Exploring early implementation factors related to novel PrEP formulations for pregnant and postpartum women in Kenya

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Abstract

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New long-acting HIV pre-exposure prophylaxis (LA-PrEP) methods offer a promising solution to adherence challenges among pregnant and postpartum women at high risk of HIV. These options provide an alternative to daily oral PrEP, which can be difficult to maintain, particularly during pregnancy and postpartum. Despite their potential, evidence on preferred LA-PrEP attributes and acceptability in maternal and child health (MCH) systems remains limited. In high HIV-burden settings, pregnant and postpartum women face nearly double the HIV prevalence of the general population, underscoring the urgency of person-centered HIV prevention strategies. While LA-PrEP modalities demonstrate efficacy in HIV prevention and evidence of safety during pregnancy and lactation is increasing, unique considerations exist for their integration into reproductive health settings. However, implementation data are scarce. To address these gaps, we addressed

the following research objectives, 1) to identify the preferred attributes of PrEP among pregnant and postpartum women at key timepoints in the perinatal period and explore how these preferences can inform health planning to expand PrEP choices for this population, 2) to assess the acceptability of long-acting PrEP methods among pregnant and postpartum women and determine strategies to enhance their acceptability in this population, and 3) to examine the potential barriers and facilitators to implementing long-acting PrEP for pregnant and postpartum women in Kenya and identify necessary adaptations and strategies for successful implementation, we evaluated LA-PrEP acceptability, identified potential barriers and facilitators, and explored strategies to enhance its adoption in MCH systems.

For the first study, we conducted a discrete choice experiment (DCE) among HIV-negative pregnant and postpartum women in Kisumu and Siaya, Kenya, enrolled between 24-32 weeks gestation and who had a high HIV risk score. Participants completed the DCE with 12 choice sets at their 3rd antepartum and six-month postpartum visits. Attributes included effectiveness, form and dosing, safety data, side effects, collection place, cost, and multipurpose prevention (postpartum only). We fit effects-coded choice data to a conditional logit model, latent class analysis (LCA) for preference heterogeneity, and univariate multinomial logistic regressions to predict class membership by individual characteristics. A total of 512 women completed the DCE (151 pregnant, 509 postpartum). Bimonthly injections were strongly preferred, showing the highest positive utility (pregnant: 1.22, 95% CI: 1.12–1.33; postpartum: 1.24, 95% CI: 1.18–1.30). Four latent classes emerged: "Flexible PrEP Adopters" (37.2%), "Safe and Effective Injection Preference" (16.5%), "Strong Injection Preference" (37.7%), and “Oral PrEP Preference” (8.6%). Higher parity was associated with lower odds of membership in "Flexible PrEP Adopters" (OR=0.6, 95% CI: 0.4-0.8, p=0.001), "Safe and Effective Injection Preference" (OR=0.6, 95% CI: 0.4-0.8, p=0.003), and "Strong Injection Preference" (OR=0.7, 95% CI: 0.5-1, p=0.027) compared to “Oral PrEP preference”.

For our second study, we conducted an exploratory qualitative study with postpartum women in five public health facilities in Kisumu and Siaya Counties, Kenya. In-depth interviews (IDIs) were conducted with women expressing high, low, and mixed LA-PrEP interest throughout pregnancy and postpartum. Inductive and deductive content analysis was used, and themes of acceptability were explored using the Theoretical Framework of Acceptability (TFA). We conducted 70 IDIs with postpartum women between August 2023 and March 2024. The majority (62.9%) expressed consistently high interest in LA-PrEP. Most viewed LA-PrEP, especially every two-month injectables, as highly acceptable due to reduced pill burden, side effects, and dosing frequency. Concerns were raised regarding injectable PrEP safety for the baby during pregnancy and suitability of using the vaginal ring during delivery. Participants emphasized the importance of education on the safety of these methods during pregnancy and breastfeeding, and strategies for improving adherence, such as mobile reminders. Overall, women preferred LA-PrEP options over daily oral PrEP for convenience, effectiveness, and privacy, with healthcare provider education seen as crucial.

For our third study, we conducted a qualitative study using focus group discussions (FGDs) with healthcare workers and other key opinion leaders related to PrEP delivery for pregnant and postpartum women. Interview guides were informed by the EPIS and CFIR frameworks. HCW FGDs included an activity to prioritize information, training, or support strategies for LA-PrEP provision. We used a rapid qualitative analysis to identify facilitators and barriers to integrating LA-PrEP into reproductive health settings and matched potential implementation strategies. A total of 9 FGDs were conducted with 45 individuals between August and October 2023 (5 FGDs among HCWs and 4 among CAB members). They identified interconnected determinants including training, funding, personnel, and community sensitization. Some strategies clearly addressed barriers (e.g. training). However, some barriers had no clear solution, such as LA-PrEP drug availability and access to funds to conduct training and community sensitization. The

prioritization activity revealed common resources needed for LA-PrEP implementation (e.g., national guidelines, training, and personnel), but importance varied by location. A wide range of implementation strategies were identified, such as financial incentives for transportation, using community health providers to conduct community sensitization, and integrating LA-PrEP into FP clinics.

In summary, we found strong preferences for bimonthly injectables, which emphasized the need to prioritize LA-PrEP in this population. ANC settings can support diverse PrEP preference profiles with tailored counseling to account for individual preferences, PrEP experience, and obstetric history. We also found high acceptability of LA-PrEP options among postpartum women with experience taking PrEP during pregnancy, underscoring diverse preferences and key factors influencing acceptability, including safety, discretion, and convenience. HCW and CAB members were optimistic about the promise of new LA-PrEP options and identified important barriers and strategies for consideration. Future research should consider prioritizing implementation strategies and evaluating the impact of strategies on implementation barriers. This dissertation emphasizes the importance and potential impact of offering LA-PrEP options to pregnant and postpartum women.

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Dedications

I dedicate this dissertation to my husband, daughter, and parents.

To Mom, for telling me that I can. Your unwavering belief in my ability to accomplish anything has been a guiding light. You've been there for me, just a phone call away, and never once hesitated to support my early global adventures, even when they meant being cut off from all communication for months at a time.

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Chapter 1: Introduction

HIV incidence remains unacceptability high among young women in East and Southern Africa[1] and evidence suggests a two-fold higher risk of HIV acquisition during pregnancy. Women who newly acquire HIV during pregnancy and breastfeeding account for 22-26% of all vertical HIV transmissions.[2–4] This elevated risk, combined with high fertility rates in the region,[5] highlight pregnancy and postpartum as critical periods to focus HIV prevention efforts, yet this population often has delayed access to interventions.[6] Globally 150,000 infants were newly infected with HIV in 2020, mostly in low- and middle-income countries (LMICs), and more than 35,000 of the vertical transmissions occurred among women who acquired HIV during pregnancy and breastfeeding.[7] While new HIV infections among children declined by more than half (53%) from 2010 to 2020, that momentum has slowed considerably, leaving particularly large gaps in sub-Saharan Africa.[7] Reducing HIV risk among pregnant women is a high priority in the United States President's Emergency Plan for AIDS Relief (PEPFAR) elimination of mother-to-child (vertical) transmission of HIV and is aligned with the 2021-2025 NIH Strategic Plan for HIV and HIV-Related Research priorities.[8,9]

Daily oral pre-exposure prophylaxis (PrEP) is scaling up for pregnant/postpartum women in Kenya. Women at substantial risk of HIV infection require tailored combination HIV prevention, including PrEP, comprehensive counselling, repeat HIV testing, and the provision of self-testing kits for partners.[10–12] To protect mothers and reach elimination of vertical transmission of HIV, the World Health Organization (WHO) recommends oral PrEP for pregnant/postpartum women at ongoing substantial risk for HIV in high-burden settings.[12] A systematic review of 33 PrEP studies concluded that there is no safety-related rationale for prohibiting PrEP during pregnancy and/or breastfeeding.[13] Kenyan PrEP guidelines explicitly permit PrEP use in during periods of pregnancy and breastfeeding and Kenya is a leader among African countries for PrEP implementation within maternal child health (MCH) settings.[14] Despite the national and

international support for PrEP, PrEP adherence remains a challenge in areas of high HIV burden.[15] While daily oral PrEP has high acceptance by pregnant/postpartum women,[16] over 50% discontinue within 30 days of initiation when offered it during routine antenatal care (ANC).[1] Unique attributes of pregnancy and the postpartum period may influence persisting with daily oral PrEP use such as the co-occurring side effects of PrEP medication and pregnancy, demands of motherhood, and changes in perceived HIV risk.[17–22] In one Kenyan qualitative study, women had challenges distinguishing normal pregnancy symptoms from PrEP side effects and were concerned that observed side effects could be signs of danger for the infant related to PrEP exposure.[20] Conversely, the desire to remain HIV negative and have an HIV-free infant were strong motivators influencing continued use of PrEP during pregnancy.[20]

Existing data suggest that novel long-acting (LA)-PrEP methods may address some barriers to PrEP persistence during pregnancy/postpartum. Given the barriers experienced with daily pill-taking for HIV prevention, LA-PrEP methods may improve adherence and acceptability.

New LA-PrEP options, such as injectable cabotegravir (CAB-LA), the dapivirine vaginal ring (DVR), and lenacapavir (LEN), provide alternatives to daily oral PrEP for HIV prevention and have different attributes compared to daily oral PrEP (Table 1).[23–26] CAB-LA, administered every two months, and DPV-VR, replaced monthly, are both included in WHO guidelines as additional PrEP options for individuals at substantial risk of HIV, but do not yet have regulatory approval women who are pregnant or breastfeeding.[12,27,28] Existing safety data on the use of DVR and CAB-LA use in pregnancy suggest favorable safety profiles[29–32] and ongoing safety studies will provide more evidence to inform guidelines for the use of these prevention products in pregnancy. Recently published data on LEN, a capsid inhibitor with a subcutaneous injection every six months, had zero seroconversions in a trial of over 5000 cisgender women.[24] Women in this trial were not required to use contraceptives, and pregnancy outcomes were similar to those expected for the population, however there has been no formal safety evaluation during pregnancy and

breastfeeding, to date.

Table 1: PrEP product characteristics and use in pregnancy

Product	Dosing	Efficacy	Safety in pregnancy and lactation	WHO recommendation
Tenofovir-based oral PrEP	Daily	>90% among women with high adherence[33]	Systematic review of 33 studies found no statistically significant differences in: Stillbirth/pregnancy loss, preterm delivery, low birth weight, small for gestational age, birth defects, infant or maternal mortality[13]	Recommended for people, including pregnant and postpartum women, at substantial risk for HIV in high-burden settings.[12]
Dapivirine vaginal ring (DVR)	Every 28 days	>50% among women[34]	No maternal serious adverse events deemed related to vaginal ring use[29]	Recommended for women as an additional HIV prevention option for people at substantial risk of HIV infection[12]
Cabotegravir (CAB-LA)	Every eight weeks	93-95% among women[35]	Pregnancy-related adverse events & weight gain similar between CAB-LA and oral PrEP groups[30] Gestational hypertension rates similar to background rates[30] No maternal deaths in clinical trials[23,30]	Recommended as an additional HIV prevention option for people at substantial risk of HIV infection[27]
Lenacapavir (LEN)	Every six months	100%	Pregnancy outcomes in clinical trials similar to those expected for the population[24]	Convening a Guideline Development Group for the development of new guidelines in January 2025[36]

Attributes of these new LA-PrEP options are different than that of daily oral pill, for example, negative attributes of dapivirine (e.g., vaginal discomfort, difficulty inserting/removing) are different than that for pills (e.g., nausea/vomiting) that may be exacerbated during pregnancy.[37] Despite the increasing availability of LA-PrEP options, no study to date has looked at preferences that pregnant/postpartum women may have for certain attributes of these methods. Understanding preferences for LA-PrEP in this population can inform integration of LA-PrEP options into MCH systems to address PrEP persistence. Additionally, health care providers are important conduits of knowledge about PrEP, and continuity of PrEP providers throughout pregnancy facilitated adherence.[20] Women reported that health care providers' knowledge and approval of product use during pregnancy and breastfeeding was needed to mitigate anticipated fears.[37]

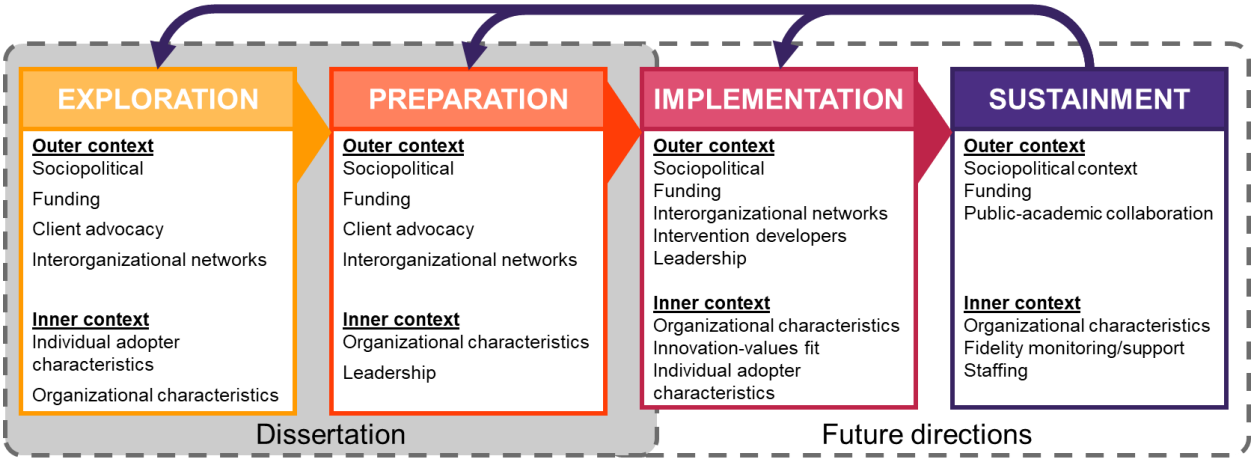
While clinical trials provide safety and effectiveness data, early implementation studies can

accelerate introduction and scale-up. Concerns about including pregnant women in research have led to a dearth of evidence to guide safe and effective treatment and prevention of HIV, despite the urgent need for effective HIV prevention and treatment during pregnancy.[6] With the increasing number of novel PrEP formulations, early implementation studies can narrow the research to practice gap.[38] The majority of research on LA-PrEP has been focused on safety and efficacy, which is essential, but there is limited data on the preferences of pregnant and postpartum women or strategies for integrating these new methods into the healthcare settings they access. This dissertation fills this gap by answering the following research questions:

1. What are the preferred attributes of PrEP among pregnant and postpartum women at key timepoints in the perinatal period, and how can these preferences inform health planning to expand PrEP choices for this population?
2. How acceptable are long-acting PrEP methods to pregnant and postpartum women, and what strategies can enhance their acceptability in this population?
3. What are the potential barriers and facilitators to implementing long-acting PrEP for pregnant and postpartum women in Kenya, and what adaptations and strategies are needed for successful implementation?

Implementation science process models can support effective implementation of evidence-based interventions (EBIs) by explicitly acknowledging variables that play critical roles at different points in the implementation process. The Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (Figure 1) highlights key phases that describe an implementation process and details factors that shape implementation within and across phases, considering both outer context (system) and inner (organizational) context.[39] The EPIS model is particularly useful for this dissertation as it was developed and is largely used for implementation of EBIs in the public sector. This dissertation is guided by the first two phases of the EPIS framework to answer questions related to implementation of LA-PrEP for pregnant/postpartum women in Kenya. In the

Exploration phase, a service system, organization, research group, or other key opinion leader(s) consider the emergent or existing health needs of the patients, clients, or communities and work



to identify the best EBP(s) to address those needs and subsequently decides whether to adopt the identified EBP. In the Preparation phase, the primary objectives are to identify potential barriers and facilitators of implementation at the outer and inner contexts, further assess needs for adaptation, and to develop a detailed plan to capitalize on implementation facilitators and address potential barriers. These two phases will be explored qualitatively and quantitatively in the subsequent chapters.

Figure 1: Abbreviated conceptual model of implementation phases and factors affecting implementation in public service sectors, adapted from Aarons et al. 2010

Chapter 2: Preferences for long-acting pre-exposure prophylaxis for HIV prevention among pregnant women without HIV in Kisumu and Siaya, Kenya: Results from a discrete choice experiment

Introduction

In settings with high HIV burden, incidence of HIV among pregnancy and postpartum women is nearly double that of the general population.[40] The World Health Organization (WHO) recommends daily tenofovir disoproxil fumarate (TDF)-based pre-exposure prophylaxis (PrEP) for pregnant and postpartum women at substantial risk for HIV in high-burden settings.[12] However, adherence to daily oral PrEP remains a challenge, with up to 50% of women discontinuing use during routine antenatal care.[1,41] The unique challenges of pregnancy and postpartum – including side effects that overlap with pregnancy symptoms, changes in behaviors associated with HIV exposure, and the demands of motherhood – may impact persistence with daily oral PrEP use.[17–22]

Given these barriers, novel long-acting (LA)-PrEP methods, such as dapivirine vaginal ring, bi-monthly injectable cabotegravir (CAB-LA), and twice-yearly lenacapavir (LEN), may offer more attractive alternatives to daily oral PrEP and enhance PrEP persistence during periods of increased risk of acquiring HIV, like pregnancy and postpartum.[23,25,26] While LA-PrEP formulations have demonstrated effectiveness, their distinct attributes and potential to improve adherence and acceptability during pregnancy and postpartum warrant further exploration.[37] Understanding preferences of pregnant and postpartum women for these LA-PrEP methods is necessary to inform person-centered HIV preventive care in maternal and child health (MCH) systems. Discrete choice experiments (DCEs) are a robust approach used to assess product preferences[42] and are increasingly used to optimize delivery of novel HIV prevention methods.[43–46] DCEs enable policymakers to prioritize service components, accurately procure and forecast resource needs, and enhance user engagement.[46] There is limited evidence around LA-PrEP preferences among pregnant women.

