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PrEP initiation, persistence, and adherence during pregnancy through the postpartum period: a prospective analysis in Kenya

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Abstract

Objective: We evaluated PrEP initiation, persistence, and adherence measured via tenofovir-diphosphate (TFV-DP) concentrations in dried blood spots (DBS) among women offered PrEP during pregnancy.

Methods: We prospectively analyzed data from participants in the PrIMA Study (NCT03070600) who were offered PrEP during the 2nd trimester and followed through 9-months postpartum. At follow-up visits (monthly in pregnancy; 6 weeks, 6 months, 9 months postpartum), self-reported PrEP use was assessed, and DBS were collected for quantifying TFV-DP concentrations.

Results: In total, 2949 participants were included in the analysis. At enrollment, median age was 24 years (IQR 21–29), gestational age 24 weeks (IQR 20–28), and 4% had a known partner living with HIV. Overall, 405 (14%) participants initiated PrEP in pregnancy with higher frequency among those with risk factors for HIV acquisition, including >2 lifetime sexual partners, syphilis during pregnancy, forced sex, and intimate partner violence ($p<0.05$). At 9-months postpartum, 58% of PrEP initiators persisted with PrEP use, of which 54% self-reported not missing any PrEP pills in the last 30 days. Among DBS randomly selected from visits where participants persisted with PrEP (n=427), 50% had quantifiable TFV-DP. Quantifiable TFV-DP was twice as likely in pregnancy than postpartum (aRR=1.90, 95% CI 1.40–2.57, $p<0.001$). Having a partner known to be living with HIV was the strongest predictor of PrEP initiation, persistence, and quantifiable TFV-DP ($p<0.001$).

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Conclusions: PrEP persistence and adherence waned postpartum, though over half of PrEP initiators persisted through 9-months postpartum. Interventions should prioritize increasing knowledge of partner HIV status and sustaining adherence in the postpartum period.

INTRODUCTION

High HIV incidence among young cisgender women in East and Southern Africa persists during pregnancy[1] and HIV acquisition risk increases by 2-fold during pregnancy and the postpartum period compared to non-pregnant periods.[2–5] The World Health Organization (WHO) recommends offering daily oral tenofovir disoproxil fumarate (TDF)-based pre-exposure prophylaxis (PrEP) to pregnant and lactating people at substantial risk for HIV.[6–9] PrEP delivery is scaling up in East and Southern Africa with notable uptake successes in PrEP implementation among pregnant women in Kenya and ongoing demonstration projects in South Africa, Lesotho, Malawi, Zambia and Zimbabwe.[6,10–14] Up to 79% of pregnant women with characteristics associated with HIV acquisition, such as having a male partner known to be living with HIV, accept PrEP pills when offered within routine antenatal care in Kenya.[15] Few data exist on longitudinal PrEP use patterns after PrEP is initiated during pregnancy and available evidence suggests early and frequent PrEP discontinuation.[15]

PrEP effectiveness depends on adherence[16–18], yet taking daily oral PrEP is challenging and the transitional periods of pregnancy and postpartum present unique PrEP adherence barriers.[10,19,20] In qualitative studies, motivation for PrEP use during pregnancy was driven by the desire to prevent HIV transmission to infants.[21,22] PrEP adherence may be reduced postpartum if perception of the infant's HIV risk is reduced, similar to waning adherence patterns among women living with HIV (WLHIV) receiving antiretroviral therapy (ART).[23,24] Additionally, common symptoms of pregnancy overlap with PrEP-related side effects, which may negatively impact adherence in pregnancy.[21,22] Existing data suggest PrEP adherence, measured via self-report, is suboptimal among pregnant women in Kenya.[25–27] Longitudinal data on PrEP initiation, persistence, and adherence among pregnant women could help elucidate the PrEP continuum of care in this unique population and identify opportunities for promoting PrEP use among those most likely to benefit.

We prospectively analyzed data from participants enrolled in the PrEP Implementation for Mothers in Antenatal Care (PrIMA) study to quantify and identify cofactors of PrEP initiation, persistence, and adherence among cisgender Kenyan women offered PrEP during pregnancy who were followed until 9-months postpartum. Our overall objective was to expand evidence on the PrEP continuum of care among pregnant and postpartum Kenyan women and inform strategies for enhancing PrEP use in this population.

METHODS

Study population and setting

The PrIMA Study protocol has been previously described (NCT03070600).[28] Briefly, the PrIMA Study was a cluster randomized trial conducted between January 2018 and July 2021 that evaluated PrEP delivery models (universal vs. risk-based PrEP offer) among pregnant cisgender women attending 20 antenatal care (ANC) clinics in Siaya and Homa Bay, Kenya–

a region with a HIV prevalence of 20% among women.[29,30] ANC attendees were eligible for enrollment if they were currently pregnant, HIV-negative, not currently using PrEP, ≥15 years old, tuberculosis negative, planned to reside in the region for at least 1-year postpartum, planned to receive postnatal care at the study facility, and were not enrolled in another study.

Study procedures

At enrollment, participants had confirmatory HIV testing. At clinics assigned to the universal PrEP offer arm, participants received PrEP counselling using a standardized script which included a list of behaviors associated with HIV acquisition and considerations for PrEP use, after which participants decided whether to initiate PrEP. At clinics assigned to risk-based PrEP offer, participants were assessed for HIV acquisition risk using an empiric HIV risk scoring tool validated to predict HIV risk in Kenyan pregnant and postpartum women[31]; only those determined to be at high risk (risk scores >6) were offered PrEP. In both arms, participants who elected to use PrEP were assessed for PrEP medical eligibility (based on Kenya Ministry of Health guidelines);[32] <1% of participants were medically ineligible for PrEP in the parent study. Participants in the risk-based PrEP offer arm were also offered HIV self-test kits (HIVST) for use with their partners. During the study period, the Kenya Ministry of Health introduced offer of partner HIVSTs to women attending ANC; thus, data on HIVST uptake was collected in both study arms. Participants had monthly study visits during antenatal care, followed by postnatal care visits at 6 weeks, 14 weeks, 6 months, and 9 months postpartum aligned with Kenyan national guidelines.

Data collection

At enrollment, questionnaires were administered on sociodemographic and psychosocial characteristics, self-efficacy, behaviors associated with HIV acquisition and HIV risk perception, partnership characteristics, intimate partner violence (IPV) using the Hurt, Insult, Threaten, Scream (HITS) scale,[33] PrEP knowledge, partner HIV status, and obstetric history. At follow-up visits, experience of PrEP-related side effects (e.g., nausea, vomiting, diarrhea, etc.) was collected. Self-reported PrEP adherence was assessed by ascertaining the number of missed doses in the past 30 days. Information on partner HIV status self-test outcomes were self-reported by participants.

