifiable in 46/49 samples (94%), but emtricitabine was detectable in 47/49 (96%) (median [IQR] concentration: 13.2 ng/mL [9.3 to 16.7]). The estimated equivalent doses an infant would ingest daily from breastfeeding were 0.47 µg/kg (IQR 0.35 to 0.71) for tenofovir and 31.9 µg/kg (IQR 21.0 to 60.8) for emtricitabine, translating into a <0.01% and 0.5% relative dose when compared to the 6 mg/kg dose that is proposed for therapeutic treatment of infant HIV infection and for prevention of infant postnatal HIV infection; a dose that has not shown safety concerns. However, maternal daily DOT and specimen collection at drug concentration steady state provided an adequate approach to address the key research question. Importantly, there was minimal variation in breast milk concentrations of tenofovir and emtricitabine (respective median trough-to-peak concentration ratio ~1), demonstrating that infants were exposed to consistent drug dosing via breast milk.

CONCLUSION:

The estimated infant doses from breast milk and resultant infant plasma concentrations for tenofovir and emtricitabine were 12,500 and >200-fold lower than the respective proposed infant therapeutic doses, and tenofovir was not detected in 94% of infant plasma samples. These data suggest that PrEP can be safely used during breastfeeding with minimal infant drug exposure

Ref: PLoS Med. 2016 Sep 27;13(9):e1002132. doi: 10.1371/journal.pmed.1002132. eCollection 2016.

Title: Assessing Risk of HIV Drug Resistance with Tenofovir/Emtricitabine PrEP in Kenya

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Introduction: Minimizing the risk of HIV drug resistance during PrEP rollout is critical to ensure the long-term efficacy of antiretroviral (ARV) medications for both PrEP and HIV treatment. We reviewed current data on HIV-1 resistance arising from the use of tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) for pre-exposure prophylaxis (PrEP) to help develop recommendations for resistance monitoring for PrEP rollout in Kenya.

Results: Resistance to tenofovir (TNV) or FTC is infrequently selected by TDF/FTC PrEP if started before HIV-1 infection has occurred, but is much more common when inadvertently started during undiagnosed acute infection. FTC resistance from M184V/I occurs more frequently than TFV resistance with K65R in seroconverters from clinical trials of TDF/FTC PrEP. Studies in macaques show that TNV-resistant virus but not FTC-resistant virus can cause breakthrough infection despite TDF/FTC PrEP. Mathematical modeling suggests that the number of HIV-1 infections averted by the use of PrEP exceeds the increase in drug-resistant infections that could occur from PrEP.

Summary: The benefit of preventing HIV-1 infections with TDF/FTC PrEP probably outweighs the risk of drug-resistant infection, although careful monitoring of resistance from PrEP is needed. The GEMS Project is working with NASCOP and PrEP implementation partners to conduct a comprehensive assessment of HIV drug resistance risk with PrEP use in Kenya.

Reference: Part of this abstract includes work published by Parikh and Mellors in *Current Opinions in HIV/AIDS*, 2016,11(1):p49-55.

Counseling Framework for HIV-Serodiscordant Couples on the Integrated Use of Antiretroviral Therapy and Pre-exposure Prophylaxis for HIV Prevention.

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BACKGROUND: For HIV-serodiscordant couples, integrated delivery of antiretroviral therapy (ART) for HIV-positive partners and time-limited pre-exposure prophylaxis (PrEP) for negative partners virtually eliminates HIV transmission. Standardized messaging, sensitive to the barriers and motivators to HIV treatment and prevention, is needed for widespread scale-up of this approach.

METHODS: Within the Partners Demonstration Project, a prospective interventional project among 1013 serodiscordant couples in Kenya and Uganda, we offered ART to eligible HIV-positive partners and PrEP to HIV-negative partners before ART initiation and through the HIV-positive partner's first 6 months of ART use. We conducted individual and group discussions with counseling staff to elicit the health communication framework and key messages about ART and PrEP that were delivered to couples.

RESULTS: Counseling sessions for serodiscordant couples about PrEP and ART included discussions of HIV serodiscordance, PrEP and ART initiation and integrated use, and PrEP discontinuation. ART messages emphasized daily, lifelong use for treatment and prevention, adherence, viral suppression, resistance, side effects, and safety of ART during pregnancy. PrEP messages emphasized daily dosing, time-limited PrEP use until the HIV-positive partner sustained 6 months of high adherence to ART, adherence, safety during conception, side effects, and other risks for HIV.

CONCLUSIONS: Counseling messages for HIV-serodiscordant couples are integral to the delivery of time-limited PrEP as a "bridge" to ART-driven viral suppression. Their incorporation into programmatic scale-up will maximize intervention impact on the global epidemic.

Ref: J Acquir Immune Defic Syndr. 2017 Jan 1;74 Suppl 1:S15-S22.

I Knew I Would Be Safer. Experiences of Kenyan HIV Serodiscordant Couples Soon After Pre-Exposure Prophylaxis (PrEP) Initiation.

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Abstract

Pre-exposure prophylaxis (PrEP) for HIV-uninfected persons is highly efficacious for HIV prevention. Understanding how people at risk for HIV will use PrEP is important to inform PrEP scale-up and implementation. We used qualitative methods to gather insights into couples' early experiences with PrEP use within the Partners Demonstration Project, an open-label implementation study evaluating integrated delivery of PrEP and antiretroviral therapy (ART). PrEP is offered to HIV uninfected partners until the HIV-infected partner initiates and sustains ART use (i.e., PrEP as a "bridge" to ART initiation and viral suppression). From August 2013 to March 2014 we conducted 20 in-depth dyadic interviews (n = 40) with heterosexual HIV serodiscordant couples participating at the Thika, Kenya study site, exploring how couples make decisions about using PrEP for HIV prevention. We developed and applied deductive and inductive codes to identify key themes related to experiences of PrEP initiation and use of time-limited PrEP. Couples reported that PrEP offered them an additional strategy to reduce the risk of HIV transmission, meet their fertility desires, and cope with HIV serodiscordance. Remaining HIV negative at follow-up visits reinforced couples' decisions and motivated continued adherence to PrEP. In addition, confidence in their provider's advice and client-friendly services were critical to their decisions to initiate and continue use of PrEP. Strategies for wide-scale PrEP delivery for HIV serodiscordant couples in low resource settings may include building capacity of health providers to counsel on PrEP adoption while addressing couples' concerns and barriers to adoption and continued use.