The aim of this study was to determine pregnant and postpartum women's preferred PrEP attributes using a DCE at important timepoints in the perinatal period with an overarching goal to inform health planning for delivering choice of PrEP products to pregnant/postpartum women.

Methods

Study setting and recruitment

This study was nested within a randomized controlled trial of pregnant women initiating PrEP in routine ANC clinics and followed through 9 months postpartum (NCT04472884) at five public health facilities in Kisumu and Siaya counties, Kenya. Facility selection and full eligibility criteria have been published.[47] The facilities were in high HIV prevalence areas with established infrastructure and collaboration with the Kenyan Ministry of Health. Facilities enrolled 600 HIV-negative pregnant women (24–32 weeks gestation) receiving ANC. Eligibility included being HIV and tuberculosis negative, HIV risk score ≥6 (translating to HIV incidence 7.3/100 person-years),[48] PrEP initiation during ANC, age ≥18, cell phone access, and plans to remain in the area and receive postpartum care at the clinic.

Survey development

We designed the DCE to identify PrEP attributes prioritized by pregnant and postpartum women. Attributes and levels were initially developed with input from stakeholders and study staff in Kisumu, Kenya. Clinic staff brainstormed factors influencing patients' decisions to take PrEP or other medications, producing a list refined to 5 attributes for pregnancy and 6 for postpartum. Attributes, levels, and images were further adapted through pilot testing with staff, with each attribute linked to 2–4 levels and corresponding figures (Table 2).

Survey design

We designed an unlabeled experiment using Lighthouse Studio Version 9.15.4 (Sawtooth Software). Participants were presented with 12 choice tasks to minimize cognitive burden while maintaining design efficiency.[49] In each task, participants were shown three hypothetical PrEP

scenarios and asked to choose their preferred one or to choose “Would rather take no PrEP at all” (Figure 2). Sample size was estimated using the following equation: $NN > 500c/ta$[50,51] where (t) is the number of choice questions asked, (a) is the number of alternatives, and (c) is the number of analysis cells (c). We used 3 alternatives (a) per choice set, 4 levels (maximum) per attributes (multiplied in order to investigate interactions 2 × 4 = 8), yielding 16 analysis cells (c), and 12 choice sets, suggesting a minimum sample size of 222.

Data collection

The DCE was conducted at participants’ 3rd study visit (~32–40 weeks gestation) and six months postpartum, aligning with WHO exclusive breastfeeding guidelines.[52] Data collection ran from February 2023 to July 2024. The survey included an introduction to DCEs, with interviewers explaining attributes and levels before participants answered 12 choice sets, each presenting three hypothetical PrEP options and a “no PrEP at all” choice. Data on demographics, PrEP use, reproductive health, and LA-PrEP interest were also collected as part of the clinical trial. Attributes were presented in a fixed order, with levels randomized using Sawtooth Software (Lighthouse Studio v9.15.4).

Predictors of interest

Participants reported missed PrEP doses over the past 30 days, categorized as perfect adherence (0 missed doses) or non-adherence (≥1 missed dose). PrEP discontinuation was recorded if stopped at the current or any prior visit. Self-efficacy was measured using the 12-item PrEP Adherence Self-Efficacy Scale (PrEP-ASES).[53] Depressive symptoms (CES-D score ≥10) [54,55] and anxiety (GAD-7: minimal ≤4, mild 5–9, moderate 10–14, severe ≥15)[56] were assessed, both scales validated in Kenya.[56,57] Perceived stress scale (PSS) was categorized as low, moderate, or high.[58] Intimate partner violence (IPV) was identified using the HITS scale (score >10).[59] Data were collected on previous pregnancy losses, high adverse childhood experiences (ACE ≥6),[60] education level (secondary or above), and infant outcomes, including live birth,

prematurity (<37 weeks), and WHO Z-scores for weight (WAZ), height (HAZ), head circumference (HCAZ), and weight-for-height (WHZ).[61]

Statistical analysis

Descriptive statistics summarized baseline and follow-up characteristics of participants who completed the DCE. Continuous variables were presented as medians and interquartile ranges (IQR), while categorical variables were summarized as frequencies and percentages.

Participant preferences for PrEP attributes were estimated using a conditional logit model with effects coding, where utility weights represent preferences relative to the mean attribute effect.[62] Positive weights indicate higher preference for a level, while negative weights indicate lower preference. The model also estimated utility for selecting “no PrEP at all”. Attribute importance was calculated as the range between the most- and least-preferred levels, divided by the total range of all attributes.[63]

We used latent class analysis (LCA) to assess preference heterogeneity.[64] We fit models with two to ten classes and selected the optimal model based on adjusted AIC, BIC, entropy, and scientific interpretability. We ran univariate multinomial logistic regressions to predict class membership based on relevant characteristics from PrEP literature such as demographics, PrEP use, sexual behavior, obstetric history, and child outcomes. We adjusted for age when the predictor variable was strongly correlated with age and could introduce confounding (e.g., number of pregnancies). Analyses were conducted using Sawtooth (Lighthouse Studio v9.15.4) and R (v4.3.0).

Ethical considerations

Ethical approval was obtained from the University of Washington IRB (STUDY00010797) and the Kenyatta National Hospital ERC (P319.05/2021). The clinical trial was registered at ClinicalTrials.gov (NCT04472884). All participants provided written informed consent.

Role of the funding source

The funder of this study had no role in study design, data collection, data analysis, data

interpretation, or writing of the report.

Results

Participant characteristics

A total of 513 women completed a DCE survey, 151 in pregnancy and 509 at postpartum visit. Among these, 147 women (28.7%) completed the DCE at both timepoints, 4 women (0.8%) only in pregnancy, and 362 women (70.6%) only postpartum. The lower number of DCEs conducted during pregnancy can be attributed to several factors, including missed visit or delivery before the 3rd antepartum visit due to either early delivery or late gestational age at enrollment. The median gestational age at the pregnancy DCE was 37.0 weeks (IQR: 36.2 – 38.4), and the median weeks postpartum at the postpartum DCE was 26.3 weeks (IQR: 26.0 – 27.0) (Table 3).

Participants who completed the DCE at both pregnancy and postpartum time points exhibited similar baseline characteristics. The randomization arm distribution was comparable, with approximately half in the mWACh arm (48.3% at pregnancy and 50.5% at postpartum). The median age was 24 years (IQR: 21.5 – 29.0) during pregnancy and 25 years (IQR: 22.0 – 29.0) during postpartum. Both pregnant and postpartum participants had a median of 2.0 previous pregnancies (IQR: 1.0 – 3.0). Among postpartum participants, nearly all (99.0%, n = 504) had a live birth. Nearly all (92.7%, n = 467) postpartum participants were currently breastfeeding.

PrEP characteristics were assessed at the time of the DCE. At the 3rd antepartum visit, 22.5% (n = 34) of participants had discontinued PrEP, compared to 35.0% (n = 178) at the 6-month postpartum visit. Among those still using PrEP, half missed one or more PrEP pills in the previous month, with 50.0% (n = 58) during pregnancy and 56.7% (n = 187) during postpartum. Side effects were reported by 20.3% (n = 25) of pregnancy participants and 15.4% (n = 56) of postpartum participants.

Participant preferences

For pregnancy and postpartum groups, the "form and dose" attribute was the most important

factor, though it was slightly more emphasized postpartum (pregnancy: 50.2%, postpartum: 53.7%). "Effectiveness" ranked as the second most important attribute for both groups (pregnancy: 22.7%, postpartum: 23.7%), followed by "safety data" (pregnancy: 17.7%, postpartum: 12.9%). The next most important attribute for postpartum participants was “multipurpose prevention technologies (MPT)” with 4.7%. The least important attributes for both groups were “collection place and associated cost” (pregnancy: 5.1%, postpartum: 3.0%) and “potential side effects” (pregnancy: 4.3%, postpartum: 2.0%).

Pregnancy and postpartum DCE utilities

Among both pregnant and postpartum participants, the bimonthly injection was strongly preferred, showing the highest positive utility (pregnant: 1.22, 95% CI: 1.12 to 1.33; postpartum: 1.24, 95% CI: 1.18 to 1.30; Figure 3). Good safety was the next most favored attribute, and utility was slightly higher among pregnant participants (0.39, 95% CI: 0.32 to 0.45) compared to postpartum participants (0.28, 95% CI: 0.25 to 0.31). A 10% increase in PrEP effectiveness also showed similar positive utilities (pregnant: 0.26, 95% CI: 0.21 to 0.30; postpartum: 0.27, 95% CI: 0.24 to 0.29). Daily oral PrEP was moderately preferred by both groups, with a utility of 0.24 (95% CI: 0.10 to 0.38) for pregnant participants and 0.32 (95% CI: 0.25 to 0.39) for postpartum participants. Postpartum participants also valued MPTs that prevent pregnancy, with a utility of 0.10 (95% CI: 0.07 to 0.13).

Free collection from a health facility was slightly preferred by pregnant participants (0.13, 95% CI: 0.01 to 0.26), while postpartum participants slightly favored free collection from antenatal clinics (0.08, 95% CI: 0.01 to 0.15). Collection from pharmacies or home delivery with associated costs had negative utilities for both groups. Participants in both groups preferred no side effects (pregnant: 0.06, 95% CI: -0.05 to 0.17; postpartum: 0.04, 95% CI: -0.02 to 0.10). Weight gain was more tolerated by pregnant participants (0.08, 95% CI: -0.03 to 0.19), while postpartum participants viewed weight gain and loss neutrally or slightly negatively. Negative utilities were

associated with attributes like a 5 kg weight loss (pregnant: -0.11, 95% CI: -0.22 to 0.00; postpartum: -0.05, 95% CI: -0.11 to 0.01) and nausea for both groups.

Overall, both groups disfavored the vaginal ring (pregnant: -0.98, 95% CI: -1.12 to -0.83; postpartum: -1.11, 95% CI: -1.20 to -1.03) and event-driven oral PrEP (pregnant: -0.48, 95% CI: -0.61 to -0.36; postpartum: -0.45, 95% CI: -0.52 to -0.38). Additionally, both preferred some form of PrEP over none, as reflected by negative utilities for the option “Would rather not take PrEP” (pregnant: -0.11, 95% CI: -0.24 to 0.02; postpartum: -0.20, 95% CI: -0.27 to -0.14).

Preference heterogeneity

A four-class model was selected based on priori hypotheses and statistical tests (Table 4). The LCA results for pregnancy and postpartum DCEs were comparable. Detailed postpartum results are presented here (Figure 4) and full pregnancy results are in Figure 5. The first class, "Oral PrEP Preference," comprised 8.6% of the sample. This group showed a strong preference for daily oral PrEP (utility: 3.49, 95% CI: 2.95–4.03) and choosing no PrEP at all (utility: 1.39, 95% CI: 0.99–1.79), with significant aversions to injectable PrEP (utility: -0.67, 95% CI: -0.91 to -0.43) and the vaginal ring (utility: -3.23, 95% CI: -3.78 to -2.68). The second class, "Flexible PrEP Adopters," made up 37.2% of the sample. This group showed mixed preferences, with a slight preference for bimonthly injections (utility: 0.53, 95% CI: 0.39–0.67) but no strong aversion to other methods and a strong aversion to taking no PrEP at all (utility: -3.24, 95% CI: -3.43 to -3.06). They had a strong preference for good safety data (utility: 0.34, 95% CI: 0.21–0.47) and a PrEP option that could prevent pregnancy (utility: 0.20, 95% CI: 0.15–0.25). The third class, "Safe and Effective Injection Preference," which accounted for 16.5% of the sample, had a strong preference for bimonthly injectable PrEP (utility: 1.76, 95% CI: 1.63–1.89) or no PrEP at all (utility: 2.12, 95% CI: 1.99–2.25), and showed significant aversions to the vaginal ring (utility: -2.86, 95% CI: -3.12 to -2.60). This group placed high importance on a 10% increase in effectiveness (utility: 0.05, 95% CI: 0.03–0.07), good safety data (utility: 0.94, 95% CI: 0.84–1.04), and no side effects (utility:

0.18, 95% CI: 0.11–0.25). The largest class, "Strong Injection Preference," consisted of 37.7% of the sample. This group showed a strong preference for bimonthly injections (utility: 3.59, 95% CI: 3.48–3.71) but also expressed some positive attitudes towards daily oral PrEP (utility: 0.82, 95% CI: 0.71–0.93), while significantly disfavoring the vaginal ring (utility: -2.31, 95% CI: -2.43 to -2.19), event-driven oral PrEP (utility: -2.10, 95% CI: -2.22 to -1.98). They preferred to collect free PrEP from ANC clinics (utility: 0.24, 95% CI: 0.20–0.28), and valued PrEP with good safety data (utility: 0.15, 95% CI: 0.08–0.21).

The multinomial univariate logistic regression revealed several factors that distinguish "Flexible PrEP Adopters", "Safe and Effective Injection Preference", or "Strong Injection Preference" membership from “Oral PrEP Preference” (Table 5). Full univariate associations can be found in Table 6. Age was negatively associated with being in "Strong Injection Preference" (OR=0.9, 95% CI: 0.9-1.0, p=0.021) but no other classes. Secondary education or higher was associated with higher odds of being in "Flexible PrEP Adopters" (OR=2.9, 95% CI: 1.5-5.6, p=0.002), "Safe and Effective Injection Preference" (OR=3.1, 95% CI: 1.5-6.6, p=0.003), and "Strong Injection Preference" (OR=2.0, 95% CI: 1.0-3.9, p=0.036). Participants who were married had lower odds of being in "Strong Injection Preference" (OR=0.3, 95% CI: 0.1 - 0.7, p=0.009) while those who had greater than two people per room per household had a higher odds of being in "Safe and Effective Injection Preference" (OR=2.7, 95% CI: 1.1 - 6.7, p=0.039).

Discontinuing PrEP was associated with higher odds of being in "Flexible PrEP Adopters" (OR=11.7, 95% CI: 3.5-39.0, p<0.001), "Safe and Effective Injection Preference" (OR=12.1, 95% CI: 3.5-42.2, p<0.001), and "Strong Injection Preference" (OR=5.0, 95% CI: 1.5-16.9, p=0.009). Missing one or more pills in the last month showed a trend toward significance for "Flexible PrEP Adopters" (OR=2.0, 95% CI: 1.0-4.2, p=0.067). Experiencing side effects associated with higher odds of being in "Flexible PrEP Adopters" (OR=7.1, 95% CI: 2.3-22.3, p=0.001) and "Safe and Effective Injection Preference" (OR=3.8, 95% CI: 1.1-13.0, p=0.037. A higher PrEP self-efficacy

score was associated with lower odds of being in "Flexible PrEP Adopters" (OR=0.7, 95% CI: 0.6 - 0.8, p<0.001), "Safe and Effective Injection Preference" (OR= 0.8, 95% CI: 0.6 – 1.0, p=0.022) and "Strong Injection Preference" (OR =0.8, 95% CI: 0.6 – 1.0, p=0.030).

Regressions for the number of previous pregnancies, being primigravida, number of previous live births and number of live children were adjusted for age. A higher number of previous pregnancies was associated with lower odds of being in "Flexible PrEP Adopters" (OR=0.6, 95% CI: 0.4-0.8, p=0.001), "Safe and Effective Injection Preference" (OR=0.6, 95% CI: 0.4-0.8, p=0.003), and "Strong Injection Preference" (OR=0.7, 95% CI: 0.5-1, p=0.027). The number of previous live births and number of live children had parallel results. Similarly, being primigravida was significantly associated with higher odds of being in "Safe and Effective Injection Preference" (OR=2.8, 95% CI: 1.0-7.9, p=0.046). None of the child outcomes, such as low WAZ, premature birth, or child illness since birth, were significantly associated with class membership.

In the pregnancy DCE, receiving mobile adherence support was associated with a lower odds of being in "Flexible PrEP Adopters" (OR: 0.3, 95% CI: 0.1 - 1.5, p=0.151), "Safe and Effective Injection Preference" (OR: 0.2, 95% CI: 0.0 - 1.3, p=0.099), and "Strong Injection Preference" (OR: 0.1, 95% CI: 0.0 - 0.7, p=0.019), although only "Strong Injection Preference" was statistically significant (Table 7). Other magnitudes of effect were like that in postpartum.

Discussion

This DCE among pregnant and postpartum women in Kenya provides valuable insights into preferences for PrEP attributes. We found clear preferences for bimonthly injectable PrEP, which had the highest utility of any PrEP characteristic both in pregnancy and postpartum. Other important attributes such as effectiveness and safety data underscore the importance of providing women with PrEP options that are both highly efficacious and supported by robust safety evidence. These findings align with previous studies indicating that PrEP options that are long-acting and less burdensome are preferred by women during pregnancy and postpartum.[65] A DCE

conducted among postpartum women in South Africa and Zimbabwe similarly found that duration of protection was the most important feature of long-acting HIV prevention.[66]

We identified four distinct preference profiles: Oral PrEP Preference, Flexible PrEP Adopters, Safe and Effective Injection Preference, and Strong Injection Preference, reinforcing that a one-size-fits-all approach to PrEP delivery may not be optimal. The smaller Oral PrEP Preference class strongly preferred daily oral PrEP or no PrEP, over injectables or the vaginal ring. This may reflect a fear of injections, comfort with familiar options, or concerns about newer formulations.[67,68] Most participants favored LA injectable PrEP. Flexible PrEP Adopters and Safe and Effective Injection Preference groups were open to multiple forms if safe and effective, while the largest class, Strong Injection Preference, strongly favored injectable PrEP but still had some positive views on daily oral PrEP. Bi-monthly injectables offer convenience and address challenges with daily adherence, particularly for pregnant and breastfeeding women managing pregnancy, newborn care, or postpartum recovery.[69–74] A South African study found postpartum women and those with prior pregnancies were 15% and 25% more likely to discontinue daily oral PrEP, respectively.[69] Additionally, the discreet nature of injectables may appeal to women facing stigma or privacy concerns around HIV prevention.[75,76]

The multinomial logistic regression analysis revealed several important predictors of class membership. Women with a higher number of previous pregnancies, live births, and live children were less likely to belong to classes that favored injectables. The direction and magnitude of effect was similar among pregnancy DCE participants, although small sample size limited our confidence intervals. These findings are in line with previous studies that multiparous women may experience barriers to oral PrEP adherence and particularly benefit from LA-PrEP formulations.[70]

This study highlights key implications for PrEP delivery in antenatal and postpartum care. The strong preference for bimonthly injectables underscores the need to prioritize LA-PrEP availability for pregnant and breastfeeding women, who require self-controlled, discrete HIV prevention

options,[77] yet national guidelines and clinical safety data are still lagging.[73] Distinct preference groups suggest ANC settings should offer multiple PrEP modalities with tailored counseling based on individual preferences, prior PrEP use, and obstetric history. Decision support tools have been used to support family planning method choice[78,79] and PrEP persistence among adolescent girls and young women in Kenya[80] and could be a valuable implementation strategy to help women make informed choices and address the complexity of offering diverse PrEP options.

