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## Pre-exposure prophylaxis uptake and early continuation among pregnant and postpartum women within maternal child health clinics in Kenya: results from an implementation programme

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### Abstract

**Background:** Pregnant women in high HIV prevalence settings are at increased risk of HIV acquisition and subsequent vertical transmission. We implemented and evaluated a novel program to provide PrEP in maternal child health (MCH) clinics in Kenya.

**Methods:** In collaboration with Kisumu County Department of Health, we integrated PrEP delivery within 16 MCH clinics in Kisumu County. Women seeking MCH services were interviewed to assess for HIV behavioral risk factors and offered PrEP Correlates of PrEP initiation and continuation were determined using Poisson regression.

**Findings:** Between November 2017 and June 2018, 9376 pregnant and postpartum women were assessed for behavioral risk factors and willingness to initiate PrEP. Overall, 2030 (22%) initiated PrEP; 153 (79%) of women with partners living with HIV (PLWH), 1178 (37%) of women with partners of unknown HIV status, and 696 (11%) of women with HIV-negative partners. Predictors of PrEP initiation were age <24 years (adjusted prevalence ratio [aPR])=1.14, 95% CI: 1.02, 1.28), having a PLWH (aPR=7.21, 95% CI: 5.05, 10.28) or partner of unknown HIV status

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Conceived and designed the program: GJS, JK, JMB; Collected data: JK, FA, HL, DO, JP, JD, KKM; Analyzed the data: JP, EB; Drafted the paper: JK, JP, GJS; Critically reviewed manuscript: JK, JP, FA, KKM, HL, DO, EB, JD, JMB GJS.

Declaration of interests

JMB received grants from PEPFAR and personal fees from Gilead Sciences, Janssen, and Merck. JK, JP, FA, KKM, HL, DO, EB, JD, and GJS have no competing interests.

(aPR=2·82, 95% CI: 2·10, 3·79), gestational age <26 weeks (aPR=1·22, 95% CI: 1·02, 1·46), and intimate partner violence during past six months (aPR=1·93, 95% CI: 1·40, 2·66) Overall, 786 (39%) women who initiated PrEP continued use after the first one month, with 67% continuation among those with PLWH. Frequent reasons for discontinuation were side effects and low HIV risk perception. No incident HIV infection was reported among women on PrEP.

**Interpretation:** Many women attending MCH clinics had risk factors for HIV and elected to use PrEP indicating that routinely accessed MCH clinics can be an effective platform for PrEP delivery for young women. As PrEP awareness rises, PrEP provision in routine clinical settings such as MCH may contribute to decreased HIV incidence among young women.

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### Background

High HIV incidence has been reported among pregnant and postpartum women in sub-Saharan Africa.(1-3) A meta-analysis of 19 studies among pregnant and postpartum women representing 22,803 person-years estimated HIV incidence of 3.8 per 100 person-years.(4) This rate is similar to that reported among high risk groups such as female sex workers and HIV-discordant couples.(5, 6) High HIV incidence estimates in pregnancy and postpartum are particularly concerning since these estimates included all women, even those with HIV-uninfected partners, and occurred despite reduced sexual activity in pregnancy and postpartum.(7) A recent study modeling the per-coital act risk of transmission among women with HIV-infected partners, found higher risk throughout pregnancy and postpartum, indicating a potential biologic basis for greater susceptibility.(8) Increased susceptibility may also be due to male partners' sexual behavior during this period (9). It is estimated that ~30% of new infant HIV infections are due to maternal HIV acquisition in pregnancy or postpartum.(10, 11) The relative contribution of acute maternal HIV infection to pediatric HIV is likely to rise as prevention of mother-to-child HIV transmission (PMTCT) programs routinely identify and treat women living with HIV. Therefore, primary HIV prevention during pregnancy and postpartum period is critical to keep HIV negative women uninfected and to achieve elimination of MTCT of HIV.

The World Health Organization (WHO) recommends a comprehensive HIV prevention package for pregnant and breastfeeding women that includes partner HIV testing and treatment, condom use, management of sexually transmitted infections (STIs) and offer of pre-exposure prophylaxis (PrEP) to women with substantial HIV risk.(12) PrEP is an effective HIV prevention strategy that allows the woman to be in charge of her HIV protection, does not require approval or knowledge of male partner, and is safe for infants. (5, 13) Kenyan guidelines recommend PrEP for pregnant and breastfeeding women at substantial risk of HIV. (14) Maternal and child health clinics (MCH) offer a convenient platform for PrEP delivery since most women visit MCH clinics during pregnancy and after delivery. In a recent qualitative study, women expressed fears of being mistaken as HIV-infected if they were seen collecting drugs from HIV clinics.(15) MCH clinics attend to women living with HIV and those not infected and provide medications such as prenatal vitamins and thus may be a less stigmatizing platform for PrEP delivery.