Ref: *AIDS Patient Care STDS*. 2016 Feb;30(2):78-83. doi: 10.1089/apc.2015.0259.

Project Name: Prevention Options for Women Evaluation Research – The formative work

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Background: Young women and adolescent girls (YWAG) aged 15 to 24 have higher incidence of infection and increased vulnerability to HIV (5-6%) despite the current prevention options. Drivers of HIV risk among these young women include early age at first sexual debut, unprotected sex, sexually transmitted infections, older partners, multiple partners, low negotiating power in relationships, intimate partner violence, sex work, and alcohol use and or abuse. YWGA are often unable to discuss prevention of HIV options; negotiate partner testing, or condom use due to concerns about preserving the partnership, gender-based violence, and economic loss.

This study sort to find out YWGA's independent' prevention choice (uninfluenced), understanding of themselves, their important personal relationships, and their social and environmental context with the aim of assessing their understanding of HIV prevention with a focus on oral PrEP among YWGA in Kisumu, Kenya to develop communication messages about PrEP.

Description: This was a qualitative formative research that employed a mental model assessment to understand potential end users & their influencers' perceptions of HIV risk & PrEP among young women aged 16-25 and Men 18 years and above in Kenya, Kisumu. A total of 33 participants were enrolled.

Key lessons learned: Mental models methodology was grounded in behavioral decision research, it characterized the mental models with respect to a specific decision or set of decisions about unsafe sex, HIV testing, taking 1st PrEP pill, continuing to take PrEP pill. Interview methods began with open-ended questions designed to elicit participant's own language and framing. Prompts became more and more specific, eventually eliciting risk estimates as well as causal logic.

Perceptions of Risk: Young women and men perceive the risk of pregnancy as less than risk of contracting HIV, 84% and 92% respectively believe it would be worse to become infected with HIV than to get pregnant. They believe that risk of infection accumulates over repeated exposures. Given the expectation that they should contract HIV if exposed, some ascribe their negative status to "being immune," not trusting risk information, or being "protected by God." HIV risk loses salience over a period of one year. Overall, not many participants had heard of PrEP but had a high level of interest in PrEP. The questions participants asked included; whether PrEP can be taken concurrently with other medications, if it can it be taken on an empty stomach, if one should continue if they become sick (or experience side effects)—since it is seen as a medication that impacts the 'immune system,' many young women did not understand how PrEP would accumulate over time in the bloodstream to protect them.

Conclusions/Next steps: To prioritize PrEP for HIV prevention in young women there is a need to address the myths and misconceptions that may affect YWAG's risk perceptions and act as barriers to PrEP use. We therefore need to assess with YWAG their risk perceptions, fears and uncertainties to HIV infection for a productive change through targeted messaging and counselling. Possible utilization of PrEP champions/ambassadors may help create demand.

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Integrated Delivery of Antiretroviral Treatment and Pre-exposure Prophylaxis to HIV-1-Serodiscordant Couples: A Prospective Implementation Study in Kenya and Uganda.

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BACKGROUND: Antiretroviral-based interventions for HIV-1 prevention, including antiretroviral therapy (ART) to reduce the infectiousness of HIV-1 infected persons and pre-exposure prophylaxis (PrEP) to reduce the susceptibility of HIV-1 uninfected persons, showed high efficacy for HIV-1 protection in randomized clinical trials. We conducted a prospective implementation study to understand the feasibility and effectiveness of these interventions in delivery settings.

METHODS AND FINDINGS: Between November 5, 2012, and January 5, 2015, we enrolled and followed 1,013 heterosexual HIV-1-serodiscordant couples in Kenya and Uganda in a prospective implementation study. ART and PrEP were offered through a pragmatic strategy, with ART promoted for all couples and PrEP offered until 6 mo after ART initiation by the HIV-1 infected partner, permitting time to achieve virologic suppression. One thousand thirteen couples were enrolled, 78% of partnerships initiated ART, and 97% used PrEP, during a median follow-up of 0.9 years. Objective measures of adherence to both prevention strategies demonstrated high use ($\geq 85\%$). Given the low HIV-1 incidence observed in the study, an additional analysis was added to compare observed incidence to incidence estimated under a simulated counterfactual model constructed using data from a prior prospective study of HIV-1-serodiscordant couples. Counterfactual simulations predicted 39.7 HIV-1 infections would be expected in the population at an incidence of 5.2 per 100 person-years (95% CI 3.7-6.9). However, only two incident HIV-1 infections were observed, at an incidence of 0.2 per 100 person-years (95% CI 0.0-0.9, $p < 0.0001$ versus predicted). The use of a non-concurrent comparison of HIV-1 incidence is a potential limitation of this approach; however, it would not have been ethical to enroll a contemporaneous population not provided access to ART and PrEP.

CONCLUSIONS: Integrated delivery of time-limited PrEP until sustained ART use in African HIV-1-serodiscordant couples was feasible, demonstrated high uptake and adherence, and resulted in near elimination of HIV-1 transmission, with an observed HIV incidence of $<0.5\%$ per year compared to an expected incidence of $>5\%$ per year.