In this DCE, we found an aversion to collection locations that were associated with a cost (home delivery or pharmacy) highlighting the importance free PrEP access.[81] Postpartum women may face higher barriers to accessing PrEP, including transportation costs, logistical challenges, financial constraints, and lack of childcare, which make clinic visits burdensome and limit consistent access.[70] Integrating LA-PrEP into routine maternal healthcare, particularly ANC clinics, has demonstrated acceptability and feasibility in Kenya and South Africa[41,82,83] and can increase accessibility,[41,84] reduce stigma,[82] streamline care,[82] improve adherence,[41] and provide women with tailored support.[20,82]

Strengths and limitations

There are several limitations to generalizability that should be considered. First, the DCE was conducted within a randomized trial which specifically enrolled women from ANC clinics, who took PrEP. Enrolling women from ANC clinics, potentially limits applicability to women who do not seek ANC services. Additionally, all participants had experience taking PrEP prior to the DCE. Thus, we are unable to capture decision-making processes of women who have not yet initiated PrEP. Participants were selected based on a high HIV risk score, which limits generalizability to populations with lower risk profiles. However, prioritizing PrEP for individuals at highest risk of HIV acquisition has the highest impact for reducing HIV incidence.[48,85–87]

DCEs are valuable for understanding decision-making, though hypothetical scenarios may not fully reflect actual behavior. Despite this, there is evidence that stated preference can predict

revealed behavior[88] and this research advances person-centered care by uncovering the nuanced preferences and decision-making processes of diverse populations. Using preference data can enhance our ability to address disparities, align strategies with needs of historically marginalized communities, and facilitate the prioritization and evaluation of implementation determinants, ultimately contributing to more informed policy and program development.[89]

Conclusion

Overall, these findings contribute to the growing body of evidence supporting the need for differentiated PrEP delivery models that align with women's preferences during pregnancy and postpartum. By incorporating women's preferences, we can better meet their needs and ultimately improve HIV prevention outcomes.

Table 2: DCE attributes and levels

Attribute	Levels
Effectiveness: How well the PrEP product works at preventing HIV. It is described as a percent.	1. 60% 2. 85% 3. 90% 4. 99%
Form and dosing: How the PrEP drug looks, size of the product, how much and how often it needs to be taken. It also describes what the packaging looks like.	1. Large oral pill taken once a day, comes in a pill bottle 2. Injection taken once every two months 3. Large oral pill, taken before and after HIV risk event (2 pills before sex, 1 pill 24 hours after sex, and 1 pill 48 hours after sex), comes in a blister pack. 4. Flexible vaginal ring inserted once every month
Available safety data: Data to support the safety of taking this PrEP product for pregnant and breastfeeding women. Safety and follow up data usually show that there is no harmful impact of the medication on the developing baby.	1. Little to no data on the effect of this medication on the baby 2. Data show this medication is safe for the baby
Side effects: This attribute describes side effects like dizziness, nausea, or weight gain that can be experienced when taking PrEP.	1. About 5kg weight loss 2. About 5kg weight gain 3. Nausea/vomiting 4. No side effects
Collection place & cost: Collection place describes where PrEP is available for individuals in need of it and cost is associated with some collection places. Some collection places offer PrEP for free.	1. Health facility (free) 2. Pharmacy (for an added cost) 3. ANC (free) 4. Home delivery (for an added cost)
Multipurpose Prevention Technology (MPT): This attribute describes if the PrEP medication also prevents pregnancy, or if contraception is separate. This attribute is only used in the postpartum DCE.	1. This medication also prevents pregnancy 2. This medication does not prevent pregnancy

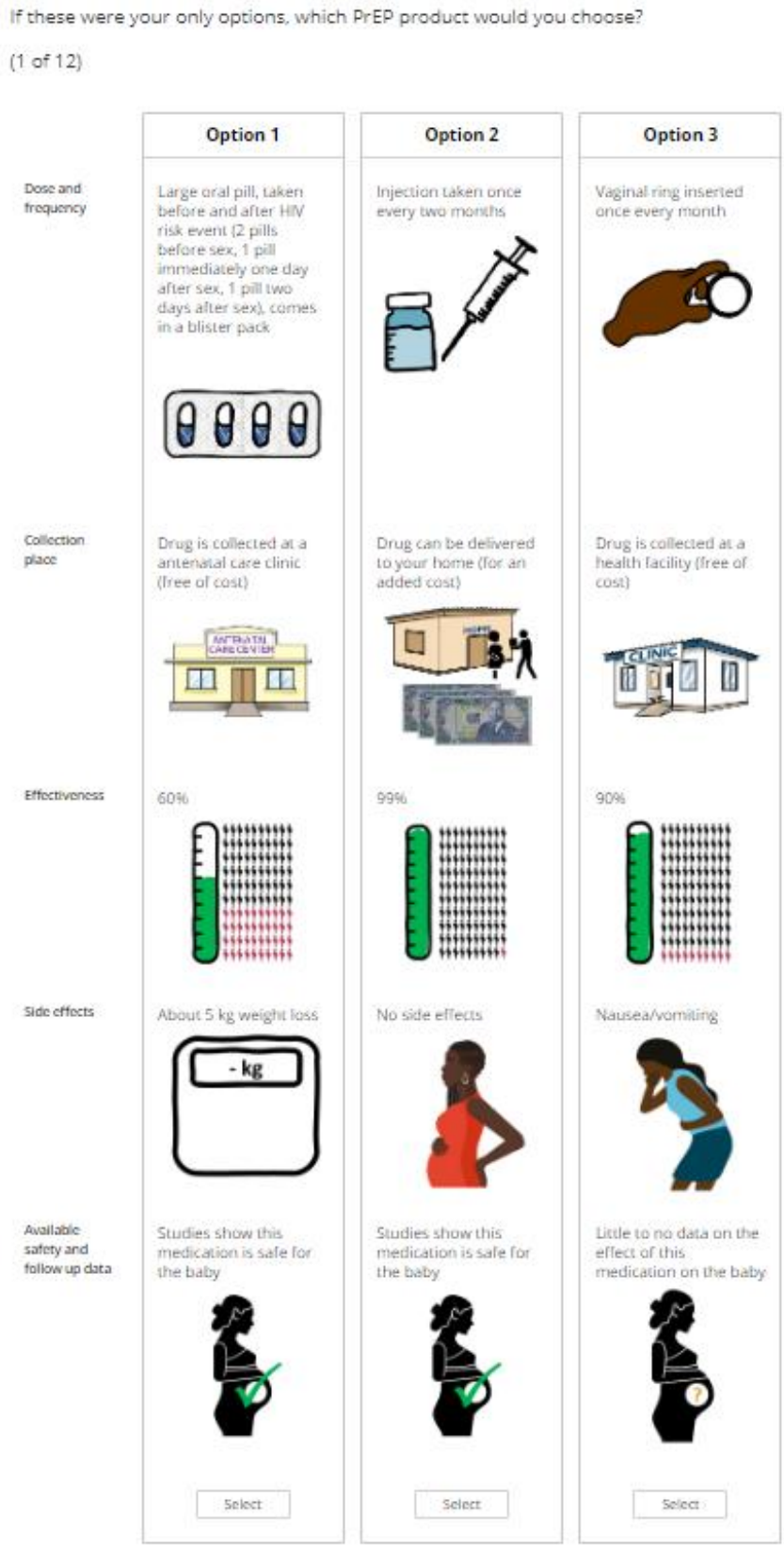


Figure 2: Example DCE choice set for postpartum participants

Table 3: Demographic, PrEP taking, sociobehavioral, and obstetric characteristics of pregnant (N=151) and postpartum (N=509) women who completed a DCE on LA-PrEP preferences

	3rd antepartum follow-up, N = 151[1] Gestational weeks: 37.0 (36.2, 38.4)	**6-months postpartum**, N = 509[1] Weeks postpartum: 26.3 (26.0, 27.0)
Enrollment characteristics		
Randomization arm		
mWACh	73 (48.3%)	257 (50.5%)
SOC	78 (51.7%)	252 (49.5%)
Age	24.0 (21.5, 29.0)	25.0 (22.0, 29.0)
Married	106 (70.2%)	359 (70.5%)
Secondary education or higher	97 (64.2%)	319 (62.7%)
Has regular employment	33 (21.9%)	106 (20.9%)
>2 people per room in household	42 (27.8%)	147 (28.9%)
High ACE score	40 (26.5%)	130 (25.5%)
PrEP characteristics		
Discontinued PrEP	34 (22.5%)	178 (35.0%)
Missed ≥1 PrEP pills last month*	58 (49.6%)	187 (56.5%)
Missing	1	1
Experienced side effects*	25 (21.4%)	52 (15.7%)
PrEP self-efficacy score*	8.7 (7.5, 10.0)	9.0 (7.7, 10.0)
Sociobehavioral characteristics		
Elevated depressive symptoms	2 (1.3%)	8 (1.6%)
Anxiety symptom score		
Minimal	151 (100.0%)	496 (97.4%)
Mild	0 (0.0%)	10 (2.0%)
Moderate	0 (0.0%)	3 (0.6%)
Sexual behavior characteristics		
Partner HIV status		
HIV negative	5 (3.3%)	28 (5.5%)
HIV positive	6 (4.0%)	15 (2.9%)
Unknown status	128 (84.8%)	436 (85.7%)
No partner	12 (7.9%)	30 (5.9%)
Number of lifetime sexual partners	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)
Has ever exchanged sex for money	2 (1.3%)	18 (3.5%)
Has been diagnosed with or treated for an STI	2 (1.3%)	6 (1.2%)
Obstetric history		
Previous pregnancies	2.0 (1.0, 3.0)	2.0 (1.0, 3.0)
Previous pregnancy loss	20 (13.2%)	64 (12.6%)
Gestational age when starting PrEP	24.0 (24.0, 26.0)	26.0 (24.0, 29.0)
Currently on FP		240 (65.6%)
Missing		143**
Currently using injectable FP		58 (11.4%)
Current pregnancy and child outcomes		
Live birth		504 (99.0%)
Baby premature (<37 weeks)		19 (3.8%)
Missing		5
Low WAZ		22 (4.6%)
Missing		34
Low HAZ		33 (7.0%)
Missing		36
Low WHZ		30 (6.3%)
Missing		36
Currently breastfeeding		467 (92.7%)
Missing		5
Child ill since birth		77 (15.1%)
Child hospitalized since birth		4 (0.8%)

[1]n (%); Median (IQR), *among those who continued with PrEP; **Data abstracted from PrEP card not available at this study visit; ACE: Adverse childhood experience, FP: family planning, STI: Sexually transmitted infection, WAZ: Weight-for-age z-score, HAZ: Heigh-for-age z-score, HCAZ: Head circumference-for-age z-score, WHZ, weight-for-height z-score

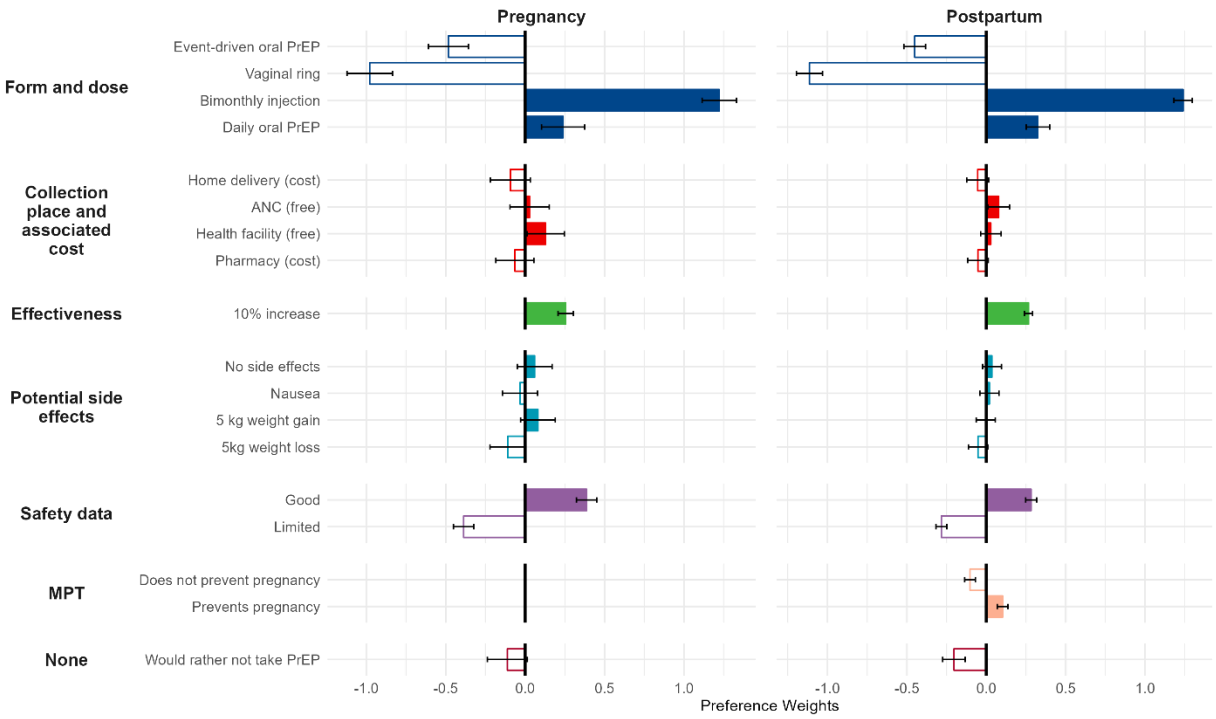


Figure 3: Positive (filled in) and negative (outlined) LA PrEP attribute utilities by perinatal stage

Table 4: Goodness of fit statistics for latent class models in pregnancy (n=151) and postpartum (n=509) DCEs

Classes	Log-likelihood	AIC	CAIC	BIC	ABIC	Chi-Square	Relative Chi-Square	Entropy
Pregnancy								
2	-1793.75	3637.50	3800.02	3775.02	3695.59	1428.11	57.12	0.90
3	-1663.40	3402.81	3649.83	3611.83	3491.10	1688.81	44.44	0.93
4	-1577.89	3257.78	3589.31	3538.31	3376.29	1859.83	36.47	0.95
5	-1523.63	3175.26	3591.30	3527.30	3323.97	1968.35	30.76	0.93
6	-1480.98	3115.96	3616.50	3539.50	3294.87	2053.65	26.67	0.94
7	-1439.15	3058.31	3643.35	3553.35	3267.43	2137.31	23.75	0.94
8	-1411.27	3028.54	3698.10	3595.10	3267.87	2193.07	21.29	0.95
9	-1377.22	2986.43	3740.49	3624.49	3255.97	2261.18	19.49	0.96
10	-1369.78	2997.56	3836.13	3707.13	3297.31	2276.05	17.64	0.96
Postpartum								
2	-6000.37	12062.74	12301.95	12270.95	12172.44	4920.37	158.72	0.90
3	-5524.67	11143.34	11506.01	11459.01	11309.66	5871.77	124.93	0.92
4	-5313.77	10753.54	11239.68	11176.68	10976.48	6293.57	99.90	0.94
5	-5172.49	10502.97	11112.58	11033.58	10782.54	6576.14	83.24	0.94
6	-5070.20	10330.40	11063.47	10968.47	10666.59	6780.71	71.38	0.93
7	-4983.53	10189.06	11045.59	10934.59	10581.86	6954.05	62.65	0.92
8	-4914.51	10083.02	11063.02	10936.02	10532.45	7092.08	55.84	0.91
9	-4848.96	9983.93	11087.39	10944.39	10489.98	7223.18	50.51	0.91
10	-4790.35	9898.69	11125.62	10966.62	10461.36	7340.42	46.17	0.92