However, there are unanswered questions regarding PrEP implementation in MCH clinics. It is unknown whether pregnant and breastfeeding women perceive their HIV risk and will accept PrEP. While there is a reassuring body of evidence demonstrating PrEP safety during pregnancy and breastfeeding, women and their providers may remain concerned about effects of the drug on the fetus or baby which could influence uptake.(13) It is also unclear which pregnant or breastfeeding women should be offered PrEP and whether gastrointestinal (GI) side-effects with PrEP initiation could exacerbate pregnancy-related GI side-effects and discourage adherence. In addition, while there is extensive data about PrEP implementation in developed countries, and some data about implementation in 'key populations' in Africa, very little is known about PrEP implemented a novel PrEP delivery program within MCH clinics. The goal of the PrEP Implementation for Young Women and Adolescents (PrIYA) program was to provide real-world evidence on delivering PrEP to women attending MCH clinics in a high HIV prevalence region, particularly among adolescent girls and young women.

### Methodology

### Study settings

The PrIYA program was implemented by University of Washington in collaboration with the Kisumu County Department of Health (KCDH) from July 2017. Between July and October 2017, implementation was disrupted by strikes among public sector health workers and breaks in services due to political unrest. During this period, medication supply systems were optimized, procedures were piloted in faith-based and private clinics, and data abstraction systems were refined. The program reinitiated in all facilities in November 2017.

We worked closely with the National AIDS & STI Control Programme (NASCOP) under the Ministry of Health and Kisumu County Department of Health in planning the program implementation. The KCDH was consulted in selection of MCH facilities and ensured availability of PrEP medications. In addition, KCDH was involved in staff training and provided facilitators for sessions on PrEP commodity management and use of Ministry of Health reporting tools. At each facility, we conducted sensitization sessions to introduce the program, educate facility staff on PrEP and seek advice on the best way to integrate PrEP delivery at the facility. Importantly, the program participated in County PrEP Technical Working Group meetings where the framework of implementing PrEP was developed

PrEP counseling was provided by 40 dedicated PrIYA program nurses. In partnership with KCDH and NASCOP, we provided the nurses with a 3-day training that included on overview of PrEP, didactic and practical sessions on PrEP counseling, review of the HIV risk assessment screening tool (RAST), HIV retesting and consenting processes, point-of-care creatinine testing, and review of case scenarios developed by NASCOP to assist providers understand indications of PrEP. PrIYA nurses enhanced their counseling skills through role playing and debriefing. Three program supervisors conducted visits to offer technical support and address challenges. PrIYA nurses were integrated in the clinics and provided

MCH services when they were not offering PrEP counseling. We have previously described our approaches and time-and-motion data on PrEP delivery.(16)

### Study design and participants

The program was implemented in 16 MCH clinics (public, faith-based, and private sector ) selected in consultation with the KCDH based on client volume and geographical location to ensure that all seven sub-counties in Kisumu were included. Facilities varied in size from health centers with ~500 first antenatal clinic attendees per year to large county hospitals with over 1500 attendees per year. Kisumu County has the second highest HIV incidence rate in the in Kenya contributing almost 14% of new infections.(17). HIV prevalence is ~20% which is 3.4 times higher than the national prevalence and is higher among women (21%) than in men (18%).(17), More than half (51%) of all new HIV infections in Kenya in 2015 occurred among adolescents and adults aged 15–24 years, most (~65%) among adolescent girls and young women.

Women >15 years seeking antenatal care or child welfare services at MCH clinics at participating facilities, who tested HIV negative at that visit or within a month and were willing to receive PrEP counselling were invited to participate. Program nurses approached all eligible women and provided PrEP counseling as part of routine MCH clinic processes. The protocol, implementation plan, data collection tools, and patient education materials were reviewed and approved by the Kenyatta National Hospital-University of Nairobi Ethics Research Committee and University of Washington Human Subjects Review Committee. In addition, approval was obtained from the KCDH and administrators in respective health facilities. Women provided oral consent for all program activities.

### Procedures

Women presenting for first antenatal care visit had HIV testing and syphilis screening. HIV testing was conducted by facility provider or PrIYA nurses as per the Kenya HIV Testing guidelines.(18) Syphilis screening was by rapid plasma reagin (RPR). Other sexually transmitted infections were managed syndromically.

We used paper-based forms to collect data which were subsequently abstracted to an encrypted cloud-based database using tablets. Among women who were pregnant, data on gestational age, prior antenatal care attendance and RPR test results were collected. All women were asked about behavioral HIV risk factors using the PrEP rapid assessment screening tool (RAST) adapted from the NASCOP PrEP screening tool.(14) The tool assessed the woman's knowledge of HIV status of her sexual partner(s) and whether in preceding 6 months, she had sex without a condom with a partner(s) of unknown or positive HIV status, engaged in sex in exchange for money or other favors, had been diagnosed with or treated for an sexually transmitted infection (STI), shared needles while engaging in intravenous drug use (IDU), been forced to have sex against her will, was physically assaulted by sexual partner(s), or had used post-exposure prophylaxis at least two times.