Laboratory procedures

Participants received HIV testing at all study visits following Kenyan national guidelines. Dried blood spots (DBS) were collected for tenofovir diphosphate (TFV-DP) quantification by study nurses who received standardized training on DBS collection via fingerstick. Previous studies demonstrated that DBS from fingerstick and venipuncture can be used for TFV-DP quantification.[34] DBS were transported to a central −20C freezer for storage within a 48-hour window after collection. DBS were collected at all follow-up visits for participants who accepted PrEP.

DBS were tested for TFV-DP in red blood cells using validated ultra-performance liquid chromatography-tandem mass spectrometry (LC-MS/MS) methods at the University of Colorado.[35] Values below the lower limit of quantification for TFV-DP (25 fmol/punch)

were considered unquantifiable.[34] TFV-DP has a half-life of 17 days in red blood cells and DBS provides a marker of cumulative adherence over the prior 1–2 months once steady state is achieved (typically 1 month).[34] TFV-DP concentration results were not returned to participants as TFV-DP quantification is not an approved clinical test in Kenya.

Analysis

Participants were included in the current analysis if they enrolled during the 2nd trimester to allow for similar follow-up time in pregnancy, were followed until 9-months after their pregnancy end date, and remained HIV-negative throughout follow-up. PrEP initiation, persistence, and adherence were evaluated as primary outcomes in the current analysis. Confirmed PrEP initiation was defined as participant-report of swallowing PrEP pills at a follow-up visit after PrEP acceptance at a prior visit. PrEP persistence was assessed at every follow-up visit and defined as participant report of continuing with PrEP medication. At each follow-up visit, self-reported PrEP adherence was dichotomized as those who reported no missed doses versus those who reported missing any doses in the past 30 days. Among a randomly selected subset of PrEP users, PrEP adherence was also defined using TFV-DP concentrations with TFV-DP for DBS collected from visits with self-reported PrEP use. We summarized frequency of having any quantifiable TFV-DP and also the distribution of adherence benchmarks established in IMPAACT 2009 for pregnant and postpartum women (e.g., ≥600 fmol/punch indicating ~7 doses/week) who used directly-observed daily oral TDF/FTC-based PrEP for >4 weeks).[36]

We used univariate Poisson regression models with clustering by site to identify potential correlates of PrEP initiation, persistence, and adherence by comparing characteristics between: 1) women who initiated PrEP vs. those who did not initiate PrEP, 2) women who persisted with PrEP use until 9-months postpartum (i.e., never stopped PrEP use) vs. those who discontinued and did not restart among those who initiated, and 3) women with quantifiable TFV-DP levels vs. those with unquantifiable levels and/or those who discontinued or did not report PrEP use among the random subset. We also compared the subsets for analyses of each respective outcome with the overall PrIMA study population and sub-group of PrEP initiators to evaluate representativeness. Multivariable models were adjusted for age (years), primigravity (yes/no), education (<12 vs. ≥12 years), and partner HIV status (positive, negative, or unknown) based on the known association of these characteristics with PrEP use outcomes.[13,37] We conducted exploratory analyses to evaluate trajectories of PrEP persistence among the subset of participants who had complete self-reported adherence information and attended all postpartum follow-up visits. We also evaluated trajectories of PrEP adherence among the subset of participants who had more than one visit randomly selected for TFV-DP quantification. All analyses were conducted using Stata SE 17.0 (StataCorp, College Station, TX).

Considerations for human subjects

Protocols were approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (P73/02/2017) and University of Washington Institutional Review Board (STUDY00000438). All participants provided written informed consent.

RESULTS

Overall, 2949 participants enrolled during the 2nd trimester, were followed through 9-months postpartum, and met inclusion criteria for the current analysis; there were no appreciable differences between participants included in this analysis and overall PrIMA participants (Supplemental Material). The median age was 24.2 years (interquartile range [IQR] 21.0–28.6), 5.6% were ≤18 years, and 14.4% were formally employed (Table 1). The median gestational age at enrollment was 24 weeks (IQR 20–28), 22.9% were primigravida, and 4.3% had a partner known to be living with HIV.

PrEP initiation

Overall, 14% (95% CI 13%–15%) of women (n=405) enrolled during pregnancy initiated PrEP use. In multivariable analyses, pregnant women were more likely to initiate PrEP if they had characteristics associated with HIV acquisition, including having >2 lifetime sexual partners, having a syphilis diagnosis during pregnancy, being forced to have sex in the last 6 months, and experiencing IPV ($p<0.05$, Table 2). Pregnant women were also more likely to initiate PrEP if they had higher education, had a partner known to be living within HIV or of unknown HIV status, knew someone taking PrEP, and had high perceived risk of HIV acquisition ($p<0.05$). Frequency of PrEP initiation was 4.7-fold higher among women who had high self-efficacy for daily pill taking compared to low self-efficacy (adjusted risk ratio[aRR]=4.67, 95% CI 2.97–7.36, $p<0.001$) and 2.6-fold higher among women with high HIV risk scores compare to lower risk scores (aRR=2.63, 95% CI 1.88–3.67, $p<0.001$). Women who were primigravida were less likely to initiate PrEP during pregnancy than women who had prior pregnancies (aRR=0.70, 95% 0.58–0.85, $p<0.001$). Among women who were offered HIV self-tests for male partners (n=1461), accepting HIVST for at-home couples or partner testing was not associated with PrEP initiation (p=0.775).

PrEP persistence

Overall, 363 women who initiated PrEP in pregnancy either persisted with PrEP use through 9-months postpartum or stopped use without restarting; 42 women restarted PrEP after stopping and were excluded from the persistence analysis. There were no appreciable differences between participants included in the subset and overall PrEP initiators (Supplemental Material). At 9-months postpartum, 58% (95% CI 53%–64%) had persisted with PrEP use and 54% (95% CI 47%–61%) of those who persisted reported not missing any PrEP pills in the last 30 days. Among women with information on reasons for PrEP discontinuation (n=66), the most frequent reasons for discontinuation included traveling (24%), change in location of residence (20%), and feeling healthy and not at-risk for HIV (18%).

Participants with partners known to be living with HIV at enrollment were more likely to persist with PrEP use through 9-months postpartum compared to participants with partners who were presumed to be HIV-negative (80% vs. 53%, aRR=1.34, 95% CI 1.14–1.57, $p<0.001$); there was no significant difference between women with partners presumed to be HIV-negative and those of unknown HIV status. PrEP persistence at 9-months postpartum was also associated with having a syphilis diagnosis in pregnancy (aRR=1.40, 95% CI:1.12–

1.76, p=0.003). Compared to participants ≥24 years, those <24 years were less likely to persist with PrEP use at 9-months (aRR=0.72, 95% CI 0.57–0.90, p=0.005). Women who were primigravida at PrEP initiation were also less likely to persist with PrEP use (aRR=0.62, 95% CI 0.43–0.91, p=0.013) as were women with a partner known to be living with HIV on ART (p=0.001); only 3 women with had a partner living with HIV not on ART. There was no association between PrEP persistence at 9-months postpartum and other demographic, behavioral, or pregnancy-related characteristics or partner HIV self-test use (Table 3).