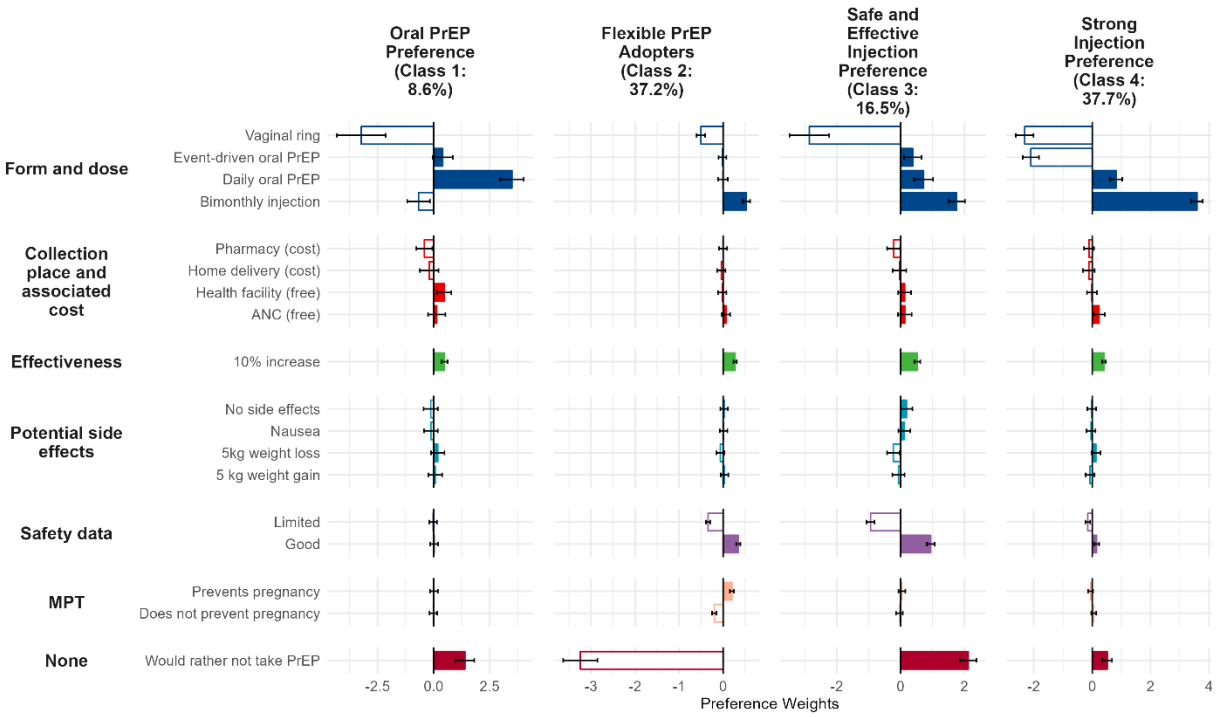
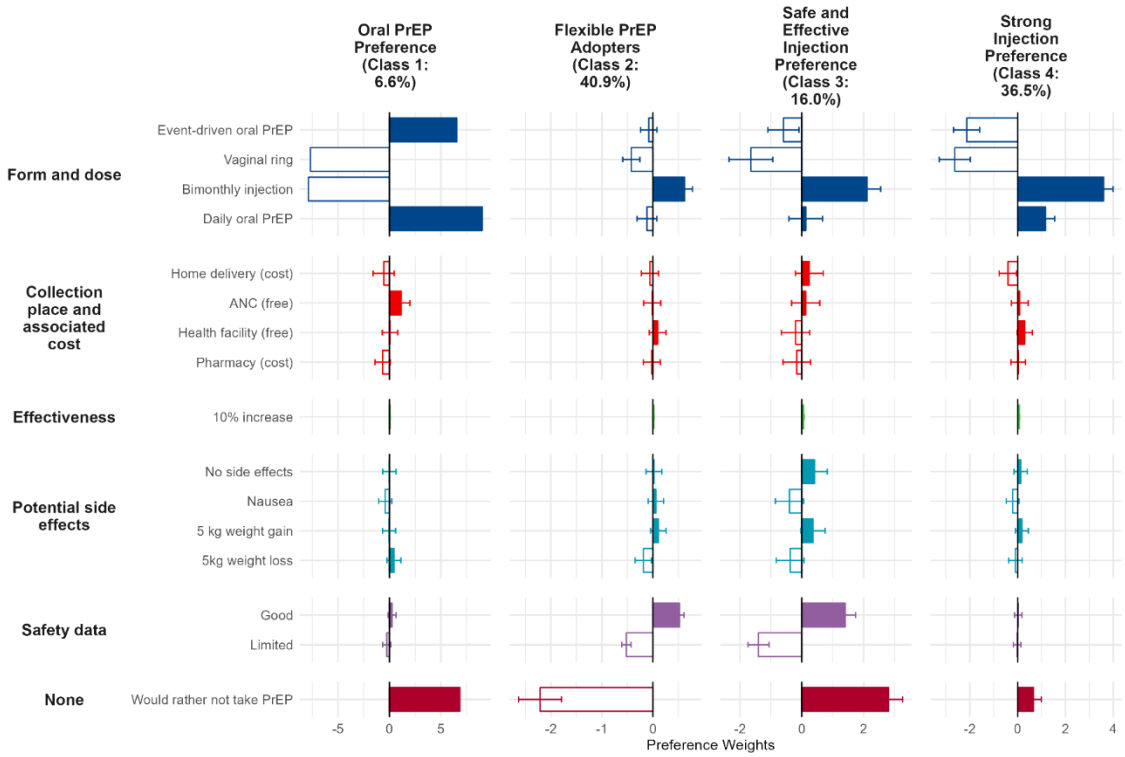


Figure 4: Positive (filled in) and negative (outlined) LA PrEP attribute utilities by latent class assignment among postpartum participants (n=509)



* To improve readability, confidence intervals are not shown for “event driven oral PrEP” (95% CI: -111.0 - 124.0), “daily oral PrEP” (95% CI: -109.0 - 127.0), and “would rather not take PrEP” (95% CI: -111.0 - 124.0) in Class 1. Confidence intervals for “vaginal ring” and “bimonthly injection” in Class 1 could not be estimated.

Figure 5: Positive (filled in) and negative (outlined) LA PrEP attribute utilities by latent class assignment among pregnant participants (n=151)

Table 5: Univariate associations of baseline, PrEP taking, and obstetric characteristics with latent class assignment among postpartum participants*

	"Flexible PrEP adopters" *(ref: "Oral PrEP Preference")*		**"Safe, effective injection"** *(ref: "Oral PrEP Preference")*		**"Strong injection preference"** *(ref: "Oral PrEP Preference")*	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Baseline characteristics**						
Age (years)	1.0 (0.9 - 1.0)	0.108	1.0 (0.9 - 1.1)	0.951	0.9 (0.9 - 1.0)	0.021
Married	0.6 (0.2 - 1.4)	0.210	0.4 (0.2 - 1.0)	0.052	0.3 (0.1 - 0.7)	0.009
Secondary education or higher	2.9 (1.5 - 5.6)	0.002	3.1 (1.5 - 6.6)	0.003	2.0 (1.0 - 3.9)	0.036
Has regular employment	1.1 (0.5 - 2.7)	0.824	2.7 (1.1 - 6.7)	0.039	1.4 (0.6 - 3.4)	0.426
High ACE score	1.3 (0.6 - 2.6)	0.482	0.8 (0.4 - 1.8)	0.581	0.5 (0.2 - 1.0)	0.061
PrEP experience**						
Discontinued PrEP	11.7 (3.5 - 39.0)	<0.001	12.1 (3.5 - 42.2)	<0.001	5.0 (1.5 - 16.9)	0.009
Missed ≥1 PrEP pills in last month	2.0 (1.0 - 4.2)	0.067	1.9 (0.8 - 4.5)	0.172	0.7 (0.3 - 1.4)	0.295
Experienced side effects	7.1 (2.3 - 22.3)	0.001	3.8 (1.1 - 13)	0.037	1.0 (0.4 - 2.1)	0.909
PrEP self-efficacy score	0.7 (0.6 - 0.8)	<0.001	0.8 (0.6 - 1.0)	0.022	0.8 (0.6 - 1.0)	0.030
Obstetric history**						
# of previous pregnancies*	0.6 (0.4 - 0.8)	0.001	0.6 (0.4 - 0.8)	0.003	0.7 (0.5 - 1.0)	0.027
Primigravida*	2.0 (0.8 - 5.1)	0.127	2.8 (1.0 - 7.9)	0.046	2.1 (0.9 - 5.4)	0.102
# of previous live births*	0.7 (0.5 - 0.9)	0.012	0.8 (0.6 - 1.2)	0.279	0.8 (0.6 - 1.0)	0.061
# of children*	0.7 (0.5 - 0.9)	0.008	0.8 (0.6 - 1.2)	0.282	0.7 (0.6 - 1.0)	0.039
Currently using FP	1.2 (0.6 - 2.5)	0.592	1.7 (0.7 - 4.0)	0.202	2.0 (1.0 - 3.9)	0.058
Current pregnancy and child outcomes*						
Weeks postpartum	1.1 (1.0 - 1.3)	0.161	1.1 (0.9 - 1.4)	0.204	1.2 (1.0 - 1.4)	0.083

*Variables that are highly correlated with age were adjusted for age (continuous)

**Associations with a p-value >0.1 across all classes are excluded and can be found in Table 6: Received mobile adherence support, >2 people per room in household, # of lifetime sexual partners, partner HIV status, has engaged in sex in exchange for money or other favors, has been diagnosed with or treated for an STI, previous pregnancy loss, currently on injectable family planning, gestational age when starting PrEP, baby born premature, baby low WAZ, baby low WHZ, child has been ill since birth

Table 6: Full table of univariate associations of baseline, PrEP taking, and obstetric characteristics with latent class assignment among postpartum participants (n=509)*

	Frequency in sample[1]	**Class 2** *(ref: Class 1) "Flexible PrEP adopters"*		**Class 3** *(ref: Class 2) "Safe, effective injection"*		**Class 4** *(ref: Class 2) "Strong injection preference"*	
		OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Enrollment characteristics							
Received mobile adherence support	257 (50.5%)	0.6 (0.3 - 1.2)	0.138	0.6 (0.3 - 1.3)	0.227	0.7 (0.4 - 1.4)	0.323
Age (years)	25.0 (22.0, 29.0)	1.0 (0.9 – 1.0)	0.108	1.0 (0.9 - 1.1)	0.951	0.9 (0.9 – 1.0)	0.021
Married	359 (70.5%)	0.6 (0.2 - 1.4)	0.210	0.4 (0.2 – 1.0)	0.052	0.3 (0.1 - 0.7)	0.009
Secondary education or higher	319 (62.7%)	2.9 (1.5 - 5.6)	0.002	3.1 (1.5 - 6.6)	0.003	2.0 (1.0 - 3.9)	0.036
Has regular employment	106 (20.9%)	1.3 (0.6 - 2.6)	0.482	0.8 (0.4 - 1.8)	0.581	0.5 (0.2 – 1.0)	0.061
> 2 people per room in household	147 (28.9%)	1.1 (0.5 - 2.7)	0.824	2.7 (1.1 - 6.7)	0.039	1.4 (0.6 - 3.4)	0.426
High ACE score	130 (25.5%)	1.1 (0.6 - 2.3)	0.710	1.0 (0.5 - 2.3)	0.964	0.9 (0.4 - 1.8)	0.683
PrEP characteristics							
Discontinued PrEP	178 (35.0%)	11.7 (3.5 - 39)	<0.001	12.1 (3.5 - 42.2)	<0.001	5 (1.5 - 16.9)	0.009
Missed ≥1 pills in last month	187 (56.5%)**	2.0 (1.0 - 4.2)	0.067	1.9 (0.8 - 4.5)	0.172	0.7 (0.3 - 1.4)	0.295
Experienced side effects	52 (15.7%)**	7.1 (2.3 - 22.3)	0.001	3.8 (1.1 - 13)	0.037	1 (0.4 - 2.1)	0.909
PrEP self-efficacy score	9.0 (7.7, 10.0)**	0.7 (0.6 - 0.8)	<0.001	0.8 (0.6 - 1)	0.022	0.8 (0.6 - 1)	0.030
Sexual behavior characteristics							
Partner HIV negative (reference)	28 (5.8%)	Ref		Ref		Ref	
Partner HIV positive	15 (3.1%)	0.6 (0.0 - 11.3)	0.744	0.5 (0 - 10.3)	0.653	0.3 (0 - 8.2)	0.501
Partner status unknown	436 (91.0%)	0.3 (0.0 - 2.5)	0.270	0.2 (0 - 1.7)	0.144	0.7 (0.1 - 5.9)	0.740
Number of lifetime sexual partners*	3.0 (2.0, 4.0)	1.1 (0.9-1.3)	0.285	1.1 (1-1.3)	0.115	1 (0.8-1.2)	0.747
Has engaged in sex in exchange for money or other favors	18 (3.5%)	1.9 (0.2 - 16)	0.536	1.7 (0.2 - 16.6)	0.661	1.4 (0.2 - 12)	0.752
Has been diagnosed with or treated for an STI	6 (1.2%)	0.5 (0.0 - 5.3)	0.545	0.5 (0 - 8.9)	0.669	0.5 (0 - 5.2)	0.531
Obstetric history							
# of previous pregnancies*	2.0 (1.0, 3.0)	0.6 (0.4-0.8)	0.001	0.6 (0.4-0.8)	0.003	0.7 (0.5-1)	0.027
Primigravida*	325 (63.9%)	2.0 (0.8-5.1)	0.127	2.8 (1-7.9)	0.046	2.1 (0.9-5.4)	0.102
Previous pregnancy loss	64 (12.6%)	0.6 (0.3 - 1.5)	0.272	0.7 (0.3 - 1.9)	0.511	0.6 (0.3 - 1.5)	0.296
# of previous live births*	2.0 (1.0, 2.0)	0.5 (0.4-0.8)	0.003	0.6 (0.4-0.9)	0.017	0.7 (0.5-1)	0.057
# of children*	2.0 (1.0, 2.0)	0.5 (0.3-0.8)	0.001	0.6 (0.4-0.9)	0.017	0.6 (0.4-1)	0.033
Currently using FP	240 (65.6%)	1.2 (0.6 - 2.5)	0.592	1.7 (0.7 - 4)	0.202	2 (1 - 3.9)	0.058
Currently using injectable FP	58 (11.4%)	1.8 (0.5 - 6.1)	0.383	1.1 (0.3 - 4.6)	0.891	2.4 (0.7 - 8.2)	0.171
Gestational age when starting PrEP	26.0 (24.0, 29.0)	0.9 (0.8 - 1.1)	0.308	1 (0.8 - 1.1)	0.583	0.9 (0.8 - 1)	0.249
Current pregnancy and child outcomes							
Weeks postpartum	26.3 (26.0, 27.0)	1.1 (1 - 1.3)	0.161	1.1 (0.9 - 1.4)	0.204	1.2 (1 - 1.4)	0.083
Baby born premature	19 (3.8%)	1.2 (0.1 - 10.7)	0.860	2.9 (0.3 - 25.6)	0.339	1.9 (0.2 - 15.7)	0.546
Low WAZ	22 (4.6%)	1.3 (0.3 - 6.3)	0.715	0.6 (0.1 - 4.5)	0.623	1 (0.2 - 4.7)	0.966
Low WHZ	30 (6.3%)	2.7 (0.3 - 21.6)	0.352	1.8 (0.2 - 18.3)	0.602	4 (0.5 - 31.4)	0.181
Child ill since birth	77 (15.1%)	0.6 (0.2 - 1.3)	0.174	0.6 (0.2 - 1.5)	0.242	0.9 (0.4 - 2)	0.772

[1]n (%); Median (IQR), *Variables that are highly correlated with age were adjusted for age (continuous), **Among those who continued on PrEP

Table 7: Full table of univariate associations of baseline, PrEP taking, and obstetric characteristics with latent class assignment among pregnant participants (n=151)*

	Frequency in sample[1]	**Class 2** *(ref: Class 1)* *"Flexible PrEP adopters"*		**Class 3** *(ref: Class 1)* *"Safe, effective injection"*		**Class 4** *(ref: Class 1)* *"Strong injection preference"*	
		OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Enrollment characteristics							
Received mobile adherence support	73 (48.3%)	0.3 (0.1 - 1.5)	0.151	0.2 (0 - 1.3)	0.099	0.1 (0 - 0.7)	0.019
Age (years)	24.0 (21.5, 29.0)	1 (0.9 - 1.1)	0.983	1 (0.9 - 1.2)	0.848	1 (0.9 - 1.1)	0.943
Married	106 (70.2%)	0.3 (0 - 2.1)	0.205	0.3 (0 - 2.4)	0.233	0.2 (0 - 2)	0.185
Secondary education or higher	97 (64.2%)	1.4 (0.4 - 5.5)	0.631	1.5 (0.3 - 7.1)	0.593	1 (0.2 - 3.8)	0.949
Has regular employment	33 (21.9%)	0.5 (0.1 - 2.9)	0.446	1.1 (0.2 - 7)	0.911	2.1 (0.4 - 10.6)	0.391
> 2 people per room in household	42 (27.8%)	4.3 (0.5 - 36.2)	0.181	2.5 (0.3 - 24.7)	0.433	3.6 (0.4 - 30.8)	0.242
High ACE score	40 (26.5%)	4.6 (0.5 - 38.9)	0.16	4.8 (0.5 - 45)	0.169	2 (0.2 - 17.2)	0.545
PrEP characteristics							
Discontinued PrEP	34 (22.5%)	2.9 (0.3 - 24.6)	0.335	5.8 (0.6 - 53.8)	0.123	1.7 (0.2 - 15.3)	0.625
Missed 1+ pills in last month	58 (49.6%)**	5.4 (1 - 29.2)	0.048	8.8 (1.2 - 61.7)	0.029	2.2 (0.4 - 11.6)	0.365
Experienced side effects	25 (21.4%)**	2.5 (0.5 - 12.1)	0.256	8 (0.7 - 92.7)	0.096	1.4 (0.3 - 6.4)	0.676
PrEP self efficacy score	8.7 (7.5, 10.0)**	0.9 (0.6 - 1.2)	0.352	0.9 (0.6 - 1.3)	0.609	1.1 (0.8 - 1.6)	0.442
Sexual behavior characteristics							
Partner HIV negative (reference)	5 (3.6%)	Ref		Ref		Ref	
Partner HIV positive	6 (4.3%)	3.1 (0 - >100)	0.994	>100 (0 - >100)	0.96	3.1 (0 - >100)	0.994
Partner status unknown	128 (92.1%)	0 (0 - >100)	0.914	12.1 (0 - >100)	0.99	0 (0 - >100)	0.916
Number of lifetime sexual partners*	3.0 (2.0, 4.0)	1.1 (0.8-1.4)	0.657	1.1 (0.8-1.4)	0.488	1.1 (0.8-1.4)	0.694
Has engaged in sex in exchange for money or other favors	2 (1.3%)	>100 (0 - >100)	0.932	0 (0 - Inf)	0.993	>100 (0 - >100)	0.931
Has been diagnosed with or treated for an STI	2 (1.3%)	>100 (0 - >100)	0.932	0 (0 - Inf)	0.993	>100 (0 - >100)	0.931
Obstetric history							
# of previous pregnancies*	2.0 (1.0, 3.0)	0.6 (0.3-1.2)	0.170	0.6 (0.3-1.3)	0.174	0.9 (0.5-1.7)	0.709
Primigravida*	95 (62.9%)	1.8 (0.3-10.2)	0.519	2.9 (0.4-21.1)	0.282	1.2 (0.2-7.2)	0.806
Previous pregnancy loss	20 (13.2%)	0.6 (0.1 - 3.3)	0.551	0.4 (0 - 3.2)	0.373	0.7 (0.1 - 3.7)	0.644
# of previous live births*	2.0 (1.0, 3.0)	0.7 (0.3-1.6)	0.342	0.9 (0.3-2.4)	0.861	1.1 (0.5-2.5)	0.863
# of children*	2.0 (1.0, 3.0)	0.6 (0.3-1.4)	0.246	0.9 (0.3-2.3)	0.813	1.1 (0.5-2.4)	0.885
Gestational age when starting PrEP	24.0 (24.0, 26.0)	0.9 (0.6 - 1.2)	0.434	0.8 (0.6 - 1.3)	0.424	0.9 (0.7 - 1.3)	0.725

[1]n (%); Median (IQR), *Variables that are highly correlated with age were adjusted for age (continuous), **Among those who continued on PrEP

Chapter 3: Postpartum women's prospective acceptability of long-acting HIV prevention approaches in Kenya: A qualitative analysis using the Theoretical Framework of Acceptability

Introduction

In East and Southern Africa, women experience a two-fold higher risk of HIV infection during pregnancy and postpartum compared to non-pregnant periods, and acute maternal infections substantially increase risk of vertical HIV transmission.[2,90,91] The World Health Organization (WHO) recommends safe and effective HIV prevention methods among populations at substantial risk of HIV, including tenofovir disoproxil fumarate (TDF)-based oral pre-exposure prophylaxis (oral PrEP), and long-acting (LA-) PrEP methods, such as the dapivirine vaginal ring (DVR) and long-acting intramuscular injectable cabotegravir (CAB-LA).[27,28,92] Recent studies of DVR and CAB-LA use in pregnancy suggest a favorable safety profile,[30,31] but many countries await WHO guidance before approving use of these prevention products in pregnancy.