Counseling utilized risk information from the RAST tool. Women who reported that their sexual partners were living with HIV or of unknown HIV status and had one or more other risk factors were counseled about their risk for HIV. Women who did not know the HIV

status of their partners were offered HIV self- tests kits if they were willing to test with their partners at home. (19) All women (regardless of risk factors) were informed that PrEP was available if they perceived they were at risk for HIV. Among women with identified risk factors for HIV who declined PrEP, we assessed reasons for declining PrEP. In November 2017, we started collecting data on whether the woman had previously received PrEP screening

PrEP was dispensed from the MCH clinic by nurses at the same visit. Prior to PrEP initiation, women were screened for symptoms of acute HIV infection (fever, rash, pharyngitis, and lymphadenopathy). Creatinine testing was conducted using a validated point-of-care test (StatSensor<sup>®</sup> Point-of-Care Creatinine and eGFR Analyzers, Nova Biomedical)(20). PrEP was not dispensed if creatinine clearance was below 50 ml/min. Those women were referred for review by physician. Women were prescribed PrEP for a month, counseled on importance of adherence, and return visit for medication refill were scheduled (preferably to coincide with date of next antenatal or postnatal care visit. During adherence counselling, women were informed that failing to take their drug even occasionally would reduce the protective benefit, encouraged to set a time when they would be taking their medication and asked to contact PrIYA or facility staff if they had concerns. Potential barriers to adherence were explored and ways of overcoming them discussed.

At the one, three and six month post-PrEP initiation visits, women were reassessed using the Ministry of Health client encounter form used for PrEP follow-up. The form captured demographics, blood pressure, weight and height, HIV test results, behavioural risk assessment, and presence of chronic illness or co-morbid conditions Additional data included signs/symptoms of acute HIV infection and PrEP regimen prescribed and duration. HIV retesting was conducted and PrEP refill prescribed if women tested HIV-negative after counseling on the importance of adherence and HIV risk reduction were offered and up-to 3 months of PrEP medication dispensed.

### Statistical analysis

Analyses for this evaluation used data from women enrolled between November 2017 and June 2018, with follow-up through July 2018 and restricted to first time screeners. Descriptive analysis using proportions, median and interquartile ranges was used to summarize PrEP uptake, partner HIV testing, HIV risk factors and reasons for not initiating PrEP among women with risk factors. We used Poisson regression clustered by clinic to determine correlates of PrEP initiation, and continuation. Age, marital status, reported male partner HIV status, and pregnancy status were considered a priori to have substantial influence on uptake and continuation, and were subsequently included in the multivariate analysis. PrEP continuation rates at 1-, 3 and 6-months post-initiation visits.

### Role of the funding source

The funding source had no involvement in the study design, data collection or analysis, interpretation of results, and writing of this report. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication without involvement of the funding source.

### Results

Overall, 9376 women were offered PrEP between November 2017 and June 2018. The median age was 24 years, 49% were between 18 and 24 years and most (86%) were married or cohabitating, of whom 4% were in polygamous marriages (Table 1). Majority of women were pregnant. Women with partners living with HIV were older, compared to women with HIV-negative partners or partners of unknown HIV status. Overall, during the 6-month period prior to assessment for PrEP, almost all women reported having sex without a condom. The proportion of women reporting sex without condom in the previous six months was lower among women with PLWH compared to those with HIV-negative partners and those with partners of unknown HIV status.

Overall, 22% of women initiated PrEP; 79% among women with partners living with HIV, 37% among women with partners of unknown HIV status, and 12% of women with HIV-negative partners. Almost half of women who initiated PrEP were under 24 years of age.

In univariate analyses, women who were younger than 24 years, unmarried/not cohabiting, postpartum compared to pregnant were more likely to initiate PrEP (Table 2). Women with partners living with HIV or partners of unknown HIV status were much more likely to initiate PrEP compared to those with HIV-negative partners. Women<26 weeks gestation were more likely to initiate PrEP than those 26 weeks gestation

In multivariable analysis, age <24 years, having a PLWH or partner of unknown HIV status gestational age <26 weeks among pregnant women, or in the previous six months having experienced IPV or sharing needles while engaging in IDU were associated with PrEP initiation.

In the sub-group of women with partners of unknown HIV status, associations remained similar to the overall analysis (appendix 1 page 1). In a multivariable analysis, postpartum period compared to during pregnancy STI, forced sex, sharing needles, or recurrent PEP use were associated with PrEP initiation. Unlike the overall group of women, in the sub-group of women with HIV-negative partners, those who were married or cohabiting were significantly less likely to initiate PrEP than those who were not (appendix 1 page 2). Similar to the overall analysis, women with risk factors were more likely initiate PrEP

The most common self-reported reasons for initiating PrEP were: having a partner living with HIV or partner of unknown HIV status and feeling at risk for acquiring HIV. Among PrEP initiators, women with HIV-negative partners more often reported that they felt at risk of acquiring HIV than those with partners of unknown HIV status or partners living with HIV. Among women with risk factors for HIV, the most common reasons for declining PrEP were need to consult partner and low perceived HIV risk (Table 4a).