Among women who initiated PrEP with information on side effects (n=350), 34% experienced at least one side effect and the most frequent side effects reported were dizziness (14%), nausea (13%), and vomiting (11%); frequency of having any side effects of dizziness, nausea, or vomiting was more common in pregnancy than postpartum (28% vs. 5%, p<0.001). Experiencing side effects was not associated with PrEP persistence (p=0.425).

PrEP adherence

Overall, 198 participants (49% of PrEP initiators) were randomly selected for inclusion in the PrEP adherence analysis and were similar to overall PrEP initiators in PrIMA (Supplemental Material). Each participant contributed a median of 3 visits to the analysis (IQR 2–4). Among visits from the subset (n=454), 94% (427/454, 95% CI 91%–96%) of women reported any PrEP use in the last 30 days. Among DBS from these visits (n=427), 50% (95% CI 45%–55%) had quantifiable TFV-DP of which 26% (95% CI 20%–32%) had TFV-DP concentrations indicating <2 doses/week, 65% (95% CI 58%–71%) 2–6 doses/week, and 9% (95% CI 6%–14%) 7 doses/week. Having a partner known to be living with HIV was associated with a 2-fold higher likelihood of any quantifiable TFV-DP compared to having partners who were presumed HIV-negative (aRR=2.03, 95% CI 1.33–3.09, p<0.001). Quantifiable TFV-DP was also twice as likely during pregnancy compared to postpartum (53% vs. 27%, aRR=1.87, 95% CI 1.38–2.53, p<0.001). Among postpartum visits, 33% had quantifiable TFV-DP at 6 weeks (n=114), 23% at 6 months (n=65), and 20% at 9 months (n=65). Self-reporting no missed pills in the last 30 days was associated with higher likelihood of TFV-DP quantification (aRR=1.48, 95% CI 1.03–2.12, p=0.035), though only 122/254 (48%) of DBS from visits where participants reported no missed pills had any quantifiable TFV-DP.

A higher likelihood of quantifiable TFV-DP was also associated with high perceived HIV risk (aRR=1.34, 95% CI 1.02–1.77, p=0.033) and trended towards an association with experiencing IPV (aRR=1.35, 95% CI 0.99–1.83, p=0.059). Participants who experienced side effects were less likely to have quantifiable TFV-DP aRR=0.68, 95% CI 0.47–0.99, p=0.042). There was no association between quantifiable TFV-DP and other demographic, behavioral, or pregnancy-related characteristics or partner HIV self-test use (Table 4).

Among participants with more than one visit randomly selected for the PrEP adherence analysis (n=156, median of 3 visits), 25% had quantifiable TFV-DP at all visits. Participants with partners known to be living with HIV were 5.5 times more likely to have quantifiable TFV-DP at all visits compared to women with partners who were perceived to be HIV-

negative or of unknown HIV status (RR=5.5, 95% CI 2.7–11.01, p<0.001); power was limited to detect associations with other correlates (data not shown).

Exploratory analyses

Overall, 119 women had complete self-reported information on PrEP pill-taking and attended all follow-up visits after PrEP initiation. Among this subset, 40% of participants who continued PrEP use through 9 months postpartum reported missing no PrEP pills in the last 30 days; having this trajectory of PrEP use was associated with syphilis diagnosis in pregnancy and having a partner known to be living with HIV (p<0.05; data not shown). Frequency of PrEP continuation and self-reporting no missed PrEP pills decreased from pregnancy through 9-months postpartum (Figure 1).

DISCUSSION

In this large prospective evaluation among Kenyan women in a high HIV prevalence area who were offered PrEP in pregnancy, over half of those who initiated PrEP continued use through 9-months postpartum, and a substantial proportion of PrEP users had quantifiable TFV-DP levels, indicating at least some PrEP pill-taking. PrEP continuation and adherence waned throughout the postpartum period, though over half of all PrEP initiators continued use through 9-months postpartum. In a recent meta-analysis, pooled PrEP discontinuation in the 6 months following PrEP initiation was 43.3% (95% CI 27.5–60.6) among cisgender women and 47.5% (95% CI 29.4–66.4) among studies from sub-Saharan Africa[38], similar to the rates of discontinuation (42%) we found at 9 months postpartum after approximately 12 months of PrEP use. Our findings demonstrate that women desire PrEP and persist with PrEP during the peripartum period and illustrate need for further interventions to support PrEP adherence during this critical period. Our evaluation contributes to the very few data on the PrEP continuum of care among pregnant and postpartum women.

Our findings support that knowledge of partners' HIV status is important for PrEP use and that women with partners known to be living with HIV are highly motivated to use daily oral PrEP, similar to studies among pregnant PrEP users in South Africa.[39] Dispensing HIV self-tests to pregnant women attending antenatal care to give to their male partners is scaling up in East and Southern Africa to increase testing coverage among men.[28,40–43] Few studies have evaluated HIV self-test distribution with PrEP,[44] though existing data suggest acceptance of self-tests is not associated with PrEP uptake within family planning clinics.[45] Increasing awareness of male partner HIV status could be a powerful strategy for promoting PrEP use among women most likely to benefit.

Pregnant women with characteristics associated with HIV acquisition frequently initiated PrEP in our study, similar to findings of studies among pregnant women in South Africa[10,46] and our team's prior work among Kenyan women.[13] One-third of participants who initiated PrEP experienced side effects and this was associated with lower PrEP adherence, similar to previous studies.[13] In populations other than pregnant women, less than 10% of PrEP users experience any side effects (as low as <2% in some studies).[47] Generally, PrEP side effects occur during the "start-up" period and go away within 2 weeks,[47] though side effects may be altered or exacerbated in pregnancy. We also found that primigravida women and

those <24 years were less likely to persist with PrEP use. Tailored support for women who initiate PrEP during pregnancy that includes managing side effects and addresses concerns for first-time and young mothers could help sustain adherence.[11,20,48] Some factors (IPV, self-efficacy, knowing someone on PrEP, etc.) associated with initiating PrEP were not associated with PrEP persistence, perhaps because the initiators are a subset with these selected characteristics and thus, there is less heterogeneity to discern differences in these characteristics among those who persist.

To date, few PrEP studies among pregnant and postpartum women have incorporated objective markers of PrEP adherence. A recent study that followed South African women who initiated PrEP in pregnancy until 12-months postpartum found that 72% of all DBS samples had TFV-DP concentrations corresponding with <2 doses/week[46] and frequency of any quantifiable TFV-DP was higher in pregnancy than postpartum.[39] We similarly found high frequency of TFV-DP concentrations corresponding with <2 doses/week (64% overall) and lower adherence levels postpartum than pregnancy. These data suggest PrEP adherence wanes in the postpartum period, a time critical for HIV prevention as sexual activity resumes and vertical transmission of HIV via breastfeeding poses a risk to infants.[49] Interventions that support PrEP adherence postpartum could be especially beneficial and one ongoing study is testing an SMS intervention to promote postpartum PrEP adherence (NCT04472884). Another study is evaluating implementation of injectable long-acting cabotegravir (CAB-LA) within postpartum services in a primarily breastfeeding population in Botswana (NCT05515770). These studies will accrue data on interventions and newer PrEP agents that address adherence challenges postpartum.