Oral PrEP has robust evidence supporting its safety, efficacy, and acceptability during pregnancy and postpartum periods. However, pregnant and postpartum women often face challenges with adherence and persistence, often due to co-occurring side effects with pregnancy and the demands of motherhood.[20,70,93] LA-PrEP methods, such as DVR and CAB-LA, may alleviate some of these burdens[65,94,95] and quantitative studies of LA-PrEP preferences among pregnant and breastfeeding women highlight the importance of offering a long-acting method with strong effectiveness and safety during pregnancy and breastfeeding, and an option that is free of charge.[65] Qualitative evaluations of LA-PrEP acceptability among pregnant and breastfeeding women are limited to DVR, highlighting both concerns about intravaginal use and benefits of discreet usage and a long-acting regimen.[96] Understanding acceptability of various PrEP methods from an end-user perspective is important to inform implementation and scale-up strategies.[77,97,98] Specifically, components of acceptability can inform PrEP counselling messaging, adherence support, and use of PrEP materials tailored to pregnancy and breastfeeding.[73] Despite this, there

is limited qualitative evidence of pregnant and postpartum women's perspectives on the relative acceptability for oral, vaginal ring, and injectable PrEP modalities.

The Theoretical Framework of Acceptability (TFA) was designed to support the assessment of acceptability of healthcare interventions within the development, piloting and feasibility, outcome and process evaluation, and implementation phases.[95] In this paper, we applied the TFA to in-depth interviews (IDIs) conducted among postpartum women who initiated daily oral PrEP during pregnancy. Our objective was to evaluate acceptability of LA-PrEP methods and identify strategies to enhance acceptability for pregnant and postpartum women.

Methods

Study design, setting and population

We conducted an exploratory qualitative study using content analysis among postpartum women receiving mobile PrEP-adherence support in the mWACh PrEP trial (ClinicalTrials.gov: NCT04472884). The trial took place in five public health facilities within Kisumu and Siaya Counties in Kenya. Participating facilities enrolled 600 pregnant women who were HIV negative, between 24 and 32 weeks of gestational age, and received antenatal at the facility. Women had monthly study visits during pregnancy and at six-weeks, 14-weeks, six months, and nine months postpartum. Detailed descriptions of the trial design, methods, and findings are published elsewhere.[47] We purposively selected 70 participants who indicated having consistently high or consistently low interest in LA-PrEP to participate in a single interview. IDIs were conducted after participants completed all clinical trial study visits.

Data collection

All trial participants completed nurse administered quantitative questionnaires at each study visit that assessed sexual behavior; infant outcomes; and PrEP attitudes, use, and adherence. At enrollment, participants were asked about their demographic and social factors, such as household characteristics and adverse childhood experiences (ACE).[60] Participants were

informed about PrEP products that may be available to them in the future, including a bi-monthly injectable PrEP and a monthly vaginal ring. At each study visit, participants were also asked "*A new form of PrEP might be available soon, which is an injection (e.g., shot) you would have to take every 8 weeks. How interested would you be in this form of PrEP delivery*?" Consistent high interest in LA-PrEP was defined as responding with "Very interested" or "Interested" at least once and never responding with "Neutral", "Slightly interested", or "Not interested" at any study visit. Consistent low interest in LA-PrEP was defined as responding with "Not interested" at least once and never responding with "Slightly interested", "Neutral", "Interested", or "Very interested" at any study visit. We used these data to purposively select women with consistent high and consistent low interest in LA-PrEP.

Three authors (SO, HA, CO) were trained and internally piloted materials during a 3-day training session in July 2023. The interviewers were female, held a bachelor's degree, and were employed as qualitative researchers. They had prior training in qualitative interviewing and were from the same region as the participants. Interviewers used semi-structured interview guide with a section devoted to themes around LA-PrEP acceptability, informed by the TFA [95]. A study staff member familiar with the selected participants contacted them by phone and introduced them to the interviewer, who then invited them to participate. Participants also received a refresher on potential future LA-PrEP formulations. All IDIs were conducted in person at the clinic where the participant sought their perinatal care in a private room with no one else present. IDIs were conducted in the participants preferred language (English, Luo, or Swahili) and lasted approximately 60-90 minutes.

Data management and analysis

IDIs were audio-recorded, transcribed, and translated into English. Interviewers completed debrief reports within 24 hours of completing an IDI. Ten percent of IDIs were back translated for quality assurance. Three authors reviewed transcripts for accuracy (EA, JN, SW). Two authors

(JN and EA) developed an initial codebook and six authors (EA, TC, HA, SO, BMS, MS) refined the codebook using an inductive-deductive thematic approach [99]. First, all transcripts were reviewed, and a preliminary codebook was developed based on interview guides. Three transcripts were group-coded, and new themes were inductively added to the codebook. Codes and themes were continuously reviewed and revised, with discrepancies between coders resolved during weekly meetings until an agreement was reached. Once consensus was achieved, the remaining transcripts were divided among three authors (EA, SO, HA) for primary coding. Another three authors (TC, MS, BMS) secondary coded all transcripts to ensure consistency and accuracy. Coding and codebook refinement was conducted in Dedoose (Version 9.2.22, Los Angeles, CA). After coding was completed, key themes were summarized, and themes were organized into the domains of the TFA (Table 8). Implementation strategies to address specific areas of acceptability and illustrative quotes were also identified.

We acknowledge that our experiences, education, and positions may have contributed to data collection, interpretation, and presentation of our study findings. Our team included individuals with training in HIV counseling and testing, quantitative and qualitative methods, and socio-behavioral research. At least one author of the same gender and geographic area as the participants was included in each step of data analysis to ensure appropriate interpretation of results. The consolidated criteria for reporting qualitative studies (COREQ) was used as a guide throughout data collection and analysis.[100]

Ethical approvals

The University of Washington and Kenyatta National Hospital institutional review boards approved this study. All participants provided informed consent and consented to be audio recorded.

Results

We conducted 70 IDIs with postpartum women between August 2023 and March 2024. No participants refused to participate or dropped out. A total of 44 participants (62.9%) had high

consistently LA-PrEP interest throughout pregnancy and postpartum, one participant (1.4%) had consistently low LA-PrEP interest, and 25 participants (35.7%) had mixed LA-PrEP interest. Participants were approximately one year postpartum when interviewed (Median: 12.3 months, interquartile range [IQR]: 11.3 – 13.7 months). Median age at study enrollment was 25 years old (IQR: 22 – 30.5), most (n=49, 70.0%) were currently married and had a secondary education or higher (n=46, 65.7%) (Table 9). A total of 44.3% (n=31) had discontinued PrEP prior to the end of the study. About one third were primigravida (n=26, 37.1%).

Overall, most participants thought that LA-PrEP methods would be highly acceptable for themselves and pregnant/postpartum women in general, with especially high acceptability identified for bi-monthly injectable PrEP. Figure 6 summarizes key themes identified and demonstrates how they fit within distinct profiles of preferred PrEP option

Acceptability themes related to pregnancy and postpartum periods

During pregnancy, some women preferred oral PrEP due to its familiarity and perceived safety for the baby and deferred taking injectable PrEP until after delivery (**Affective attitude**). Daily adherence was seen as a burden in part due to competing household priorities and co-occurring side effects in pregnancy (**Burden**).

> *"… the injectable one, they are still doing research, the research is not complete. Maybe for the safety of the baby, if you are not pregnant it is okay, you can use it, like for me now I can use that injectable because I am not pregnant but because I have used the daily pill, the effects were not there, there were no effect on my baby, so I prefer maybe the pregnant women to just use the daily pill. Yeah, but if you are not pregnant, you can use the vaginal ring and the injectable" (31 years, stopped PrEP in postpartum, high LA PrEP interest)*

> *"Taking pills while you are pregnant is very hard, there are women who are given even the folic acid tablets to take and they don't take it due to nausea" (27 years, continued on*

PrEP, high LA PrEP interest)

"There are no issues of forgetting, especially because forgetting is an issue with pregnant mothers, you just need to remember the TCA date [Treatment Continuity and Adherence] after a while" (38 years, continued on PrEP, mixed LA PrEP interest)

Many women believed that the injectable PrEP was the most effective option for HIV prevention, as it minimized opportunities for missed doses and ensured consistent coverage. In contrast, several participants had concerns about the rings' ability to function in certain scenarios, such as delivery (**Perceived effectiveness**). They noted that PrEP choice requires comprehensive information about the side effects and safety of each method. In particular, they noted that women should be educated on how PrEP (all forms) can protect (and won't harm) their babies in pregnancy and breastfeeding (**Ethicality**).

"To the breastfeeding mothers I know most of them might be afraid taking PrEP… She might have refused taking the PrEP thinking it will affect [her] baby, so they should be informed." (22 years, stopped PrEP in pregnancy, high LA PrEP interest)

However, some participants voiced concerns about injectable PrEP, such as safety during pregnancy. Several women were also uneasy about vaginal ring use during pregnancy and had concerns around the ring being in the vagina during delivery (**Intervention coherence**).

"Something that will make me fear is that it is injected direct in the blood, what if it can cause some illnesses, or if it can affect pregnant women and probably affect the unborn child. (24 years, stopped PrEP in postpartum, high LA PrEP interest)

"Because with injectable, you will just get an injection but with this one, it is inserted. What about when you are due for delivery, it will still be inside the vagina." (31 years, continued on PrEP, mixed LA PrEP interest)

Women were confident in their ability to manage injectable PrEP, relating it to FP injections. They

noted that they could align and conceal injection visits with clinic visits for their pregnancy or baby. Some women thought the vaginal ring would be better for postpartum women as they can manage it themselves (**self-efficacy**).

> *"If I get injected, who will know that I have been injected? Nobody, only me, yes. When I come to clinic, he [husband] will know that I have taken a baby to clinic" (27 years, stopped PrEP in pregnancy, high LA PrEP interest)*

> *"Pregnant women will prefer the injectable or the oral and the postpartum women will prefer the ring. Because I feel that there are women who just prefer the ring because they know when to replace it, and there are some who fear the injection and others also fear swallowing PrEP." (33 years, stopped PrEP in postpartum, high LA PrEP interest)*

<u>General themes of acceptability</u>

Participants also endorsed themes of acceptability that were not unique to pregnancy and postpartum periods. They expressed strong preferences for long-acting injectable PrEP due to its simplicity, convenience, and non-intravaginal use, favoring it over the vaginal ring, which had mixed reactions. While some appreciated the ring for its long duration and non-injectable nature, others disliked it due to discomfort, fears of insertion, or social stigma: *"The ring is a no for me. Some people say it can get lost inside your vagina." (38 years, continued on PrEP, mixed LA PrEP interest).* However, both long-acting methods were considered easier to manage than daily oral PrEP due to reduced adherence burden.

> *"I would prefer to use it because it is just inserted and removed. Another reason why I like the ring more than the injectable, you know when you are injected it will last for two months, but the ring also lasts for 28 days, they are still all long term. I prefer the ring because I will not be injected." (32 years, stopped PrEP in postpartum, high LA PrEP interest)*

Some women were concerned about forgetting injection dates, while others liked the routine nature of daily pills.

> *"As for the injection … also you can forget, let's say after two months, you can forget then you say … ah this date expired yesterday… But you see, about the oral and you are seeing the bottle there, you will say let me go before this drug are over" (18 years, stopped PrEP in postpartum, mixed LA PrEP interest)*

Privacy was important to women, with injectable PrEP seen as more private and socially acceptable than oral PrEP. Women emphasized the importance of providing choices and information to make informed decisions and that they could choose the PrEP form that worked best for them.

> *"If I find that injection is good, it doesn't cause me dizziness and backache, and doesn't cause me any problem then I would continue with it. But in case it is causing me problems, then it will make me go back to the one that I was swallowing, because with it I don't have much problem." (27 years, continued on PrEP, high LA PrEP interest)*

<u>Strategies to support acceptability</u>

Women recommended several strategies to support acceptability of various PrEP options in pregnant and postpartum periods. They emphasized that healthcare workers played an important role in educating their pregnant and postpartum patients about PrEP options, side effects, safety, and effectiveness. They highlighted the value of information coming from doctors or healthcare professionals, stating "*we always believe what the doctors tell us, so as long as you assure me of its safety, I'll be okay to use it."* (28 years, stopped PrEP in postpartum, mixed LA PrEP interest)

Several women mentioned that the vaginal ring could be misinterpreted to prevent pregnancy, and education on how it works is particularly important for postpartum women. Women emphasized the need for detailed information and education on how each method would affect

their health, the potential side effects, and the proper way to use them.

> *"Later she might be regretting of her problem or the health care worker. That is why I said it is good for them to have a basic information such they know that the vaginal ring is only for preventing HIV and not pregnancy. Also other question can be if I am using it, can I use other forms of family planning, like coil?" (20 years, continued on PrEP, high LA PrEP interest)*

> *"Yes, you need to be open and tell us about the side effects of all these PrEP. For example, when I had the injection with the side effects, I may withdraw. But if we are told, we will stick to it as we allow the body to get used to it." (35 years, continued on PrEP, mixed LA PrEP interest)*

Many women mentioned how mobile adherence support tools could be adapted to include LA-PrEP methods. Specific aspects of adherence support included reminding users about injection dates, addressing concerns promptly, and providing education about side effects. Some participants suggested the introduction of visit reminders using SMS systems or aligning injection timepoints with pregnancy and postpartum visits.

Discussion

We identified nuanced aspects of acceptance for these PrEP approaches in pregnant and postpartum periods, highlighting the heterogenous preferences and diverse needs of the population. Long-acting options were broadly accepted and perceived to alleviate the burden of daily pill taking. Injectable PrEP specifically was valued for its discretion, alignment with familiar family planning methods, and long-duration. Despite the broad acceptance of new LA-PrEP methods, participants identified several themes specific to pregnancy and the postpartum period that could influence their acceptability. Concerns were raised about the safety of these products and the potential side effects during pregnancy, highlighting the need for robust safety data and comprehensive PrEP counseling when introducing new options. Opinions on the vaginal ring were

divided—some women valued its discretion and ease of use, while others were uncomfortable with the concept of self-insertion. Additionally, participants noted that clinic visits for their baby could serve as a convenient way to discreetly attend follow-up appointments for injectable PrEP. This study offers valuable insights to support the integration of LA-PrEP methods into ANC settings and identifies strategies to promote their acceptability and adoption among this population.

In contrast to previous literature, women in this study more often expressed an aversion to the vaginal ring. Previous studies conducted in South Africa, Malawi, Zimbabwe, and Uganda found that both pregnant and breastfeeding participants with experience using dapivirine vaginal ring considered it acceptable, easy to use, user-friendly, and minimally burdensome.[96,101,102] The current study asked women about hypothetical acceptance and participants only had experience using daily oral PrEP. This notable difference in vaginal ring experience and acceptability highlights that barriers to acceptability for this option may be overcome with appropriate education, counselling, and support. Future studies should explore offering all available forms of PrEP to postpartum women to better understand their acceptability and preferences for different options within the local context.

There were several themes of acceptability that were unique to pregnancy and breastfeeding periods. Women mentioned that their acceptability of any PrEP option was driven by safety for their baby while pregnant, and that was less important in postpartum. However, they indicated that counseling or information from healthcare providers about safety data could enhance their confidence in its use during pregnancy. Participants further noted that if the safety of these options was well established, they would be open to using LA-PrEP during pregnancy. These components of acceptability are in line with previous literature around the importance pregnant and breastfeeding women place on safety for their baby.[74,93,102] As more PrEP options become available for this population, it is crucial to address concerns and knowledge gaps about how

active agents may affect the baby, while also recognizing the strong motivations of pregnant women to keep their baby HIV-free.[20]

Women in this study identified several strategies that were important to support acceptance of different PrEP methods. Most often identified was education from healthcare workers on availability of PrEP options, side effects, safety, and effectiveness. Safety for their baby was especially important for pregnant and breastfeeding mothers and often the driver of their acceptance for different PrEP choices. Including pregnant and breastfeeding women in PrEP clinical trials and bolstering safety profiles of new PrEP options is imperative to ensure acceptability in this important population.[103] Additional strategies such as video-based PrEP information in the waiting bay[83] and decision support tools[80] have been shown to improve PrEP knowledge and persistence and can be adapted for LA-PrEP options as well. Elements of acceptability elucidated in this study can be used to adapt existing PrEP support tools for pregnant and postpartum women.