Overall, 786 (39%) women returned for PrEP refill at least one month after initiation, all retested HIV-negative and were dispensed PrEP; return for PrEP refill was 68% among women with partners living with HIV, 38% with partners of unknown HIV status, and 34% with HIV-negative partners. Compared to women with HIV-negative partners, women with

HIV-positive partners were more likely to continue PrEP at one month (Table 3). Age, marital status, client type (pregnant or postpartum), gestational age, and HIV risk factors at PrEP initiation did not differ between women who continued PrEP and those who did not. In univariate analysis having a partner living with HIV was significantly associated with PrEP continuation.

Among the sub-group of women with HIV-negative partners and partners of unknown HIV status, age, marital status, client type, gestational age, and HIV risk factors were not associated with PrEP continuation (appendix 1 page 3, 4). Among the subgroup of women with partners living with HIV, postpartum period compared to during pregnancy and engaging in transactional sex were associated with PrEP continuation (appendix 1 page 5).

Of the 2030 women who initiated PrEP at least 3 months prior to this evaluation, 441 (22%) returned for PrEP refill, all retested HIV-negative and continued PrEP. Of these, 20% were below 24 years and 23% were 24 years or older (p=0.05). Frequency of 3-month continuation was 50% (76/153) among women with partners living with HIV, 21% (242/1178) with partners of unknown HIV status, and 18% (123/696) with HIV-negative partners. Of the 1618 who initiated PrEP at least 6 months prior to this evaluation, 189 (12%) had continued PrEP for at least 6 months after initiation and all were HIV negative on retesting; 35% among women with PLWH, 10% with partners of unknown HIV status, and 9% with HIV-negative partners. Frequency of PrEP continuation at 6 months was lower among women below 24 years of age compared to those older than 24 years (10% vs. 13%, p=0.06).

Of 1244 women who discontinued PrEP, reasons for discontinuation was ascertained in 427 cases. The most common reasons cited for discontinuation were side effects, no longer perceiving HIV risk and partner known to be HIV-negative (Table 4b). We have previously reported that initiation of PrEP during pregnancy was associated with more side-effects than postpartum and side-effects were a more frequent contributor to discontinuation during pregnancy than postpartum(21).

### Discussion

In this first-of-its-kind large PrEP implementation program in MCH clinics in a high HIV prevalence region in Africa, there was high uptake and modest continuation of PrEP among pregnant and postpartum women, including adolescents and young women, and no incident HIV infections were detected. Our results demonstrate that MCH clinics can be an effective platform for PrEP delivery. MCH clinics currently deliver PMTCT services including HIV testing and retesting and can thus identify women at risk for HIV who could benefit from PrEP. Attendance in MCH clinics is high, enabling access to large population of at-risk women.

While factors such as transactional sex, STI or IPV were infrequently reported by women attending MCH clinic, these factors significantly influenced decision to initiate PrEP. Our findings suggest that counseling resulted in 'appropriate' PrEP use, even though PrEP was offered to all women. WHO recommends that HIV risk should be assessed periodically as

the woman's circumstances may change over time either making PrEP no longer necessary or recognizing new risks and need for PrEP.(22) Potential changes in HIV risk over time underscores the importance of open discussion about HIV prevention to empower women to seek PrEP in periods of increased HIV vulnerability.

Low male partner participation in PMTCT results in pregnant women often being unaware of their partners HIV status.(23) Having a male partner with unknown HIV status has been found to be highly predictive of HIV acquisition during pregnancy and breastfeeding. (24) A study in South Africa among pregnant and postpartum women found that among woman who acquired HIV and whose partners tested HIV-positive, partners first accepted HIV testing only after the woman seroconverted.(25) Innovative strategies such as HIV self-testing may increase male partner testing and woman's awareness of partner HIV status.(26) We previously reported that in our program,53% of women with partners of unknown HIV status offered partner HIV self-tests received the kits which potentially increases accuracy of a women's estimation of HIV risk and PrEP decision-making.(19)

PrEP is an attractive HIV prevention option for women with partners of unknown HIV status who find it difficult to negotiate condom use. Condoms are not widely used by pregnant or postpartum women, who are usually married.(7) PrEP offers protection while allowing time for the woman to encourage her partner to get tested and initiate treatment if HIV-infected PrEP could therefore serve as a bridge allowing time for partner living with HIV to become virally suppressed.

The most common reason cited for initiating PrEP was that the woman felt she was at risk of acquiring HIV In a qualitative study among HIV-uninfected pregnant women, women reported that pregnancy was a time of high HIV risk because they desired sex less frequently, which may lead their partners to have outside partnerships.(15) Need to consult partner reported by women with risk factors for HIV suggests that male partners could impede PrEP use. In a previous qualitative study, women reported that they feared that male partners could react negatively, including becoming physically violent, if they discovered that women used PrEP.(15) Women felt that health providers were better placed to explain PrEP to their male partners.(15) However, low male attendance at MCH clinics limits utility of this approach.