Participants in our study were more likely to initiate PrEP and persist with PrEP use following a syphilis diagnosis in pregnancy. Participants with higher perceived HIV risk were also more likely to initiate PrEP, though overall <10% perceived themselves to be at high risk for HIV. Previous studies have shown an imbalanced relationship between perceived versus actual HIV risk among pregnant women, based on solely self-reported sexual behaviors.[50,51] Low perceived HIV risk is a common reason for declining PrEP among pregnant women, even when male partner HIV status is unknown.[52] Within ANC, syphilis testing could inform HIV risk assessment and perception, and subsequently PrEP decision-making. Several countries, including Kenya, conduct universal antenatal syphilis screening using rapid syphilis testing to accelerate maternal treatment and prevention of newborn complications of syphilis,[53,54] though similar efforts to scale up screening of other STIs have not been implemented.[55,56] Data suggest that STIs are common among pregnant PrEP users in Kenya and South Africa[57–59] and a STIs are facilitator of PrEP initiation. In a recent study, 93% of HIV-negative South African women with an STI diagnosed in pregnancy started taking PrEP.[46] Intervention studies that evaluate STI testing as a strategy to enhance PrEP initiation among women in HIV high-burden settings could be useful for informing PrEP decision-making and the burden of STIs in this population.

Our study has limitations. We relied on self-report of PrEP persistence, though we included evaluation of TFV-DP levels as an objective marker of adherence. The study was designed to offer PrEP during pregnancy, and we did not systematically evaluate PrEP uptake in the postpartum period. Less than 15% of PrEP initiators in the parent study initiated PrEP

postpartum (n=70) which limits our statistical power to evaluate postpartum PrEP uptake. We relied on self-report for HIV status and self-testing outcomes among male partners, similar to other studies of HIV self-test secondary distribution in Kenya.[45,60] We also did not systematically capture information on viral suppression of male partners living with HIV or timing of ART initiation which may influence PrEP discontinuation when PrEP is used as a bridge until viral suppression of the partner living with HIV is achieved.[61] We purposively selected a subset who enrolled in the second trimester based on the median gestational age at enrollment among PrIMA participants and to allow for similar follow-up time for longitudinal analyses and therefore cannot evaluate timing of PrEP initiation in pregnancy and PrEP outcomes. We did not detect differences between the subset and overall PrIMA participants though the subset may not be representative of all ANC attendees in this setting. Patterns of stopping and restarting PrEP were also not systematically captured in the parent study, though this accounts for <10% of all PrEP initiators in this study population. Reasons for discontinuing PrEP were also missing for a substantial portion of participants who discontinued. Future studies should examine newer long-acting PrEP products, once available approved for use in pregnancy, to evaluate whether patterns of use are similar with additional PrEP options.

In conclusion, we found that PrEP persistence and adherence waned in the postpartum period among participants who initiated PrEP pregnancy, though overall approximately half of PrEP initiators continued through postpartum. Interventions should prioritize increasing knowledge of partner HIV status, refining risk assessment, potentially with STI testing, and sustaining adherence support systems in the postpartum period.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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GJG, JMB, JK, JH, and JP conceived and designed the study. JK, FA, MM, SW, and BO conducted data collection. JP, LG, JCD, and JS analyzed the data. PA analyzed laboratory specimens. JP and GJS drafted the paper. All authors critically reviewed the manuscript. The authors would like to gratefully thank the study participants and PrIMA staff for their time and contributions. We thank the Kenyan Ministry of Health nationally, the Kisumu County Department of Health, and the facility heads and in-charges for their collaboration with this study.

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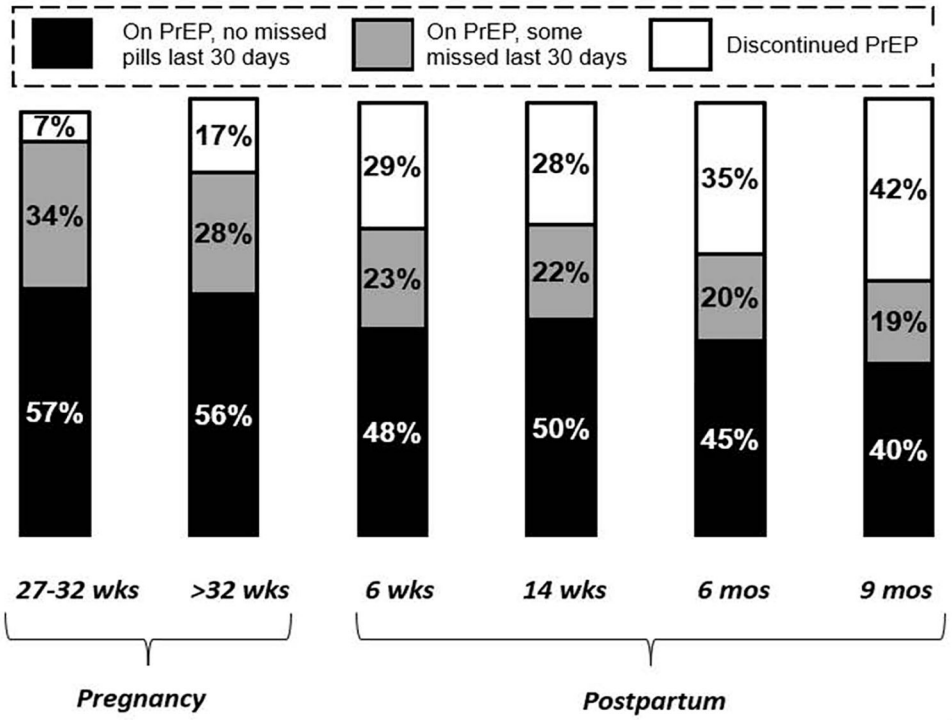

	Frequency of PrEP persistence N (%)					
	Pregnancy		Postpartum			
	27-32 weeks (n=119)	>32 weeks (n=119)	6 weeks (n=119)	14 weeks (n=119)	6 months (n=119)	9 months (n=119)
On PrEP (no pills missed last 30 days)	71 (57.0)	66 (55.5)	57 (47.9)	60 (50.4)	54 (45.4)	47 (39.5)
On PrEP (some pills missed last 30 days)	40 (33.6)	33 (27.7)	27 (22.7)	26 (21.9)	24 (20.2)	22 (18.5)
No pills taken or discontinued	8 (6.7)	20 (16.8)	35 (29.4)	33 (27.7)	41 (34.5)	50 (42.0)

Figure 1. Frequency of PrEP persistence over time among participants who initiated PrEP during pregnancy and had complete information on PrEP use at all follow-up visits (n=119)

[1] n=48 participants initiated PrEP at 14–26 weeks gestation and n=71 participants initiated PrEP 27–32 weeks gestation; all attended follow-up visits at 27–32 weeks and >32 weeks gestation

[2] Excludes all visits prior to PrEP initiation

[3] If a participant had >1 visit during the pregnancy windows (14–26 weeks, 27–32 weeks, or >32 weeks), the visit with their first indication of PrEP use was included.