Limitations

This study has several limitations that should be considered when interpreting the findings. First, the eligibility criteria for the clinical trial focused exclusively on women at high risk for HIV who were not PrEP-naïve and most women who participated in these IDIs were over a year postpartum. As a result, there is a potential for recall bias when participants were asked to reflect on the acceptability of interventions during pregnancy which limits the applicability of the findings to women currently experiencing pregnancy. Second, social desirability bias may have influenced participants' responses, particularly when discussing sensitive topics such as HIV prevention and intervention strategies. Participants may have been inclined to provide responses they believed were expected or socially acceptable rather than fully sharing their personal experiences or opinions. Lastly, the identified strategies to support acceptability were primarily centered around SMS-based support tools, which all participants received. This focus may have limited

participants' consideration of alternative strategies or innovative ideas outside the SMS system, potentially constraining the breadth of the feedback and suggestions provided. Despite these limitations, the study provides valuable insights into the perspectives of women at high risk for HIV and highlights important considerations for future intervention design and implementation.

Conclusion

This qualitative study offers valuable insights into the acceptability of different HIV PrEP options among postpartum women with experience taking PrEP during pregnancy, a population often underrepresented in HIV prevention research. The findings reveal diverse preferences and highlight key factors influencing acceptability, including safety, discretion, and convenience. While long-acting options, particularly injectable PrEP, were broadly accepted, the vaginal ring's acceptability was more variable, emphasizing the importance of tailored education and support. The study also underscores the distinct needs of pregnant versus postpartum women, particularly their concern for their baby's safety during pregnancy. Addressing knowledge gaps and enhancing support strategies, including healthcare worker education and innovative tools, are important next steps for improving PrEP uptake and persistence among pregnant and postpartum women at high risk for HIV.

Table 8: Operationalized definitions of the Theoretical Framework of Acceptability (TFA) constructs

TFA construct	Operationalized definition
Affective attitude	Postpartum women's feelings about using different PrEP methods
Perceived effectiveness	The extent to which different PrEP methods are perceived by postpartum women as likely to prevent HIV
Ethicality	The extent to which different PrEP methods have a good fit with postpartum women's value system
Intervention Coherence	The extent to which postpartum women understand different PrEP methods and how they work
Opportunity Costs	The extent to which benefits, profits, or values must be given up by postpartum women to use different PrEP methods
Self-Efficacy	Postpartum women's confidence that they can perform the behavior(s) required to use different PrEP methods

Table 9: Clinical trial enrollment characteristics of IDI participants (n=70)

	N = 70[1]
Age (years)	25.0 (22.0, 30.5)
Currently married	49 (70.0%)
High ACE score	16 (22.9%)
Secondary education or higher	46 (65.7%)
Has regular employment	13 (18.6%)
2 or more people per room	13 (18.6%)
Partner HIV status	
HIV negative	7 (10.0%)
Unknown status	60 (85.7%)
No partner	3 (4.3%)
Previous number of pregnancies	2.0 (1.0, 3.0)
Primigravida	26 (37.1%)
Previous pregnancy loss	7 (10.0%)
Discontinued PrEP in pregnancy	7 (10.0%)
Discontinued PrEP in postpartum	25 (35.7%)
Used FP by 9 months postpartum	51 (72.9%)
Used injectable FP by 9 months postpartum	20 (28.6%)

[1]n (%); Median (IQR)
ACE: Adverse childhood experience; FP: Family planning

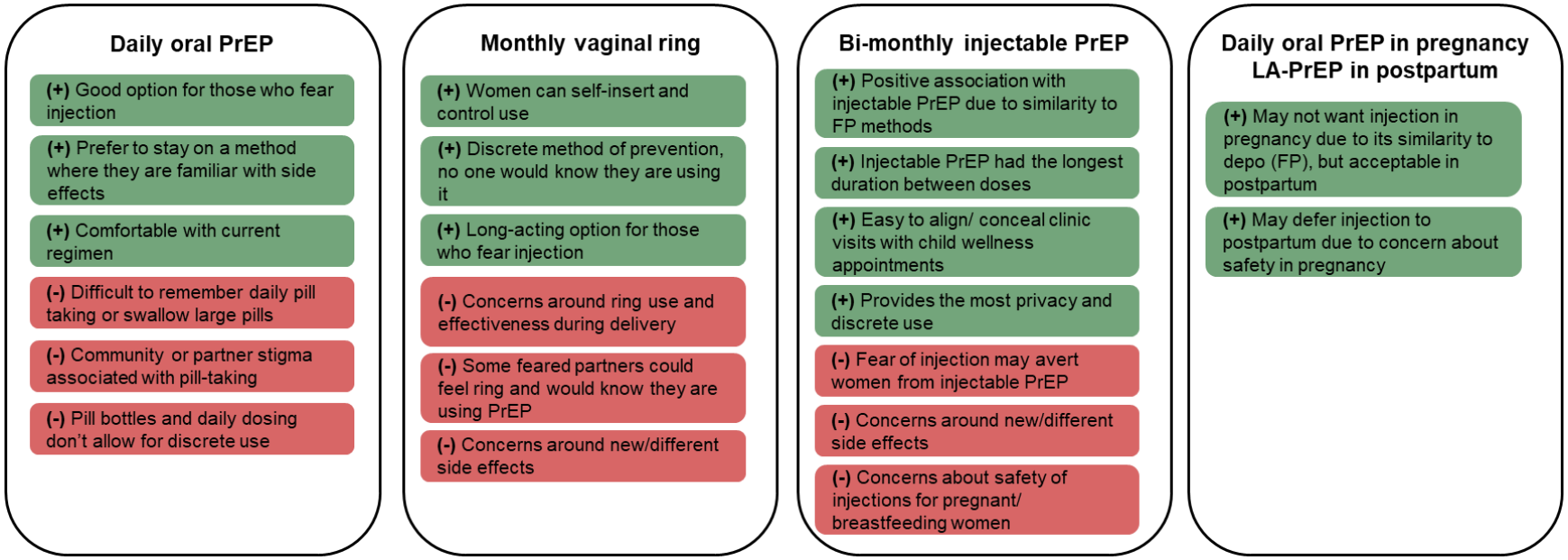


Figure 6: Participant's perceived acceptability of PrEP options

Chapter 4: Identifying Determinants and Strategies to Prepare for Implementation of Long-Acting PrEP in Antenatal Care Settings in Kenya: Results of a Rapid Qualitative Analysis

Background

Women accounted for 520,000 new HIV cases globally, in 2023, and 63% of all new HIV infections in 2022.[104,105] In high HIV burden settings, the incidence of HIV among pregnant and postpartum women is nearly double that of the general population.[2,91] Further, models estimate that up to 30% of vertical transmission is attributable to acute maternal HIV infection, highlighting the need for effective HIV prevention strategies during the perinatal period.[3,106] The World Health Organization (WHO) recommends oral pre-exposure prophylaxis (PrEP) for pregnant and postpartum women in high HIV-incidence settings, yet despite the proven safety and efficacy of oral PrEP for pregnant and breastfeeding women and their infants, its uptake remains low.[12,73,84,107–109] Integration of oral PrEP into reproductive health setting – such as maternal child health (MCH) clinics, antenatal care (ANC) clinics, and family planning (FP) clinics – improves uptake, service delivery, and client satisfaction.[110–112] However, studies also identified considerable barriers to integration, including workforce time burdens,[112] staff shortages,[82] insufficient PrEP training, limited privacy for delivering PrEP, and a lack of systematic scale up.[113]

New long-acting (LA-) PrEP modalities, such as every two-month cabotegravir (CAB-LA), twice-yearly lenacapvir (LEN), and the monthly dapivirine vaginal ring (DVR), effectively prevent HIV, with growing evidence supporting their safety for pregnant and lactating populations.[23–26,30,114,115] Notably, LA-PrEP may improve adherence, give women more options and greater autonomy, and is often favored by women for being discreet.[25,104,116] Ensuring high-quality PrEP delivery in pregnancy and postpartum requires understanding the role of the community, assessing the impact of PrEP integration on workload and client volume, examining provider attitudes and beliefs, and ensuring provider training with clinical delivery, yet scarce implementation data exists to address the unique considerations of this context.[73] As countries work towards regulatory

approval and introduction of new LA-PrEP formulations, early implementation studies can help narrow the research-to-practice gap; however, there is a lack of information on barriers to and strategies for integrating LA-PrEP into reproductive health settings.[38]

Implementation science process frameworks are valuable tools for studying LA-PrEP integration, are useful for eliciting and categorizing determinants of implementation and employ a systematic approach to identifying barriers, optimizing strategies, and tailoring interventions to meet the unique needs of this population. Specifically, we aimed to identify potential barriers and facilitators for adoption and uptake of LA-PrEP for pregnant and postpartum women in Kenya, further assess needs for adaptation, and to identify strategies to for implementation.

Methods

Study design

We conducted an exploratory qualitative study using content analysis with healthcare workers and other key opinion leaders related to PrEP delivery for pregnant and postpartum women. Focus group discussions (FGDs) were conducted as part of a larger clinical trial (NCT04472884) of PrEP adherence for pregnant and postpartum women.[47] A section of the interview guides was devoted to questions about LA-PrEP implementation. FGDs were held with two groups: healthcare workers (HCWs) at participating clinics and the study's community advisory board (CAB). Focus groups were limited to a maximum of five participants to encourage a dynamic exchange of diverse perspectives while ensuring that each participant had the opportunity to contribute meaningfully to the discussion. HCWs were purposively sampled to include perspectives from different areas related to ANC-PrEP delivery at all five study sites. All members from the parent study's CAB were invited to participate. Each FGD aimed to include five participants.

Data collection

Interviewers (SO, HA, CO) attended a 3-day training session in July of 2023 and internally piloted

materials. They were from the same region as participants, were female, held a bachelor's degree, and have prior training and current employment in qualitative interviewing. Interviewers used a semi-structured interview guide with a section devoted to themes around LA-PrEP acceptability, informed by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework[39] and updated Consolidated Framework for Implementation Research (CFIR)[117] with additional domains and constructs added for use in LMICs.[118] A study staff member familiar with the selected participants contacted them by phone and introduced them to the interviewer, who then invited them to participate in an FGD. Each focus group had a facilitator who led the discussion and a note-taker who kept detailed notes to support transcription and FGD debriefs. All FGDs were conducted in person in a private room with no one else present. FGDs were conducted in the participants preferred language (English, Luo, or Swahili) and lasted approximately 90-120 minutes. No repeat or follow-up interviews were conducted.

HCW FGDs also included a prioritization activity. In the prioritization activity, HCW were asked "What information, training, or support would you need to feel comfortable offering a long-acting form of PrEP to pregnant and postpartum women?" The FGD note taker recorded all suggestions on a large poster. The group then ranked all suggestions first, from easiest to hardest to implement ("Which of your suggested ideas would be the easiest to implement or do in your clinic?") and next, from most to least helpful ("Which of your suggested ideas would be the most helpful to make you feel comfortable offering a long-acting PrEP in your clinic"). In cases of differing opinions, the facilitator encouraged the group to reach a consensus.

Data management and analysis

FGDs were audio-recorded, transcribed, and translated into English (SO, HA, CO). Interviewers completed debrief reports within 24 hours of completing an FGD. Weekly meetings were held to ensure protocol fidelity. One HCW and one CAB FGD were back-translated for quality assurance. Two authors reviewed transcripts for accuracy (EA, JN). We used a rapid qualitative analysis

approach (RQA) to identify facilitators and barriers to integrating LA-PrEP into antenatal care settings and potential implementation strategies needed to ensure successful implementation.[119–121] This approach was chosen based on our structured interview guide, to streamline data synthesis, and to enable timely responses to our research objective, allowing for swift identification of determinants and strategies while preserving data richness and rigor. First, authors (TC and MS) created a summary sheet template deductively based on the semi-structured interview guides. The template included brief domain names corresponding to interview guide questions. We piloted the template with two transcripts to ensure reliability across researchers. Summary sheets included sections for brief quotes or transcript line numbers allowing authors to re-examine original data as needed for clarification, validation, and expansion. Second, transcripts were divided between researchers and each summarized interview findings according to summary sheet domains. Third, we developed matrices to organize themes, whereby rows were individual FGDs and columns were summary sheet domains. Matrices were developed in Microsoft Word (Microsoft® Word for Microsoft 365 MSO, Version 2409) and reviewed by the lead author (TC). Fourth, we extracted themes by reviewing matrix data within each column. Fifth, we used CFIR constructs and domains to code points within the matrices using Microsoft Excel (Microsoft® Excel® for Microsoft 365 MSO, Version 2501). Concurrently we mapped any participant-identified implementation strategies onto Expert Recommendations for Implementing Change (ERIC) implementation strategies. Implementation barriers and strategies were summarized by domain, and FGD transcripts were reviewed again to identify any missing items. The consolidated criteria for reporting qualitative studies (COREQ) and Planning for and Assessing Rigor in Rapid Qualitative Analysis (PARRQA) were used as a guide throughout data collection and analysis.[100,122]

Ethical considerations

The University of Washington and Kenyatta National Hospital institutional review boards approved

this study. All participants provided electronic written informed consent before study participation and consented to be audio recorded.

Results

A total of 9 FGDs were conducted among 45 individuals between August and October 2023 (5 FGDs among HCWs and 4 among CAB members) with five participants in each FGDs. One HCW was unable to join due to a work conflict, so a replacement with a similar role was invited. Both HCW and CAB participants were predominantly female (72% of HCW and 60% of CAB) (Table 10). Median age was 35 years for HCW (range: 28 – 63) and 43 years for CAB members (range: 23 – 70). Most FGD participants had a university/college education (92% of HCW and 75% of CAB).

LA-PrEP implementation determinants

Grounded in the CFIR, we identified HCW perceptions of important determinants influencing implementation determinants for future integration of LA-PrEP into reproductive health settings such as MCH clinics, ANC clinics, and FP clinics. FGDs explicitly identified determinants that were interconnected and dependent on one another (Figure 7). Training emerged as a central determinant, with links to other factors such as funding, personnel, service location, and community stigma. Participants noted that training cannot occur effectively without the availability of necessary commodities, such as injectable PrEP or rings, emphasizing the importance of ensuring that these products are accessible. Similarly, financial resources were identified as essential to support training activities, reimburse participants for transport, and ensure the availability of required materials, with one participant highlighting that funding gaps can lead to delays in implementation. Personnel were also highlighted as a key determinant for LA-PrEP implementation, with participants emphasizing the need to retain staff through both training and financial incentives.

FGD participants identified many implementation barriers and facilitators to implementing LA-

PrEP in their settings. CFIR constructs and supporting quotations can be found in Table 11.

Intervention Characteristics

HCW and CAB participants largely agreed that injectable PrEP has significant advantages over daily oral PrEP due to its discreet use and convenient dosing schedule (CFIR construct: **relative advantage**). Some participants were aware of recent clinical trials and referenced the high effectiveness of bi-monthly and twice-yearly injectable PrEP (CFIR construct: **evidence-base**). However, they emphasized that pregnant and postpartum women would be particularly concerned about safety for their baby. Injectable PrEP was noted as simple to administer (CFIR construct: **complexity**) and could be integrated into clinics in a manner similar to family planning injections (CFIR construct: **design**). Concerns were raised about costs, including participant affordability (CFIR construct: **cost**).

> *"When we talk about vulnerability, someone who has constrain in finances will find it difficult to get drugs. That is moving from home to the facility to get the drugs." – Male, community leader, CAB*

Outer Setting

Despite broad agreement that multiple PrEP options would be beneficial for pregnant and postpartum women, CAB member still expressed concerns related to unfaithfulness with a more discreet option (CFIR construct: **Local attitudes**). One CAB member noted that environmental conditions like extreme weather, could impact communities' access to information about new LA-PrEP options (CFIR construct: **Local conditions**). Participants emphasized that successful implementation requires strong partnerships between government, health providers, and community leaders (CFIR construct: **partnerships & connections**). Local leaders, including village elders, clan elders, church leaders, community health volunteers, chiefs, and their assistants, were identified as important opinion leaders. Both CAB and HCW noted that national guidelines from the government were essential for LA-PrEP implementation (CFIR construct:

policies & laws):

> *"People tend to believe that anything which is not signed by the government is null and void. If someone is taking samples of blood and the chief doesn't know, then no one will partake in it." – Male, community leader, CAB*

Inner Setting

HCW and CAB members drew parallels between LA-PrEP and family planning implementation. Some HCWs believed it could be smoothly integrated into existing services, such as family planning, while others raised concerns about limited space and high workload (CFIR construct: **structural characteristics**). Participants had mixed opinions on how the addition of multiple PrEP options would impact workflow (CFIR construct: **compatibility**), some thought it would reduce workload due to less frequent dosing schedules and alignment with existing family planning procedures, while others highlighted that they are already overwhelmed, and demand might increase with an injectable option.

> *"On the same note, I feel it will reduce our workload because we shall be giving these injections for two months, this mother stays at home for two months then she comes back, unlike the orals whereby you keep on reminding them through the message." – Male, clinical officer, HCW*

> *"Another challenge is the workload. I am in family clinic, and I give a lot of services. You will find me doing antenatal checkup for pregnant mothers, I do cancer screening, and I have to give the information about PrEP. So, at times, I feel so overwhelmed." – Female, nurse, HCW*

HCWs expressed confidence that proper training would enable them to counsel on multiple PrEP options effectively (CFIR construct: **access to knowledge and information**). HCWs cautioned that insufficient data could lead to injectable hesitancy, akin to what was observed with the COVID-19 vaccine. They noted that ongoing training, or refresher trainings, would be helpful to

keep them up to date on new information and train new staff.