In our program, few women cited fear of violence from their partner as reason for not initiating PrEP. Previous studies have shown that pregnant women who experience IPV are at increased risk of HIV acquisition, and could potentially benefit from PrEP.(27) However, IPV has been associated with PrEP non-adherence, which limits PrEP effectiveness. (28) Strategies to promote PrEP uptake and adherence among women at risk of IPV should be evaluated. Pill burden was cited as a barrier to PrEP uptake. This is an important consideration for women given that adherence is less forgiving than in men and may be particularly important in pregnant women, who may need higher dosing.(29). PrEP programs could consider use of short message systems texts that may improve adherence and retention in care.(30)

Among women who initiated PrEP almost 40% continued PrEP for at least one month, with 67% of those with partners living with HIV continuing. Similar PrEP continuation rates have been observed in female sex workers, men who have sex with men and among US heterosexual women, most of whom had a HIV-infected male partner.(31, 32) Higher PrEP continuation rates, over 80%, were observed in an open-label demonstration project in East Africa evaluating delivery of PrEP in heterosexual HIV serodiscordant couples.(33) Since PrEP is recommended during periods of HIV vulnerability, it was not surprising for women to discontinue PrEP when they learned their partners were HIV-negative, or when they felt no longer at risk because they were not sexually active. A recent prospective cohort study reported reduced frequency of sexual activity during pregnancy with gradual increase after delivery.(7)

It appears that when women discuss PrEP with providers, some envision their potential risk and decide to initiate PrEP at the visit. However, on returning home they either start PrEP or reconsider risk and elect to not start PrEP. Over time they continue to reassess risk and PrEP experience. If a woman finds out her partner is uninfected, does not have sex for a certain time period, or finds PrEP intolerable or stigmatizing she may discontinue PrEP. Further qualitative studies are needed to better understand why women discontinue PrEP.

Our program was donor funded which allowed us to hire dedicated program nurses whose prime responsibility was to counsel women on PrEP, conduct HIV risk assessment and deliver PrEP. However, most facilities in our settings suffer from inadequate workforce limiting utility of this approach. In absence of a dedicated PrEP nurse, a model where the HIV testing counselor offers PrEP to women during post-test counseling and refers those willing to initiate to the nurse for PrEP prescription is an attractive option which has been feasible in some clinics.

Our evaluation had several strengths. The large number of women offered PrEP ensured that we had adequate power to assess correlates of PrEP initiation and continuation. Use of dedicated nurses facilitated implementation of the program in settings with nurse shortages. (16) Our evaluation also had limitations. Assessment was conducted as a part of program implementation rather than research, limiting depth of exploration of factors associated with initiation and continued PrEP. Not all women who initiated PrEP returned to the clinic limiting our ability to ascertain reasons for PrEP discontinuation. It is almost certain that women who did not return did not continue PrEP, suggesting that our continuation rate estimates are valid. However, given the large drop off, our findings on reasons for discontinuation may be biased and less generalizable. Incentives for transport to return could increase retention and improve ascertainment of reasons for discontinuation, but this was not possible in a programmatic evaluation.

In conclusion, we found that a substantial proportion of women attending MCH clinics had risk factors for HIV. Many women elected to use PrEP when offered indicating that MCH clinics served as an effective platform for PrEP delivery. Adolescents and women younger than 24 years were more likely to initiate PrEP than older women. Awareness of male partners' HIV status was low underscoring need for strategies to optimize partner HIV testing. For a pregnant or breastfeeding woman who does not know her partner's HIV status,

PrEP can be used discreetly to protect herself and her baby as she encourages her partner to get HIV tested. PrEP is currently a novel intervention among MCH clients in high HIV prevalence settings. As PrEP awareness rises in these communities and clinics, uptake and continued use may increase reducing the high HIV incidence reported especially among adolescent girls and young women.

### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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### Table 1.

Characteristics of pregnant and postpartum women offered PrEP at MCH clinics, by partner HIV status (N=9376)