[4] On PrEP defined as responding "yes" to the questionnaire item, "*Are you currently taking PrEP?*"

Table 1.

Demographic, clinical, and behavioral characteristics of participants offered PrEP between 14–32 weeks gestation (n=2949)

	N	n (%) or Median (IQR)
Demographic characteristics		
Study arm	2949	
Universal PrEP offer		1488 (50.5)
Targeted PrEP offer		1461 (49.5)
Age (years)	2948	24.2 (21.0, 28.6)
Age category (years)	2948	
<24		1392 (47.2)
≥24		1556 (52.8)
Currently married	2914	2527 (86.7)
Education (years)	2886	10 (8, 12)
Education category (years)	2886	
<12		1843 (63.9)
≥12		1043 (36.1)
Regular employment	2904	418 (14.4)
People per room	2917	1.7 (1, 2.5)
2+ people per room	2917	1428 (49.0)
Pregnancy characteristics		
Gestational age at enrollment (weeks)	2949	24 (20, 28)
Previous pregnancy	2934	2261 (77.1)
Previous abortion/miscarriage	2930	314 (10.7)
Previous premature birth (<37 weeks)	2949	30 (1.0)
Behavioral characteristics		
No. of lifetime sexual partners	2939	2 (2, 3)
HIV status of primary sexual partner(s)	2942	
Positive		126 (4.3)
Negative		1880 (63.9)
Unknown		902 (30.7)
No male partner		34 (1.2)
Partner on ART if HIV-positive	121	116 (95.9)

	N	n (%) or Median (IQR)
Syphilis Positive (RPR, HIV/Syphilis dual)	2895	29 (1.0)
In the last 6 months:		
Exchange sex for money or favors	2937	51 (1.7)
Diagnosed or treated for an STI	2937	70 (2.4)
Forced to have sex against will	2936	145 (4.9)
Experience intimate partner violence [1]	2932	230 (7.8)
Shared needles during drug use	2936	7 (0.2)
Used PEP >2 times	2934	8 (0.3)
High HIV risk score [2]	2949	1075 (36.5)
Psychosocial characteristics		
Heard of PrEP before	2922	1438 (49.2)
Know someone on PrEP	2932	205 (7.0)
High perceived HIV risk [3]	2928	250 (8.5)
High self-efficacy to take daily medication [4]	2811	1966 (69.9)

STI=sexually transmitted infection

[1] HITS score ≥ 10

[2] HIV risk score ≥6 (translating to HIV incidence 7.3 per 100 person-years) [31]

[3] Self-perceived HIV risk assessed by asking “What is your gut feeling about how likely you are to get infected with HIV?”, with possible responses of “extremely likely”, “very likely”, “somewhat likely”, “very unlikely”, “extremely unlikely”. (High self-perceived HIV risk: Extremely likely/Very likely = “Yes”, Somewhat likely/very unlikely/extremely unlikely = “No”).

[4] Self-efficacy to take a daily oral medication assessed by asking participants to rank on a 0–10 scale (0=Cannot do it at all, 10=Completely certain can do it) their response to the question: “How confident are you that you can integrate a daily medication into your daily routine? (High self-efficacy to take daily medication: >=5)

Table 2.

Correlates of PrEP initiation during pregnancy among women offered PrEP between 14–32 weeks gestation (n=2949)

Demographic characteristics		*N*	*n (%)*		*Univariate Poisson models*		*Multivariate Poisson models*	
			Ever initiated PrEP During Pregnancy					
			No (N=2544)	*Yes (n=405)*	*Risk Ratio (95% CI)*	*p-value* [1]	*Adj Risk Ratio (95% CI)*	*p-value* [1]
Study arm		2949						
	Universal PrEP offer	1488	1270 (49.9)	218 (53.8)	1.14 (0.77–1.69)	0.498		
	Targeted PrEP offer	1461	1274 (50.1)	187 (46.2)	ref			
Age category (years)		2948						
	<24	1392	1229 (48.3)	163 (40.3)	0.75 (0.64–0.88)	**<0.001**	1.08 (0.92–1.27)	0.347[4]
	≥24	1556	1314 (51.7)	242 (59.8)	ref		ref	
Currently married		2914						
	Yes	2527	2166 (86.2)	361 (90.3)	1.42 (0.95–2.12)	0.088		
	No	387	348 (13.8)	39 (9.8)	ref			
Education (years)		2886						
	<12	1043	1557 (62.5)	286 (72.8)	1.51 (1.21–1.89)	**<0.001**	1.30 (1.05–1.61)	**0.015** [5]
	≥12	1843	936 (37.6)	107 (27.2)	ref		ref	
Regular employment		2904						
	Yes	418	364 (14.5)	54 (13.6)	0.94 (0.74–1.18)	0.583		
	No	2486	2143 (85.5)	343 (86.4)	ref			
2+ people per room		2917						
	Yes	1428	1198 (47.6)	230 (57.5)	1.41 (1.14–1.74)	**0.001**	1.18 (0.97–1.45)	0.099[6]
	No	1489	1319 (52.4)	170 (42.5)	ref		ref	
Primigravida		2934						
	Yes	673	620 (24.5)	53 (13.1)	0.51 (0.40–0.64)	**<0.001**	0.70 (0.58–0.85)	**<0.001** [7]
	No	2261	1910 (75.5)	351 (86.9)	ref		ref	
Risk assessment chacteristics								