> *"I will comfortably be providing the information [about LA-PrEP] but still we need additional training to keep us more up to date. Things change here and there and us providers we need to be top of it all to give the correct information every time." Male, pharmacy tech, HCW*

FGD participants expressed concerns related to training, particularly that only few individuals within healthcare systems are trained and others are left without information (CFIR constructs: **relative priority, collective efficacy**)

> *"How do we integrate? What about the partners who are pulling out, who will continue with these services? So they [government] choose people [select HCW] to take to seminars or to the training" – Male, healthcare planner, CAB*

> *"They [other HCW] were complaining, 'You people of the program, you do take your people for training, and you leave us behind. Now we can't offer the services.'" – Female, counselor, HCW*

<u>Individuals</u>

Participants emphasized the role of government-to-government relationships in ensuring a stable supply of PrEP (CFIR construct: **high-level leaders**). HCWs reported being comfortable counseling clients on multiple PrEP options, including LA-PrEP (CFIR construct: **innovation deliverers**). Some individuals expressed that their patients may have concerns about new methods, such as fears that vaginal rings could "disappear" inside the body, postpartum women feeling unready for intravaginal options, and pregnant women finding vaginal ring insertion uncomfortable (CFIR construct: **innovation recipients**). Community health providers (CHPs) and youth groups were suggested as effective channels for PrEP education (CFIR construct: **implementation facilitators**).

"Through the CHPs [community health providers] in the community and even in the community meeting where HCW can be invited to give that information [about LA-PrEP] to different groups of people" – Female, healthcare planner, CAB

Implementation Process

HCWs stressed the importance of assessing the needs of pregnant and postpartum women to recommend the most suitable PrEP method (CFIR construct: **assessing needs: innovation recipients**)

Characteristics of Systems and the Intervention

CAB members highlighted the need for a reliable supply chain to ensure injectable PrEP and vaginal rings are readily available and accessible once the community is informed about these options (**resource continuity**). Funding was also a concern, with external donors playing a key role in sustainability. There were fears that if partners withdraw support, PrEP programs could collapse (CFIR constructs: **resource source, perceived sustainability**). Participants noted that some donors prioritize training for their own staff rather than facility-based HCWs, leaving gaps in knowledge and implementation capacity (CFIR construct: **external funding agent priorities**)

"…as of now, if the partners pull out, you'll start from zero, because the information will be gone with the partners who were…the staffs who were working with the partners." – Female, healthcare planner, CAB

"even the partner when they come, they only concentrate on their particular staffs, so their trainings for their staffs everything that they are doing is that they are just concerned about their staff." – Female, healthcare planner, CAB

Strategies to support LA-PrEP implementation

HCW and CAB discussions identified strategies across six ERIC clusters (Table 12). HCW and CAB discussions identified key strategies to support LA-PrEP implementation across multiple ERIC clusters. To enhance acceptability, participants suggested adapting LA-PrEP options to

include pregnancy prevention, which could increase uptake within communities (ERIC strategy: **Promote adaptability**). Infrastructure changes were also emphasized, with HCWs and CAB members identifying alternative service sites, such as family planning clinics, that have the necessary setup for administering injections. Additionally, expanding access points to trusted community spaces, like pharmacies, was seen as a way to improve uptake (ERIC strategy: **Change service sites**). Stakeholder engagement was another crucial factor, with government workers, community health providers (CHPs), and teachers identified as key opinion leaders in promoting LA-PrEP (ERIC strategy: **Involve executive boards**). While CHPs play a critical role in disseminating information at the household level, their heavy workloads necessitate targeted sensitization efforts to ensure effective outreach (ERIC strategy: **Identify and prepare champions**). Other trusted community figures, including teachers, youth groups, and churches, were also recognized as important avenues for raising awareness.

To further engage consumers, participants recommended a multi-faceted approach to increasing awareness, including door-to-door outreach, information placement in pharmacies, and leveraging mass media (ERIC strategy: **Increase demand, use mass media**). However, they stressed that initial communication should come from trusted local sources, such as village elders and CHPs, before mass media campaigns are launched. Additionally, pregnant women were suggested as key advocates to encourage their peers to use PrEP during pregnancy (ERIC strategy: **Involve patients/consumers and family members**). Training for HCWs was highlighted as a recurring need, with participants emphasizing that providers require continuous education to confidently counsel patients on multiple PrEP options (ERIC strategy: **Conduct ongoing training**). CAB members also stressed the importance of training all facility providers to foster a collaborative learning environment (ERIC strategy: **Create a learning collaborative**). Finally, financial constraints were identified as a major barrier, with transportation reimbursements proposed as a way to encourage clinic visits for refills and testing (ERIC strategy: **Alter**

patient/consumer fees).

Strategy prioritization

HCW discussions identified key tools, resources, and support needed to implement LA-PrEP in their settings, with common themes including training, space, commodities, and guidelines. However, the prioritization of these elements varied across HCW groups for "Ease of implementation" and "Most helpful" (Table 13). One focus group did not rank resources in terms of “Most helpful” due to time constraints. Differences in ranking order reflected varying needs based on local contexts, with training and personnel consistently highlighted, alongside logistical considerations such as space and commodities.

Discussion

In our qualitative exploration grounded in the CFIR and ERIC frameworks, HCW and CAB members in Kenya provided insights into determinants and strategies for LA-PrEP implementation in reproductive healthcare settings. Determinants for the implementation of LA-PrEP into ANC and FP settings in Kenya, such as training, funding, and personnel, are intrinsically interdependent. Some strategies clearly addressed barriers (e.g. **conducting ongoing training** to support **access to knowledge/information**). However, some barriers had no clear solution, such as drug availability of long-acting options at clinics and access to funds to conduct training and community sensitization. As found in the prioritization activity, strategies for LA-PrEP implementation may vary by location in terms of helpfulness and ease, based on existing resources and infrastructure. The wide range of strategies identified, such as financial incentives for transportation, using CHPs to conduct community sensitization, and integrating LA-PrEP into FP clinics, hint at the multi-pronged approach needed to support implementation of LA-PrEP in this setting. Existing evidence indicates that both DVR and CAB-LA are safe for use during pregnancy and lactation; however, ongoing studies continue to evaluate their safety profiles.[29,30] Suggested implementation determinants and strategies identified in this study should be further

explored to better understand when and how to best employ these approaches.

Many of the implementation barriers identified in these FGDs are long-standing barriers for daily oral PrEP, but several are unique considerations for LA-PrEP methods. Barriers such as workforce shortages, limited time to address topics during visits, and challenges with drug availability are well-documented in the implementation of oral PrEP,[73,123–125] and may be exacerbated with the introduction of new LA-PrEP methods.[126] In our study, HCW expressed concerns around patient acceptance of DVR related to ring insertion, especially for pregnant and postpartum women. Existing evidence shows that DVR is safe and acceptable for pregnant women, and initial concerns are often alleviated with study staff support and increased product use experience.[29,96,102] The concerns highlighted by HCW in this study emphasize the need for patient education and provider training about DVR insertion and safety for use during pregnancy and breastfeeding. Conversely, HCW expressed confidence in their ability to administer injections for CAB-LA or LEN, drawing on their experience and familiarity with providing injectable contraceptives as a comparable skill. Similarly, studies on LA-PrEP acceptability among pregnant and postpartum women report high acceptance of injectable PrEP.[127,128] Many FGD participants highlighted the appeal of LA-PrEP options for their discreet nature and their potential to reduce the stigma associated with daily pill-taking. However, LA-PrEP is not entirely free from stigma-related challenges. Previous studies of CAB-LA implementation have noted potential stigmatization due to healthcare workers' moral judgments regarding the sexual behaviors of individuals using injectable PrEP,[129] similar to themes found in our study. Additionally, if injections are administered in HIV clinics, they may still carry stigma due to their association with HIV-related care.[125]

Additionally, it is also important to consider implementation barriers which did not come up in these FGDs but may still play an important role. Previous studies have noted that engagement with facility leadership as essential for overcoming challenges related to PrEP adoption and

feasibility,[123] but this theme did not appear in our study. HCW in our study expressed concerns about increased workloads associated with PrEP counseling, ring insertion, and administering injectables but there are other potential factors that could further complicate workloads, such as the need for additional HIV testing for CAB-LA monitoring.[123,125] Future studies can conduct quantitative evaluation of clinics' service availability and readiness to track longitudinal implementation of the introduction of LA-PrEP options.[113] ANC systems can be evaluated for readiness in terms of the WHO Building Blocks of service delivery, health workforce, health information systems, access to essential medicines, financing, and leadership/governance to support LA-PrEP in their settings,[130] areas which were explicitly mentioned as implementation barriers in this study.

In our study, HCW and CAB participants identified several strategies to support the integration of LA-PrEP. Several of the strategies identified in these FGDs have robust supporting evidence in the areas of family planning and oral PrEP delivery and could be adapted for use in LA-PrEP implementation in ANC settings. For example, training providers to offer a range of options and allowing women to switch between PrEP methods based on their pregnancy and/or breastfeeding status could address the unique needs of these populations, similar to that done for FP options.[131] Evidence on decision-making support tools suggests that, while these tools may serve as a useful aid for providers, they are not sufficient on their own to improve contraceptive use.[132–134] CHPs and other key opinion leaders, like teachers and youth groups, play key roles in disseminating health information, as evidenced in maternal health and family planning initiatives.[135] Strategies for engaging consumers, such as using trusted peers, community sources and mass media, can build on approaches successfully used for oral PrEP knowledge campaigns.[136,137] Additionally, innovative financial strategies, like transport reimbursement for clinic visits, could also be adapted from other health programs to enhance uptake,[138,139] however, there are mixed results on the long-term impacts of using incentives to modify behavior.[140] These approaches collectively

highlight opportunities for applying known strategies to integrate LA-PrEP into Kenyan ANC settings effectively and future studies should evaluate when, how, and how many strategies should be employed in this setting.

Building on the findings of this research, we have identified several next steps to support the integration of LA-PrEP into ANC settings. Both HCWs and CAB members highlighted the importance of offering patients a choice of PrEP options that best suit their individual needs. Ensuring this level of patient-centered care requires health systems to proactively plan and forecast resource needs to support the availability of diverse PrEP methods. Accurate forecasting of resource needs for commodities and services requires a clear understanding of client preferences, which are not always available. Lessons from the FP sector underscore the value of integrating client perspectives early in the planning process.[141] Stated preference methods such as discrete choice experiments can help generate actionable insights to guide resource allocation and inform demand projections, ensuring that patient preferences are adequately considered in health system planning.[127] In addition, future research should test the strategies proposed to address these barriers, as well as probing for additional barriers that may not have been captured in the current analysis. Explicitly connecting the implementation barriers and strategies will be essential for designing effective packages to support the implementation of LA-PrEP. Moreover, systematically evaluating the direction and strength of influence of each determinant can help researchers prioritize those factors with the most significant impact on implementation outcomes.[117]

This analysis has several limitations. First, the provider-identified strategies for implementing LA-PrEP may not align with how clients prefer to access information or services. Effective implementation strategies should incorporate both provider and client perspectives to ensure they address the needs and preferences of end-users. Second, some determinants of LA-PrEP implementation may be challenging to forecast without real-world experience in delivering these

interventions, potentially limiting the predictive accuracy of our findings. As a result, many of the identified determinants and strategies were not specific to MCH contexts, including pregnancy and postpartum periods. Given the unique healthcare needs and challenges faced during these stages, this lack of specificity may limit the applicability of the findings to the priority populations. Nevertheless, the HCW and CAB participants possess significant knowledge and experience with oral PrEP implementation. Pre-implementation studies, such as this one, provide valuable insights that can accelerate the translation of research into practice once LA-PrEP becomes available. Third, the HCW participants were specifically selected based on their active involvement in PrEP delivery or antenatal care. This purposive sampling approach, while valuable for gathering expert insights, may have inadvertently excluded perspectives from clinics with lower levels of PrEP integration. Consequently, the barriers to LA-PrEP delivery identified in this study may not capture the full range of challenges faced by facilities with less established PrEP programs. Similarly, the CAB members involved in this analysis were connected to studies related to PrEP use in pregnancy. Their association with these research efforts may have introduced a bias toward greater optimism regarding the acceptability and feasibility of LA-PrEP. As a result, there may be additional barriers to LA-PrEP implementation not identified in this study. By leveraging these preliminary findings, future work can address critical knowledge gaps and optimize the rollout of LA-PrEP in diverse healthcare settings.

Conclusion

HCWs and CAB members in Kenya described a complex network of implementation determinants such as training, funding, and community sensitization, with several strategies addressing barriers such as access to knowledge and information. However, unresolved barriers, like drug availability and funding sources, remain significant obstacles. Future research should focus on refining and prioritizing implementation strategies, exploring additional barriers, and integrating client perspectives to ensure that LA-PrEP implementation is both effective and aligned with the needs

of the pregnant and postpartum women.

Table 10: HCW and CAB demographics

	HCW, N = 25		CAB, N = 20
Gender			
Female	18 (72%)		12 (60%)
Male	7 (28%)		8 (40%)
Age *median (range)*	35 (28 - 63)		43 (23 - 70)
Missing			1
Highest education achieved			
Secondary	2 (8.0%)		4 (20%)
Polytechnic	0 (0%)		1 (5.0%)
University/college	23 (92%)		15 (75%)
Work location		**Role on CAB**	
MCH clinics	14 (56%)	PrEP ambassador	5 (25%)
CCC	9 (36%)	County government leader	4 (20%)
FP clinic	1 (4.0%)	Community leader	4 (20%)
MCH and FP clinic	1 (4.0%)	Healthcare planner	4 (20%)
		Health system administrator	3 (15%)
		Community health volunteer	2 (10%)
		Youth representatives	1 (5.0%)
Employment		**Employment**	
Counselor	9 (36%)	Other health services	6 (30%)
Nurse	7 (28%)	Administrative role	5 (25%)
Pharmacy technician	3 (12%)	Nurse	3 (15%)
Clinical officer	2 (8.0%)	Youth/community outreach	2 (10%)
Mentor mother	2 (8.0%)	Unemployed	2 (10%)
Department in-charge	1 (4.0%)	Civil/public service	1 (5.0%)
Other clinician	1 (4.0%)	Education	1 (5.0%)
Number of years… *median (range)*			
In current role	8 (4 – 38)		
Working on issues related to women, pregnancy, and HIV prevention	8 (2 – 23)		
Experience caring for pregnant or postpartum women	6 (3 – 25)		
Providing PrEP to pregnant or postpartum women	4 (1 – 12)		
Received specific training in…			
providing PrEP to pregnant or postpartum women	15 (60%)		
PrEP adherence counseling for pregnant or postpartum women	14 (56%)		

MCH: Maternal and child health; CCC: Comprehensive care clinic; FP: family planning

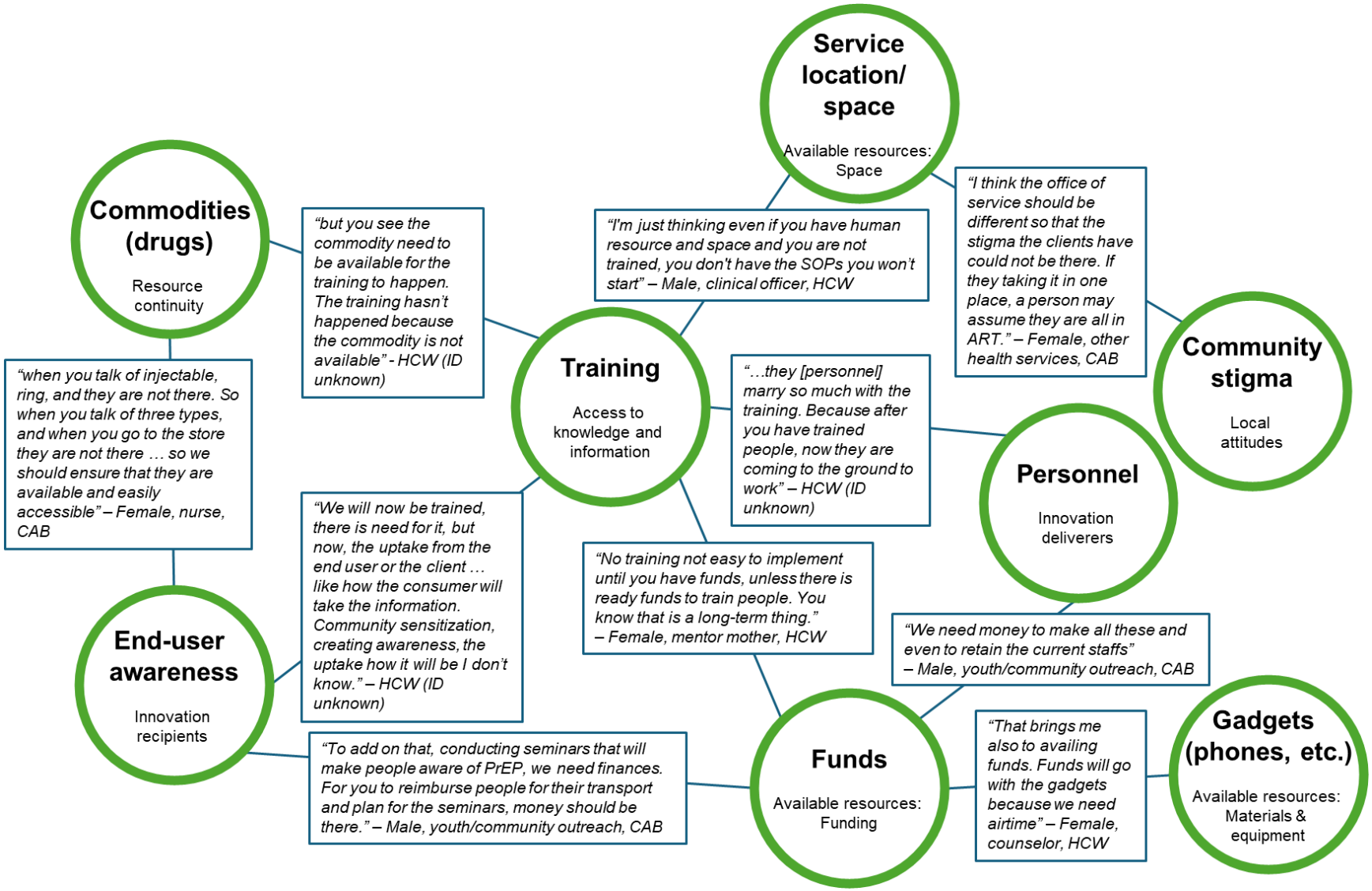


Figure 7: Connections made by HCW and CAB members between LA-PrEP implementation determinants (green circles, with associated CFIR construct)