	n (%) or Median (IQR)				
			Partner's HIV Status		
Demographic characteristics	Overall (9376)	Negative (N=5997)	Unknown (N=3165)	Positive (N=193)	P-value
Age (years)	24.0 (21.0, 28.0)	24.0 (21.0, 28.0)	24.0 (20.0, 28.0)	28.0 (24.0, 32.0)	<0.0001
Age category (years) <18	443 (4.7)	201 (3.4)	234 (7-4)	6 (3-1)	<0.0001
18–24	4590 (49.0)	3004 (50.1)	1525 (48·2)	47 (24.4)	
25–29	2623 (28.0)	1742 (29.0)	813 (25.7)	65 (33.7)	
30–34	1248 (13.3)	798 (13.3)	404 (12.8)	45 (23.3)	
35	471 (5.0)	252 (4-2)	189 (6.0)	30 (15.5)	
Marital status					<0.0001
Married/cohabiting	7993 (85.7)	5369 (89.9)	2436 (77.4)	185 (96.4)	
Not married/cohabiting	1339 (14.3)	604 (10.1)	711 (22.6)	7 (3.6)	
Marriage type					<0.0001
Monogamous	7542 (96.4)	5168 (98-2)	2217 (93-2)	155 (85-2)	
Polygamous	284 (3.6)	96 (1.8)	161 (6.8)	27 (14.8)	
Client type					<0.0001
Pregnant	4912 (52.4)	3370 (56-2)	1446 (45.7)	90 (46.6)	
Postpartum	4464 (47.6)	2627 (43.8)	1719 (54-3)	103 (53-4)	
Clinical characteristics					
Gestational age in weeks (N=4798) <sup>1</sup>	26.0 (20.0, 32.0)	26.0 (20.0, 32.0)	26.0 (20.0, 31.0)	21.5 (18.0, 28.0)	0.01
First ANC visit (N=4788) <sup>1</sup>	2167 (45.3)	1411 (42.6)	719 (50.7)	34 (59.6)	<0.0001
RPR results (N=5068) <sup><math>1</math></sup>					<0.0001
Reactive	19 (0.4)	11 (0.3)	8 (0.5)	0 (0.0)	
Nonreactive	4224 (83-3)	2998 (85.4)	1177 (79.5)	45 (63.4)	
Not done/unknown	825 (16.3)	503 (14-3)	295 (19.9)	26 (36.6)	
HIV tested as couple during ANC (N=5143) <sup>1</sup>	303 (5.9)	275 (7.7)	13 (0.9)	15 (17.0)	<0.0001
Behavioral risk factors <sup>2</sup>					
Ever had sex without a condom	8898 (94.9)	5749 (95.9)	2962 (93.6)	173 (89.6)	<0.0001
Engaged in sex in exchange of money/ favors	38 (0.4)	11 (0.2)	25 (0.8)	2 (1.0)	<0.0001

		n (%) or N	Aedian (IQR)		
			Partner's HIV Status		
Demographic characteristics	Overall (9376)	Negative (N=5997)	Unknown (N=3165)	Positive (N=193)	P-value
Diagnosed with or treated for an STI	69 (0.7)	32 (0.5)	32 (1.0)	5 (2.6)	0.001
Forced to have sex	80 (0.9)	28 (0.5)	46 (1.5)	5 (2.6)	<0.0001
Experienced IPV	217 (2.3)	92 (1.5)	118 (3.7)	7 (3.6)	<0.0001
Shared needles while engaging in IDU	11 (0.1)	3 (0.1)	8 (0.3)	0 (0.0)	0.02
Used PEP >2 times	15 (0.2)	10 (0.2)	5 (0.2)	0 (0.0)	0.85
Accepted PrEP	2030 (21.7)	696 (11.6%)	1178 (37·2%)	153 (79.3%)	<0.0001

<sup>1</sup>Among pregnant women

 $^{2}$ Experienced in the last six months IPV=Intimate partner violence, ANC=antenatal care, STI=sexually transmitted infections, IDU= intravenous drug use, PEP= Post exposure prophylaxis

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MCH services
women receiving
among all
initiation
<b>Correlates of PrEP</b>
-

	Univari	ate			Multivariable <sup>#</sup>	
	Proportion who ir	nitiated PrEP	Prevalence ratio <sup>2</sup>		Adjusted prevalence ratio <sup>2</sup>	
Demographic characteristics	Among all PrEP Initiators	Within Risk Category	(95% CI)	P value	(95% CI)	p-value
Age (years) <24	999/2030 (49-2)	999/4261 (23·4)	1.16 (1.06–1.27)	0.001	1.15 (1.07–1.25)	0.001
24	1031/2030 (50.8)	1031/5114 (20·2)	1		Ι	
Marital status Not married/cohabiting	387/2018 (19-2)	387/1339 (28·9)	1.42 (1.23–1.64)	1000-0>	1.010 (0.99–1.23)	0.08
Married/Cohabiting	1631/2018 (80.8)	1631/7993 (20·4)	1		1	
Partner HIV status						
Positive	153/2027 (7.6)	153/193 (79.3)	6.83 (5.27–8.85)	<0.0001	6.96 (5.46–8.89)	<0.0001
Unknown	1178/2027 (58·1)	1178/3165 (37·2)	3.21 (2.58–3.99)	<0.0001	3.08 (2.50–3.81)	<0.0001
Negative	696/2027 (34.3)	696/5997 (11.6)	1		1	
Client type						
Postpartum	1117/2030 (55-0)	1117/4464 (25·0)	1.35 (1.01–1.79)	0.04	1.19 (0.95 - 1.51)	0.14
Pregnant	913/2030 (45.0)	913/4912 (18·6)	1		1	
Clinical characteristics						
Gestational age $^{I}$						
<26 weeks	447/850 (52.6)	447/2269 (19-7)	1.24 (1.02 - 1.50)	0.03	1.22 (1.02–1.47)	0-03
26 weeks	403/850 (47-4)	403/2529 (15-9)	1		1	
Behavioral risk factors (last 6 1	months)					
Transactional sex $^*$						
Yes	17/2029 (0.8)	17/38 (44-7)	2.08 (1.38–3.11)	=0.001	1.33 (0.81–2.21)	0.26
No	2012/2029 (99·2)	2012/9334 (21.6)	1		Г	