Demographic characteristics		N	n (%)		Univariate Poisson models		Multivariate Poisson models	
			Ever initiated PrEP During Pregnancy					
			No (N=2544)	Yes (n=405)	Risk Ratio (95% CI)	p-value [1]	Adj Risk Ratio (95% CI)	p-value [1]
No. of lifetime sexual partners >2		2939						
	Yes	1453	1215 (47.9)	238 (59.1)	1.48 (1.26–1.72)	**<0.001**	1.24 (1.06–1.45)	**0.008** [6]
	No	1486	1321 (52.1)	165 (40.9)	ref		ref	
HIV status of primary sexual partner(s) among women with partners		2908						
	Positive	126	45 (1.8)	81 (20.2)	7.28 (4.77–11.12)	**<0.001**	6.37 (4.18–9.69)	**<0.001** [8]
	Negative	1880	1714 (68.4)	166 (41.3)	ref		ref	
	Unknown	902	747 (29.8)	155 (38.6)	1.95 (1.42–2.68)	**<0.001**	1.87 (1.37–2.54)	**<0.001** [8]
Partner on ART if HIV-positive		120						
	Yes	116	41 (97.6)	75 (96.2)	0.86 (0.45–1.65)	0.654		
	No	4	1 (2.4)	3 (3.9)	ref			
Syphilis results (RPR, HIV/Syphilis dual)		2895						
	Positive	29	19 (0.8)	10 (2.5)	2.55 (1.67–3.88)	**<0.001**	1.84 (1.24–2.75)	**0.003** [6]
	Negative	2866	2478 (99.2)	388 (97.5)	ref		ref	
Forced sex in the last 6 months:		2936						
	Yes	145	106 (4.2)	39 (9.7)	2.07 (1.35–3.17)	**0.001**	1.59 (1.10–2.29)	**0.014** [6]
	No	2791	2428 (95.8)	363 (90.3)	ref		ref	
High HIV risk score [9]		2949						
	Yes	1075	826 (32.5)	249 (61.5)	2.78 (1.95–3.96)	**<0.001**	2.63 (1.88–3.67)	**<0.001** [8]
	No	1874	1718 (67.5)	156 (38.5)	ref		ref	
HITS score ≥ 10		2932						
	Yes	230	167 (6.6)	63 (15.6)	2.17 (1.67–2.83)	**<0.001**	1.65 (1.25–2.17)	**<0.001** [6]
	No	2702	2361 (93.4)	341 (84.4)	ref		ref	
Psychosocial factors								
Heard of PrEP before		2922						

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Demographic characteristics		N	n (%) Ever initiated PrEP During Pregnancy		Univariate Poisson models		Multivariate Poisson models	
			No (N=2544)	Yes (n=405)	Risk Ratio (95% CI)	p-value [1]	Adj Risk Ratio (95% CI)	p-value [1]
	Yes	1438	1227 (48.7)	211 (52.5)	1.14 (0.96–1.35)	0.136		
	No	1484	1293 (51.3)	191 (47.5)	ref			
Know someone on PrEP		2932						
	Yes	205	167 (6.6)	38 (9.4)	1.38 (1.06–1.80)	**0.018**	1.49 (1.15–1.94)	**0.002** [6]
	No	2727	2361 (93.4)	366 (90.6)	ref		ref	
High perceived HIV risk [2]		2928						
	Yes	250	158 (6.3)	92 (22.9)	3.18 (2.21–4.57)	**<0.001**	2.01 (1.49–2.73)	**<0.001** [6]
	No	2678	2368 (93.8)	310 (77.1)	ref		ref	
High self-efficacy to take daily pill [3]		2811						
	Yes	1966	1612 (66.4)	354 (92.7)	5.43 (3.49–8.47)	**<0.001**	4.67 (2.97–7.36)	**<0.001** [6]
	No	845	817 (33.6)	28 (7.3)	ref		ref	
HIV self-test outcomes								
Ever accepted HIV self-tests during pregnancy		1461						
	Yes	993	870 (68.3)	123 (65.8)	0.91 (0.46–1.78)	0.775		
	No	468	404 (31.7)	64 (34.2)	ref			
Partner ever used HIV self-tests if accepted during pregnancy		1273						
	Yes	774	684 (61.6)	90 (55.2)	0.79 (0.41–1.55)	0.499		
	No	499	426 (38.4)	73 (44.8)	ref			

[1] Poisson regression clustered on site, relative risk of initiated PrEP during pregnancy

[2] Self-perceived HIV risk assessed by asking “What is your gut feeling about how likely you are to get infected with HIV?”, with possible responses of “extremely likely”, “very likely”, “somewhat likely”, “very unlikely”, “extremely unlikely”. (High self-perceived HIV risk: Extremely likely/Very likely = “Yes”, Somewhat likely/very unlikely/extremely unlikely = “No”).

[3] Self-efficacy to take a daily oral medication assessed by asking participants to rank on a 0–10 scale (0=Cannot do it at all, 10=Completely certain can do it) their response to the question: “How confident are you that you can integrate a daily medication into your daily routine? (High self-efficacy to take daily medication: >=5)

[4] Adjusted for primigravida (yes/no), education (<12 vs. >=12 years), and partner HIV status

[5] Adjusted for age (continuous), primigravida (yes/no), and partner HIV status

[6] Adjusted for age (continuous), primigravida (yes/no), education (<12 vs. >=12 years), and partner HIV status

[7] Adjusted for age (continuous), education (<12 vs. >=12 years), and partner HIV status

[8] Adjusted for age (continuous), primigravida (yes/no), and education (<12 vs. >=12 years)

[9] HIV risk score ≥6 (translating to HIV incidence 7.3 per 100 person-years) [31]

Table 3.

Correlates of PrEP persistence at 9-months postpartum among women who initiated PrEP during pregnancy (n=363)

Demographic characteristics		N	n (%) Persisted with PrEP use at 9-months postpartum: No (N=151)	n (%) Persisted with PrEP use at 9-months postpartum: Yes (n=212)	Univariate Poisson models: Risk Ratio (95% CI)	Univariate Poisson models: p-value [1]	Multivariate Poisson models: Adj Risk Ratio (95% CI)	Multivariate Poisson models: p-value [1]
Study arm		363						
	Universal PrEP offer	193	83 (55.0)	110 (51.9)	0.95 (0.73–1.24)	0.702		
	Targeted PrEP offer	170	68 (45.0)	102 (48.1)	ref			
Age category (years)		363						
	<24	149	85 (56.3)	64 (30.2)	0.62 (0.50–0.77)	**<0.001**	0.72 (0.57–0.90)	**0.005** [4]
	≥24	214	66 (43.7)	148 (69.8)	ref		ref	
Currently married		359						
	Yes	324	128 (86.5)	196 (92.9)	1.41 (0.93–2.14)	0.106		
	No	35	20 (13.5)	15 (7.1)	ref			
Education (years)		353						
	<12	254	88 (60.7)	166 (79.8)	1.54 (1.18–2.02)	**0.002**	1.40 (1.11–1.77)	**0.004** [5]
	≥12	99	57 (39.2)	42 (20.2)	ref		ref	
Regular employment		357						
	Yes	51	20 (13.5)	31 (14.8)	1.04 (0.88–1.24)	0.618		
	No	306	128 (86.5)	178 (85.2)	ref			
2+ people per room		359						
	Yes	204	79 (53.0)	125 (59.5)	1.12 (0.92–1.36)	0.264		
	No	155	70 (47.0)	85 (40.5)	ref			
Primigravida		362						
	Yes	312	117 (77.5)	195 (92.4)	0.51 (0.34–0.76)	**0.001**	0.62 (0.43–0.91)	**0.013** [6]
	No	50	34 (22.5)	16 (7.6)	ref		ref	
Risk assessment chacteristics								