Table 11: Implementation determinants for integration of LA-PrEP into reproductive healthcare settings, organized by CFIR constructs

CFIR CONSTRUCT	SUPPORTING QUOTE
Intervention characteristics	
Relative advantage	*"Let me talk about the pregnant women, I feel the other two options [injection and ring] will be better because, you know in pregnancy you have IFAS [iron and folic acid supplements] pill burden. Maybe you are sick, you have malaria. Then there is also this aspect of the first trimester, nausea and vomiting. The drugs cannot be accommodative. So you know if we give the injection is a better option because it is one off thing, or the ring is just inserted and is like that. So I feel talking on the basis of a pregnant woman that will favor them." – Female, counselor, HCW*
Cost	*"if there is cost implication then it should be well indicated clearly" – Female, healthcare planner, CAB*
	"When we talk about vulnerability, someone who has constrain in finances will find it difficult to get drugs. That is moving from home to the facility to get the drugs." – Male, community leader, CAB
Outer setting	
Local attitudes	*"It [long-acting PrEP] will increase unfaithfulness because you will not be walking with the drugs [oral PrEP] with you every day" – Female, PrEP ambassador, CAB*
	"Some of them [PrEP users] lie. So they should be asked, and then they say which one do you opt for? They will tell you that, 'I don't want that tablet; I have already been injected elsewhere.' You see, so those are some of the challenges we can expect." – Female, county government leader, CAB
Local conditions	*"I would try to bring in the issue of environment, environmental factors that are sometimes beyond the control of the leaders, the community and even the government. For example, when there is very harsh environmental impact like El Nino, you may have the information, you may have your willing community, you may have willing leadership, but how to get to that place during that harsh environmental condition is a problem, So sometimes environment plays a factor and even hinders physical or even communication access of information to the community." Male, health system administrator, CAB*
Partnerships & connections	*"It needs all heads to come together from the partner, national government, county government and the health providers. If they can come together for this to be rolled down." – Male, community health volunteer, CAB*
Policies & laws	*"They [the government] are also the ones that make policies that PrEP is safe for the public." – Male, community health volunteer, CAB*
	"And you know guidelines are not within our [scope]… it is national guideline." – Female, mentor mother, HCW
Policies & laws, community characteristics	*"People tend to believe that anything which is not signed by the government is null and void. If someone is taking samples of blood and the chief doesn't know, then no one will partake in it." – Male, community leader, CAB*
Inner setting	
Structural characteristics: Physical infrastructure, work infrastructure	*"Because of the setup which we have that [family planning department] is the only available space… I think structurally we have maybe rooms to implement and we also have, though limited, we have trained [personnel] and I am very sure they will still be trained." – Male, counselor, HCW*
Compatibility	*"The same work I am going to do for someone who has come for oral PrEP or the injectable PrEP, it is the same work." – Female, nurse, HCW*
	"On the same note, I feel it will reduce our workload because we shall be giving these injections for two months, this mother stays at home for two months then she comes back, unlike the orals whereby you keep on reminding them through the message." – Male, clinical officer, HCW
	"Another challenge is the workload. I am in family clinic, and I give a lot of services. You will find me doing antenatal checkup for pregnant mothers, I do cancer screening, and I have to give the information about PrEP. So, at times, I feel so overwhelmed." – Female, nurse, HCW
	"For example, the way we do it in family planning, you put everything on the table, then you discuss one by one so that you allow the client to make an informed choice. They can do it

	the same way [for] PrEP." – Female, healthcare planner, CAB
Incentive systems	*"Proper training for the people who are going to carry this exercise, give them enough knowledge because there is a new thing in the market, and motivating them because we want it to work well" – Male, healthcare planner, CAB*
Relative priority	*"How do we integrate? What about the partners who are pulling out, who will continue with these services? So they [government] choose people [select HCW] to take to seminars or to the training" – Male, healthcare planner, CAB*
Available resources: Funds	*"No training, not easy to implement until you have funds, unless there is ready funds to train people. You know that is a long-term thing." – Female, mentor mother, HCW*
Available resources: Space Access to knowledge and information	*"I'm just thinking even if you have human resource and space and you are not trained, you don't have the SOPs, you won't start." – Male, nurse, HCW*
Access to knowledge and information	*"We still don't have sufficient data, we don't want to get into a situation like the one that we found our self during the vaccination of Covid-19, then the client is there asking you the question before getting the jab, that 'is it true that I will not give birth to children'." HCW, ID unknown*
	"I will comfortably be providing the information [about LA-PrEP] but still we need additional training to keep us more up to date. Things change here and there and us providers we need to be top of it all to give the correct information every time." Male, pharmacy tech, HCW
Collective efficacy	*"Yesterday we had a meeting, and they were complaining, 'You people of the program, you do take your people for training, and you leave us behind. Now we can't offer the services.'" – Female, counselor, HCW*
Individuals	
High-level leaders	*"in Kenya now we have something called government to government. We source our commodities from outside and truly depends with the relationship between our government and the other countries government where at one point you get difficult leadership the other side and they stop the flowing of the support then we don't get commodities especially drugs, test kits and all that. So, government plays some major role in that they have to do government to government, and they must be good relationship so, that the other ideas, the other commodities flow in." – Male, county government leader, CAB*
Innovation recipients	*"…Some people are not ready to look at what is down there, so it will depend on the individual—will you be ready to see and even touch what is down there?" – Female, healthcare planner, CAB*
	"Currently we are administering [the ring] and a few concerns are some say the ring might disappear in the body and they might not get pregnant. Those are concerns that are being raised but we are trying to give relevant information, so that these clients can choose the best information." – Male, nurse, HCW
Implementation facilitators	*"through the CHPs [community health providers] in the community and even in the community meeting where HCW can be invited to give that information [about LA-PrEP] to different groups of people" – Female, healthcare planner, CAB*
Other implementation support	*"I think the best is the groupings say youth groups, we have that youth groups are a very good avenue for reaching the youths and then they can get the information." – Male, county government leader, CAB*
Implementation Process	
Assessing needs: innovation recipients	*"You can also help the patient come up with [an option] that can work with them." – Female, counselor, HCW*
Characteristics of Systems	
External funding agent priorities	*"even the partner when they come, they only concentrate on their particular staffs, so their trainings for their staffs everything that they are doing is that they are just concerned about their staff." – Female, healthcare planner, CAB*
Resource source	*"to this facility, availability of the commodity [LA-PrEP], according to the situation that we have now, if it is only left for the ministry, not donor, we may have a problem." – Female, counselor, HCW*
Characteristics of the Intervention	
Perceived sustainability	*"…as of now, if the partners pull out, you'll start from zero, because the information will be gone with the partners who were…the staffs who were working with the partners." – Female, healthcare planner, CAB*

Table 12: Implementation strategies for integration of LA-PrEP into reproductive healthcare settings identified by HCW and CAB members, with associated ERIC taxonomy

ERIC Strategy	Supporting Quote
Adapt and Tailor to Context	
Promote adaptability	*"I have really given one of the recommendations, that if we can develop a ring that at least is not mono in use can be dual, yes, that may be accepted in the community, that may increase acceptability."* — Male, health system administrator, CAB
Change infrastructure	
Change service sites	*"Because of the setup which we have, that [family planning department] is the only available space, but remember she cannot inject in the clinician room, but it can be done in the area."* — HCW, ID unknown
	"The access points should be made easier within the community and at a place that the community have confidence [such as the] community pharmacy." — Male, health system administrator, CAB
Develop stakeholder interrelationships	
Involve executive boards	*"The government should come up with innovation… let them come up with the small gadget like this one, the one that serves with health issues, where be the government will employ people and to give information, health education on this one, recordings etc., and then they send to the family or household and then they are supposed to be free."* — Male, healthcare planner, CAB
Identify and prepare champions	*"Because these services are being given at the facility, maybe in the facilities and according to researchers, the CHPs attached to these facilities need to be sensitized, even if it's two or three days of sensitization and they are aware that if they pass the information to the household level."* — Female, county government leader, CAB
	"CHPs are the ones leading the households, however much they have a lot to do." — Female, county government leader, CAB
	"Number one, using opinion leaders and key people in the society not leaving out headmasters and teachers because they offer very key populations in high school." — Male, healthcare planner, CAB
	"We have the youth groups are a very good avenue for reaching the youths, and then they can get the information… And again, we can also use an organization like churches. Yeah, we can use churches to inform the people of the new techniques that we have at times." — Male, county government leader, CAB
Engage consumers	
Increase demand, use mass media	*"Door to door and use of pharmacy in the community that they know. You go to buy those painkillers, you find the leaflets hanged around there."* —Female, PrEP ambassador, CAB
	"The main issue there is just creating awareness and getting them informed. Through road shows and also the chiefs in the barazas." — Female, PrEP ambassador, CAB
	"It is not everybody that goes to the hospital when they are sick. When they feel sick or feverish, they go and buy over-the-counter drugs. Believe me, when you put those leaflets in the pharmacy, the information can be passed very easily." — Male, community health volunteer, CAB
	"Before using mass media, it should find that a physical person that has gone on the ground to tell the community the new drug which is coming. Because people might ask that why is that we are only hearing it on the radio and nobody has told us yet we have the village elders and the CHVs. We should have our CHVs proactive towards giving the information, before we are back on the mass media." — Male, community leader, CAB
Involve patients/ consumers and family members	*"Facilities should use pregnant women also as examples to encourage other women that taking PrEP during pregnancy is also safe."* — Female, PrEP ambassador, CAB
Train and educate stakeholders	
Conduct ongoing training	*"I will comfortably be providing the information but still we need additional training to keep us more up to date. Things change here and there and us providers we need to be top of it all to give the correct information every time."* — Male, pharmacy tech, HCW
Create a learning collaborative	*"The other staff should also be given the information so that it not left to us alone. It should be for the facility."* — Male, clinical officer, HCW
Utilize financial strategies	
Alter patient/ consumer fees	*"Male, community leader: …So we realize that the financial support can also enhance them to come to the clinic for refill or testing because they know they can get the transport back home.* *Female, PrEP ambassador: Just to add on what [they] have said. The issue is financial*

	issue about transport, once the patients are promised a token as transport. They can be eager to go and take PrEP which is for their benefit. As time goes by they will see the benefit of the drug and forget about the transport." — CAB

Table 13: Prioritization activity

Ease of implementation			
HCW Group 1	**HCW Group 2**	**HCW Group 3**	**HCW Group 4**
1. Training/ sensitization/ knowledge 2. Provision of tools 3. Personnel 4. Guidelines (national level) – not easy to implement but it is key	1. Space 2. Personnel 3. Training 4. IEC materials	1. Guidelines (providing its available) 2. Training 3. Personnel 4. Space 5. Commodities	1. Training (LA-PrEP), supported by guideline 2. Commodities, tools 3. Community sensitization

Most helpful		
HCW Group 1	**HCW Group 2**	**HCW Group 3**
1. Training 2. Guidelines 3. Personnel 4. Commodities (syringes, gloves, needles) 5. Telecommunication (registers, tools for accountability)	1. Commodities 2. Training 3. Space	1. Personnel 2. Training 3. Commodities 4. Space

Chapter 5: Conclusion

This dissertation addresses the urgent need for multiple effective HIV prevention options among pregnant and postpartum women in Kenya, a population at heightened risk of HIV acquisition and subsequent vertical transmission. While daily oral PrEP is recommended and widely implemented, adherence remains a major challenge, highlighting the potential of LA-PrEP methods, such as injectable CAB-LA, the DVR, and LEN. Despite promising safety and efficacy data, little is known about pregnant and postpartum women's preferences for these new PrEP options or the strategies needed for successful implementation within MCH settings. This dissertation explores the acceptability, preferences, and implementation challenges of LA-PrEP among this population through three key research goals: (1) identifying preferred PrEP attributes across the perinatal period, (2) assessing the acceptability of LA-PrEP methods, and (3) examining barriers and facilitators to their implementation in Kenya. These research findings fill a critical gap in understanding the Exploration and Preparation phases of the EPIS framework (Figure 1) and lay the groundwork for future studies to address the subsequent Implementation and Sustainment phases.

In our DCE among pregnant and postpartum women in Kenya, we found clear preferences for bimonthly injectable PrEP, which had the highest utility of any PrEP characteristic both in pregnancy and postpartum. Other important attributes such as effectiveness and safety data underscore the importance of providing women with PrEP options that are both highly efficacious and supported by robust safety evidence. We identified four distinct preference profiles: Oral PrEP Preference, Flexible PrEP Adopters, Safe and Effective Injection Preference, and Strong Injection Preference, with the Strong Injection Preference group representing the largest proportion of the population. Flexible PrEP Adopters and Safe and Effective Injection Preference groups were open to multiple forms if safe and effective, while the largest class, Strong Injection Preference, strongly favored injectable PrEP but still had some positive views on daily oral PrEP. The smaller Oral

PrEP Preference class strongly preferred daily oral PrEP or no PrEP, over injectables or the vaginal ring. The multinomial logistic regression analysis revealed several important predictors of class membership. Women with a higher number of previous pregnancies, live births, and live children were less likely to belong to classes that favored injectables. Both pregnant and postpartum DCE groups had similar magnitude and direction of effects in analysis of preference weights, latent class assignments, and association with latent class membership

In our qualitative study on the acceptability of different HIV PrEP options among postpartum women, we identified nuanced aspects of acceptance for these PrEP approaches in pregnant and postpartum periods, highlighting the heterogenous preferences and diverse needs of the population. Long-acting options were broadly accepted and perceived to alleviate the burden of daily pill taking. Injectable PrEP specifically was valued for its discretion, alignment with familiar family planning methods, and long-duration. Despite the broad acceptance of new LA-PrEP methods, participants identified several themes specific to pregnancy and the postpartum period that could influence their acceptability. Concerns were raised about the safety of these products and the potential side effects during pregnancy, highlighting the need for robust safety data and comprehensive PrEP counseling when introducing new options. Opinions on the vaginal ring were divided—some women valued its discretion and ease of use, while others were uncomfortable with the concept of self-insertion. Additionally, participants noted that clinic visits for their baby could serve as a convenient way to discreetly attend follow-up appointments for injectable PrEP.

Finally, in our qualitative exploration grounded in the CFIR and ERIC frameworks, HCW and CAB members in Kenya provided insights into determinants and strategies for LA-PrEP implementation in reproductive healthcare settings. Determinants for the implementation of LA-PrEP into ANC and FP settings in Kenya, such as training, funding, and personnel, are intrinsically interdependent. Some strategies clearly addressed barriers (e.g. **conducting ongoing training** to support **access to knowledge/information**). However, some barriers had no clear solution,

such as drug availability of long-acting options at clinics and access to funds to conduct training and community sensitization. As found in the prioritization activity, strategies for LA-PrEP implementation may vary by location in terms of helpfulness and ease, based on existing resources and infrastructure. The wide range of strategies identified, such as repeated healthcare worker training on new HIV PrEP options, using CHPs to conduct community sensitization, and integrating LA-PrEP into FP clinics, hint at the multi-pronged approach needed to support implementation of LA-PrEP in this setting.

The findings of this research have significant implications for HIV prevention policy and the integration of LA-PrEP into antenatal and postpartum care settings. The strong preference among pregnant and postpartum women for bimonthly injectable PrEP highlights the need for policies that prioritize the availability of LA-PrEP alongside existing daily oral options. To ensure equitable access, policymakers should consider a multi-method PrEP delivery approach within MCH services, incorporating tailored counseling that accounts for individual preferences, prior PrEP use, and obstetric history. Additionally, health system readiness must be assessed using the WHO Building Blocks framework—examining service delivery, workforce capacity, health information systems, access to essential medicines, financing, and governance—to address key implementation barriers identified in this study. By addressing these structural challenges, health systems can better support LA-PrEP scale-up and sustain its integration into routine pregnancy and postpartum care.

Building on these findings, future interventions should focus on improving patient-centered PrEP delivery through informed resource planning and forecasting. Ensuring a steady supply of diverse PrEP options requires integrating client preferences into health system planning, similar to approaches used in the family planning sector. With a growing number of HIV PrEP options, health systems will have to make informed decisions on how to provide multiple prevention options in their setting. Stated preference methods, such as discrete choice experiments, can help generate

actionable insights for demand forecasting and guide resource allocation to maximize uptake and adherence. Further research should also evaluate proposed implementation strategies, identify additional barriers, and systematically assess the influence of various determinants on successful LA-PrEP adoption. By explicitly linking implementation barriers to tailored intervention strategies, this research can inform the design of effective, scalable solutions that enhance HIV prevention efforts for pregnant and postpartum women in high-burden settings.

In summary, this dissertation underscores the importance of expanding HIV prevention options for pregnant and postpartum women by integrating LA-PrEP into MCH services. The findings highlight diverse preferences, with broad acceptance of injectable PrEP and more variable receptivity to the vaginal ring, emphasizing the need for tailored education and support. Addressing knowledge gaps, enhancing healthcare worker training, and implementing differentiated PrEP delivery models that align with women's preferences can improve uptake and persistence. However, significant implementation challenges remain, including drug availability, funding constraints, and the need for community sensitization. Future research should focus on refining implementation strategies, addressing persistent barriers, and incorporating client perspectives to ensure equitable access to LA-PrEP. By prioritizing a patient-centered approach and strengthening health system readiness, these efforts can contribute to improved HIV prevention outcomes for pregnant and postpartum women at high risk of HIV, ultimately advancing global goals for maternal and child health.

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