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	Univari	ate			Multivariable#	
	Proportion who ir	nitiated PrEP	Prevalence ratio <sup>2</sup>		Adjusted prevalence ratio <sup>2</sup>	
Demographic characteristics	Among all PrEP Initiators	Within Risk Category	(95% CI)	P value	(95% CI)	p-value
STI diagnosis						
Yes	31/2029 (1.5)	31/69 (44.9)	2.09 (1.38–3.16)	=0.001	1.57 (1.20–2.06)	0.001
No	1998/2029 (98-5)	1998/9305 (21·5)	1		1	
Forced to have sex						
Yes	45/2029 (2·2)	45/80 (56·3)	2.63 (1.86–3.74)	<0.0001	182 (1.38–2.42)	<0.0001
No	1984/2029 (97.8)	1984/9292 (21-4)	1		1	
Experienced intimate partner						
violence Yes	98/2028 (4.8)	98/217 (45·2)	2.14 (1.33–3.45)	0.002	1.65 (1.10–2.48)	0.02
No	1930/2028 (95.2)	1930/9155 (21·1)	1		1	
Shared needles while engaging						
in intravenous drug use Yes	8/2030 (0-4)	8/11 (72·7)	3.37 (2.47–4.59)	<0.0001	2.43 (1.69–3.50)	<0.0001
No	2022/2030 (99-6)	2022/9362 (21·6)	1		1	
Recurrent PEP use						
Yes	6/2028 (0-3)	6/15 (40-0)	1.85 (1.13–3.03)	0-01	1.96 (1.36–2.82)	<0.001
No	2022/2028 (99-7)	2022/9358 (21-6)	1		1	
IPV=Intimate partner violence. A	NC=antenatal care. STI=sexually	v transmitted infections. IV	/D= intravenous drug	use, PEP= F	ost exposure prophylaxis	

# djusted for age, marital status, reported male partner HIV status, and pregnancy status

 $\mathcal{Z}_{\text{Accounted for clinic-level clustering}}$ 

 $I_{\rm A}$  mong pregnant women with known gestational age (N=4798) who initiated PrEP

\* had sex in exchange for money or favours,

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		Univaria	te			Multivariable	
		Proportion who con	tinued PrEP	Prevalence ratio <sup>2</sup>		Adjusted prevalence ratio <sup>2</sup>	
Demographic charac	teristics	Among all PrEP Continuers	Within Risk Category	(95% CI)	P value	(95% CI)	p-value
Client type	Postpartum Pregnant	468/786 (59-5) 318/786 (40-5)	468/1117 (41·9) 318/913 (34·8)	1·20 (0·97–1·50) 1	0.10		
Age (years)	<24 24	374/786 (47·6) 412/786 (52·4)	374/999 (37.4) 412/1031 (40.0)	0.94 (0.79–1.11) 1	0.46		
Marital status Not ma Ma	arried/cohabiting rried/Cohabiting	136/783 (17.4) 647/783 (82.6)	136/387 (35-1) 647/1631 (39-7)	0.89 (0.78–1.00) 1	0.06		
Partner HIV status	Positive Unknown Negative	104/786 (13·2) 447/786 (56·9) 235/786 (29·9)	104/153 (68-0) 447/1178 (38-0) 235/696 (33-8)	2:01 (1:52–2:66) 1:12 (0:96–1:31) 1	<0.0001	1.98 (1.54–2.55) 1	<0.0001
Clinical characteristi	ics						
Gestational age I	<26 weeks 26 weeks	161/287 (56-1) 126/287 (43-9)	161/447 (36-0) 126/403 (31-3)	1.15 (0.95–1.40) 1	0.15		
Behavioral risk facto	ors (last 6 months)						
Transactional sex No	Yes	9/786 (1-2) 777/786 (98-9)	9/17 (52.9) 777/2012 (38.6)	1.37 (0.82–2.31) 1	0.23		
STI diagnosis	Yes No	13/786 (1.7) 773/786 (98-4)	13/31 (41.9) 773/1998 (38·7)	1.08 (0.77–1.53) 1	0.65		
Forced to have sex	Yes No	19/785 (2·4) 766/785 (97·6)	19/45 (42·2) 766/1984 (38·6)	1.09 (0.78–1.53) 1	0.60		

	Proportion who con	ttinued PrEP	Prevalence ratio <sup>2</sup>		Adjusted prevalence ratio <sup>2</sup>	
Demographic characteristics A	Among all PrEP Continuers	Within Risk Category	(95% CI)	P value	(95% CI)	p-value
Experienced IPV Yes	39/786 (5-0)	39/98 (39.8)	1.03 (0.81–1.30)	0.82		
No	747/786 (95-0)	747/1930 (38·7)	1			
Shared needles while engaging in IDU						
Yes	2/786 (0.3)	2/8 (25-0)	$0.64\ (0.20{-}2.10)$	0.47		
No	784/786 (99-8)	784/2022 (38·8)	1			
Recurrent PEP use Yes	2/785 (0.3)	2/6 (33·3)	0.86 (0.38–1.97)	0.72		
No	783/785 (99.8)	783/2022 (38·7)	1			

 $^{I}{}_{\rm Among}$  pregnant women with known gestational age (N=850) who initiated PrEP,

# adjusted for age, marital status, reported male partner HIV status, and pregnancy status

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<sup>2</sup>Accounted for clinic-level clustering

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#### Table 4a.