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Demographic characteristics		N	n (%) Persisted with PrEP use at 9-months postpartum: No (N=151)	Yes (n=212)	Univariate Poisson models: Risk Ratio (95% CI)	p-value [1]	Multivariate Poisson models: Adj Risk Ratio (95% CI)	p-value [1]
No. of lifetime sexual partners >2		361						
	Yes	211	86 (57.3)	125 (59.2)	1.03 (0.87–1.23)	0.709		
	No	150	64 (42.7)	86 (40.8)	ref			
HIV status of primary sexual partner(s) among women with partners		360						
	Positive	71	14 (9.3)	57 (27.3)	1.53 (1.32–1.77)	**<0.001**	1.34 (1.14–1.57)	**<0.001** [7]
	Negative	152	72 (47.7)	80 (38.3)	ref	-	ref	-
	Unknown	137	65 (43.1)	72 (34.5)	1.00 (0.82–1.22)	0.989	1.04 (0.88–1.23)	0.657 [7]
Partner on ART if HIV-positive		69						
	Yes	66	13 (100.0)	53 (94.6)	0.80 (0.71–0.91)	**0.001**		
	No	3	0 (0.0)	3 (5.4)	ref			
Syphilis results (RPR, HIV/Syphilis dual)		356						
	Positive	8	1 (0.7)	7 (3.4)	1.53 (1.14–2.04)	**0.005**	1.40 (1.12–1.76)	**0.003** [8]
	Negative	348	148 (99.3)	200 (96.6)	ref		ref	
Forced sex in the last 6 months:		360						
	Yes	34	16 (10.7)	18 (8.6)	0.90 (0.63–1.28)	0.554		
	No	326	134 (89.3)	192 (91.4)	ref			
High HIV risk score [9]		363						
	Yes	221	86 (57.0)	135 (63.7)	1.13 (0.95–1.34)	0.178		
	No	142	65 (43.1)	77 (36.3)	ref			
HITS score ≥ 10		362						
	Yes	57	25 (16.6)	32 (15.2)	0.96 (0.80–1.14)	0.623		
	No	305	126 (83.4)	179 (84.8)	ref			
Psychosocial factors								
Heard of PrEP before		361						
	Yes	187	72 (48.0)	115 (54.5)	1.15 (0.95–1.31)	0.193		

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Demographic characteristics		*N*	*n (%)* *Persisted with PrEP use at 9-months postpartum* *No (N=151)*	*Yes (n=212)*	*Univariate Poisson models* *Risk Ratio (95% CI)*	*p-value* [1]	*Multivariate Poisson models* *Adj Risk Ratio (95% CI)*	*p-value* [1]
	No	174	78 (52.0)	96 (45.5)	ref			
Know someone on PrEP		362						
	Yes	36	15 (10.0)	21 (9.9)	1.00 (0.66–1.49)	0.983		
	No	326	135 (90.0)	191 (90.1)	ref			
High perceived HIV risk [2]		360						
	Yes	82	28 (18.7)	54 (25.7)	1.17 (0.92–1.49)	0.192		
	No	278	122 (81.3)	156 (74.3)	ref			
High self-efficacy to take daily pill[3]		343						
	Yes	315	127 (89.4)	188 (93.5)	1.29 (0.91–1.82)	0.158		
	No	28	15 (10.6)	13 (6.5)	ref			
PrEP and HIV self-test outcomes								
Ever experienced PrEP side effects		350						
	Yes	118	51 (37.0)	67 (31.6)	0.91 (0.72–1.15)	0.425		
	No	232	87 (63.0)	145 (68.4)	ref			
Ever accepted HIV self-tests		170						
	Yes	113	51 (75.0)	62 (60.8)	0.78 (0.60–1.02)	**0.071**		
	No	57	17 (25.0)	40 (39.2)	ref			
Partner ever used HIV self-tests		150						
	Yes	84	38 (64.4)	46 (50.6)	0.80 (0.65–1.00)	**0.046**	1.19 (0.96–1.48)	0.111[8]
	No	66	21 (35.6)	45 (49.5)	ref		ref	

[1] Poisson regression clustered on site, relative risk of persisted PrEP

[2] Self-perceived HIV risk assessed by asking “What is your gut feeling about how likely you are to get infected with HIV?”, with possible responses of “extremely likely”, “very likely”, “somewhat likely”, “very unlikely”, “extremely unlikely”. (High self-perceived HIV risk: Extremely likely/Very likely = “Yes”, Somewhat likely/very unlikely/extremely unlikely = “No”).

[3] Self-efficacy to take a daily oral medication assessed by asking participants to rank on a 0–10 scale (0=Cannot do it at all, 10=Completely certain can do it) their response to the question: “How confident are you that you can integrate a daily medication into your daily routine? (High self-efficacy to take daily medication: >=5)

[4] Adjusted for primigravida (yes/no), education (<12 vs. >=12 years), and partner HIV status

[5] Adjusted for age (continuous), primigravida (yes/no), and partner HIV status

[6] Adjusted for age (continuous), education (<12 vs. >=12 years), and partner HIV status

[7] Adjusted for age (continuous), primigravida (yes/no), and education (<12 vs. >=12 years)

[8] Adjusted for age (continuous), primigravida (yes/no), education (<12 vs. >=12 years) and partner HIV status

[9] HIV risk score ≥6 (translating to HIV incidence 7.3 per 100 person-years) [31]

Table 4.

Correlates of any quantifiable TFV-DP exposure at follow-up visits among women who initiated PrEP during pregnancy (n=524)

Demographic characteristics		*N*	*n (%)* *Quantifiable TFV-DP exposure* *No (N=311)*	*Yes (n=213)*	**Univariate Poisson models** *Risk Ratio (95% CI)*	*p-value* [1]	**Multivariate Poisson models** *Adj Risk Ratio (95% CI)*	*p-value* [1]
Study arm		524						
	Universal PrEP offer	282	181 (58.2)	101 (47.4)	0.77 (0.46–1.30)	0.334		
	Targeted PrEP offer	242	130 (41.8)	112 (52.6)	ref			
Age category (years)		524						
	<24	189	127 (40.8)	62 (29.1)	0.73 (0.57–0.93)	**0.010**	0.82 (0.62–1.07)	0.146[4]
	≥24	335	184 (59.2)	151 (70.9)	ref		ref	
Currently married		522						
	Yes	478	281 (90.9)	197 (92.5)	1.13 (0.59–2.19)	0.709		
	No	44	28 (9.1)	16 (7.5)	ref			
Education (years)		513						
	<12	379	213 (70.5)	166 (78.7)	1.30 (0.92–1.84)	0.133		
	≥12	134	89 (29.5)	45 (21.3)	ref			
Regular employment		522						
	Yes	83	53 (17.2)	30 (14.1)	0.87 (0.57–1.32)	0.508		
	No	439	256 (82.9)	183 (85.9)	ref			
2+ people per room		522						
	Yes	313	179 (57.9)	134 (62.9)	1.13 (0.87–1.47)	0.352		
	No	209	130 (42.1)	79 (37.1)	ref			
Primigravida		524						
	Yes	69	53 (17.0)	16 (7.5)	0.54 (0.33–0.87)	**0.013**	0.77 (0.46–1.32)	0.343[5]
	No	455	258 (83.0)	197 (92.5)	ref		ref	
Visit timing		524						