Reasons for initiating PrEP among all PrEP initiators and reasons for non-initiation among women with HIV risk factors

			Partner HIV status	<sub>5</sub> 1
Reason for initiating PrEP*	Overall (N=2027)	Positive (N=153)	Negative (N=696)	Unknown (N=1178)
Knowledge of partner's HIV status <sup>2</sup>	544 (40.9)	96 (62.8)		448 (38.0)
I feel at risk for acquiring HIV	667 (32.9)	25 (16.3)	257 (36.9)	385 (32.7)
I think my partner may have other partners	358 (17.7)	2 (1.3)	170 (24-4)	186 (15.8)
To protect my baby from HIV	39 (1.9)	3 (2.0)	11 (1.6)	25 (2.1)
I am interested in trying something new	27 (1.3)	0 (0.0)	15 (2.2)	12 (1.0)
Other. <sup>3</sup>	30 (1.5)	2 (1.3)	13 (1.9)	15 (1.3)
Reasons for not initiating PrEP	Overall N=202)	Positive (N=4)	Negative (N=109)	Unknown (N=89)
Knowledge of partner's HIV status <sup>4</sup>	29 (25.7)	3 (75.0)	26 (23.9)	
Need to consult partner	69 (34.2)	0 (0.0)	34 (31.2)	35 (39.3)
Low perceived HIV risk	61 (30-2)	0 (0.0)	44 (40.4)	17 (19-1)
Pill burden	24 (11.9)	2 (50.0)	12 (11.0)	10 (11·2)
Fear of intimate partner violence	29 (14.4)	0 (0.0)	15 (13.8)	14 (15.7)
Fear that partner will find out	15 (7.4)	0 (0.0)	6 (5.5)	9 (10-1)
Fear of side effects	2 (1.0)	0 (0.0)	1 (0.9)	1 (1.1)
Fear of effects on unborn baby $5$	1 (1.4)		0 (0.0)	1 (3.0)

<sup>1</sup>Self- reported by the woman

 $^{2}$ Client reported knowledge that partner was virally suppressed (if partner living with HIV), or did not know partner's status (N=1331)

 $^{3}$  Other reasons listed included: In a polygamous marriage and does not trust co-wife, has multiple partners, co-wife is is living with HIV, partner is away often or does not live close, partner has been treated for an STI, engages in transactional sex, and partner has previously been unfaithful.

<sup>4</sup>Client reported knowledge that partner was HIV-negative or, if living with HIV, virally suppressed (N=113).

<sup>5</sup> Among pregnant women (N=70)

#### Table 4b.

Reasons for discontinuing PrEP, among women who were known to have discontinued PrEP within one month of initiation

			Partner HIV statu	s <sup>1</sup>
Reason given	Overall (N=427)	Positive (N=9)	Negative (N=169)	Unknown (N=248)
Partner virally suppressed <sup>2</sup>	0 (0.0)	0 (0.0)		
Partner known HIV-negative $^3$	74 (17.8)		28 (16.6)	46 (18.6)
Experienced side effects	107 (25.1)	1 (11.1)	46 (27.2)	59 (23.8)
Too many HIV tests	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)
Pill burden	73 (17-1)	0 (0.0)	25 (14.8)	48 (19.4)
Fear of effects on baby	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.4)
Fear partner will find out	6 (1.4)	0 (0.0)	3 (1.8)	3 (1·2)
No perceived risk	88 (20.6)	3 (33·3)	32 (18.9)	53 (21.4)
Need to consult partner	4 (0.9)	0 (0.0)	2 (1.2)	2 (0.8)
Fear of intimate partner violence	45 (10.5)	0 (0.0)	19 (11-2)	26 (10.5)
Adverse event	3 (0.7)	0 (0.0)	2 (1.2)	1 (0.4)
My partner was unhappy about use	41 (9.6)	0 (0.0)	21 (12.4)	20 (8.1)
Other <sup>4</sup>	107 (25.1)	5 (55.6)	46 (27.2)	56 (22.6)

<sup>1</sup>Self-reported by the woman

 $^2$ Among women who discontinued and whose partner was living with HIV at time of screening (N=9)

 $^{3}$ Among women who discontinued and whose partner was known HIV-negative or had unknown status at time of screening (N=417)

<sup>4</sup>Other responses included: client will take PrEP after delivery, client is currently not sexually active, client is away from her partner or her partner is away, client is unable to return to clinic, client has been discouraged from using PrEP by someone other than her partner, client was not adherent