Demographic characteristics		N	n (%) Quantifiable TFV-DP exposure No (N=311)	Yes (n=213)	Univariate Poisson models Risk Ratio (95% CI)	p-value [1]	Multivariate Poisson models Adj Risk Ratio (95% CI)	p-value [1]
	Pregnant	280	133 (42.8)	147 (69.0)				
	Postpartum	244	178 (57.2)	66 (31.0)	1.94 (1.40–2.69)	**<0.001**	1.87 (1.38–2.53)	**<0.001** [7]
Risk assessment chacteristics								
No. of lifetime sexual partners >2		524						
	Yes	313	187 (60.1)	126 (59.2)	0.98 (0.80–1.19)	0.813		
	No	211	124 (39.9)	87 (40.9)	ref			
HIV status of primary sexual partner(s) among women with partners		519						
	Positive	104	35 (11.3)	69 (33.2)	2.25 (1.49–3.40)	**<0.001**	2.03 (1.33–3.09)	**0.001** [6]
	Negative	210	148 (47.6)	62 (29.8)	ref		ref	
	Unknown	205	128 (41.2)	77 (37.0)	1.27 (0.84–1.92)	0.252	1.30 (0.88–1.91)	0.191 [6]
Partner on ART if HIV-positive		104						
	Yes	100	35 (100.0)	65 (94.2)	0.65 (0.51–0.83)	**0.001**		
	No	4	0 (0.0)	4 (5.8)	ref			
Syphilis results (RPR, HIV/Syphilis dual)		524						
	Positive	13	8 (2.6)	5 (2.4)	0.94 (0.57–1.56)	0.824		
	Negative	511	303 (97.4)	208 (97.7)	ref			
Forced sex in the last 6 months:		524						
	Yes	35	21 (6.8)	14 (6.6)	0.98 (0.54–1.81)	0.956		
	No	489	290 (93.3)	199 (93.4)	ref			
High HIV risk score [9]		524						
	Yes	330	177 (56.9)	153 (71.8)	1.50 (0.98–2.29)	**0.060**		
	No	194	134 (43.1)	60 (28.2)	ref			
HITS score ≥ 10		524						
	Yes	91	41 (13.2)	50 (23.5)	1.46 (1.06–2.01)	**0.020**	1.35 (0.99–1.83)	0.059 [7]
	No	433	270 (86.8)	163 (76.5)	ref		ref	

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Demographic characteristics		N	n (%) Quantifiable TFV-DP exposure No (N=311)	Yes (n=213)	Univariate Poisson models Risk Ratio (95% CI)	p-value [1]	Multivariate Poisson models Adj Risk Ratio (95% CI)	p-value [1]
Psychosocial factors								
Heard of PrEP before		524						
	Yes	240	125 (40.2)	115 (54.0)	1.39 (1.06–1.82)	**0.016**	1.26 (0.92–1.72)	0.156 [7]
	No	284	186 (59.8)	98 (46.0)	ref		ref	
Know someone on PrEP		524						
	Yes	58	28 (9.0)	30 (14.1)	1.31 (0.92–1.89)	0.137		
	No	466	283 (91.0)	183 (85.9)	ref			
High perceived HIV risk [2]		520						
	Yes	125	58 (18.7)	67 (31.9)	1.48 (1.06–2.07)	**0.022**	1.34 (1.02–1.77)	**0.033** [7]
	No	395	252 (81.3)	143 (68.1)	ref		ref	
High self-efficacy to take daily pill [3]		504						
	Yes	480	285 (96.3)	195 (93.4)	0.75 (0.40–1.41_	0.371		
	No	24	11 (3.7)	13 (6.3)	ref			
PrEP and HIV self-test outcomes								
Ever experienced PrEP side effects		511						
	Yes	174	122 (40.7)	52 (24.6)	0.63 (0.42–0.95)	**0.028**	0.68 (0.47–0.99)	**0.042** [7]
	No	337	178 (59.3)	159 (75.4)	ref		ref	
Ever accepted HIV self-tests		242						
	Yes	176	107 (82.3)	69 (61.6)	0.60 (0.48–0.76)	**<0.001**	1.13 (0.78–1.64)	0.523 [7]
	No	66	23 (17.7)	43 (38.4)	ref		ref	
Partner ever used HIV self-tests		204						
	Yes	129	87 (76.3)	42 (46.7)	0.51 (0.35–0.75)	**0.001**	0.80 (0.54–1.17)	0.250 [7]
	No	75	27 (23.7)	48 (53.3)	ref		ref	
No missed PrEP pill last 30 days [8]		524						

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Demographic characteristics		N	n (%) Quantifiable TFV-DP exposure No (N=311)	Yes (n=213)	Univariate Poisson models Risk Ratio (95% CI)	p-value [1]	Multivariate Poisson models Adj Risk Ratio (95% CI)	p-value [1]
	Yes	254	122 (39.2)	132 (62.0)	1.73 (1.33–2.25)	**<0.001**	1.48 (1.03–2.12)	**0.035** [7]
	No	270	189 (60.8)	81 (38.0)	ref		ref	

[1] Poisson regression clustered on site, relative risk of persisted PrEP

[2] Self-perceived HIV risk assessed by asking “What is your gut feeling about how likely you are to get infected with HIV?”, with possible responses of “extremely likely”, “very likely”, “somewhat likely”, “very unlikely”, “extremely unlikely”. (High self-perceived HIV risk: Extremely likely/Very likely = “Yes”, Somewhat likely/very unlikely/extremely unlikely = “No”).

[3] Self-efficacy to take a daily oral medication assessed by asking participants to rank on a 0–10 scale (0=Cannot do it at all, 10=Completely certain can do it) their response to the question: “How confident are you that you can integrate a daily medication into your daily routine? (High self-efficacy to take daily medication: >=5)

[4] Adjusted for primigravida (yes/no), education (<12 vs. >=12 years), and partner HIV status

[5] Adjusted for age (continuous), education (<12 vs. >=12 years), and partner HIV status

[6] Adjusted for age (continuous), primigravida (yes/no), and education (<12 vs. >=12 years)

[7] Adjusted for age (continuous), primigravida (yes/no), education (<12 vs. >=12 years) and partner HIV status

[8] Based on self-report

[9] HIV risk score ≥6 (translating to HIV incidence 7.3 per 100 person-years) [31]