Evaluating *Chlamydia trachomatis* and *Neisseria gonorrhea* among women who initiated HIV Pre-exposure Prophylaxis during pregnancy in Kenya

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Abstract

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Cisgender women in the World Health Organization (WHO) Africa region are at a double burden of HIV and other curable sexually transmitted infections (STIs), such as *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG). Countries in the region, including Kenya, have made tremendous efforts to incorporate HIV pre-exposure prophylaxis (PrEP) for HIV prevention and routine screening for syphilis within maternal and child health settings. However, syndromic management, which broadly covers several STI types, remains the standard of care for curable STIs other than syphilis, often leading to delayed or missed treatment opportunities and antimicrobial resistance due to overtreatment. Studies within the region have found that the use of 'near patient' laboratory-based testing for CT/NG is feasible and acceptable. Additionally, empiric testing is associated with fewer missed treatment opportunities due to its high sensitivity and specificity in detecting asymptomatic infections. Data shows a high prevalence of CT/NG among non-pregnant PrEP users; however, limited data exists on pregnant

women using PrEP. Additionally, few studies prospectively follow-up PrEP users to evaluate the incidence of CT/NG.

While uptake of PrEP among pregnant women with characteristics associated with HIV exposure is high, many women discontinue PrEP soon after initiation. Since STIs are common both in pregnant and non-pregnant women, routine testing for CT/NG among women using PrEP could potentially refine risk perception and motivate PrEP use. As countries seek to expand STI testing services within PrEP programs, it is critical to explore user experiences and women's motivation for CT/NG testing during the peripartum period. The studies presented in this dissertation aim to address the above epidemiologic and implementation gaps to advance delivery of STI testing for pregnant and postpartum women on PrEP in the WHO Africa region.

To add to the existing literature on the burden of CT/NG among pregnant women, we present the prevalence, incidence, and correlates of CT/NG among women who initiate PrEP in pregnancy within routine maternal and child health settings in Kenya. Using prospective data that tested women for CT/NG in pregnancy, 6 months, and 9 months, we found a appreciable prevalence and high incidence of CT/NG. These data contribute to the limited longitudinal studies evaluating the incidence of CT/NG among PrEP users in maternal and child health settings.

Using data from a randomized control trial, we present findings examining the relationship between CT/NG testing on PrEP discontinuation. We found that testing for CT/NG in pregnancy was associated with lower PrEP discontinuation as compared to testing after delivery.

Finally, to complement our quantitative findings, we assessed user experiences of receiving CT/NG testing integrated within PrEP delivery. Women's individual motivations for CT/NG testing uptake and how testing influenced HIV and STI risk perception provides valuable insights to add to guide future implementation models.

The studies presented in this dissertation aim to address the evidence gaps on the burden of CT/NG among pregnant PrEP users, the association between CT/NG testing and PrEP use, and user experiences of testing among pregnant and postpartum women in Kenya.

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CHAPTER 1: Introduction

Globally, *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG) account for approximately 64 million and 37 million new infections annually among women of reproductive age. [1] Pregnant women in the WHO Africa region have disproportionately high rates of CT/NG, with prevalence as high as 36.8% for CT and 7.6% for NG reported. [1-4] Although curable, these infections are often missed, or diagnosis and treatment are delayed due to the asymptomatic nature, especially during pregnancy, leading to severe complications, such as spontaneous abortion, premature rupture of membranes, pre-term delivery, low birth weight, and other adverse events. [2, 5] Infants born to mothers with CT and NG have an increased risk of sepsis, conjunctivitis, and pneumonia. [6, 7] Additionally, untreated CT/NG may increase the risk of HIV acquisition among HIV-negative women following inflammation and potentially heighten the risk of vertical transmission among women living with HIV in high endemic regions. [8, 9] The high prevalence of CT/NG may also be attributed to re-infections after directly observed therapy, highlighting the need to treat sexual partners of women diagnosed with CT/NG to disrupt the transmission cycle. [10, 11]

The WHO recommends syndromic management of CT/NG in resource-limited settings due to the unavailability of diagnostic testing. [12] Syndromic algorithms begin with the patient reporting STI symptoms, which triggers a subsequent clinical assessment of signs to inform recommended treatment that broadly covers likely bacterial STIs using a standardized tool. [13] Syndromic management often leads to underdiagnosis and missed treatment opportunities; up to 50% of CT/NG infections are asymptomatic. [14-17] In a cohort of pregnant Kenyan women, our team previously found that CT and/or NG was common among young unmarried women in new relationships (38.5% prevalence) and was frequently asymptomatic. [18] The Cepheid Gene Xpert, a 'near point of care' machine, has been validated for molecular testing for CT/NG with high sensitivity and specificity (>97%) for both infections). [19-22] GeneXpert machines are already

available for rapid tuberculosis diagnosis in the WHO Africa region and are feasible and acceptable to implement with high specificity (~99%) and moderate sensitivity (~80%) for detecting CT/NG. [21, 23-28] POC testing presents a unique opportunity to increase testing and same-day treatment, especially in the maternal and child health (MCH) settings. [29] The growing interest in POC STI testing has prompted the WHO to introduce additional guidelines for using molecular assays with same-day results, when available, to enhance diagnosis and reduce missed treatment opportunities associated with syndromic management. [28-30] Studies in the WHO Africa region have explored barriers and facilitators of implementing POC testing and EPT in the ANC setting and identified testing characteristics, client factors, and structural factors as the overarching themes. [28, 31-36]

Kenya has made tremendous strides in incorporating preexposure prophylaxis (PrEP) for HIV prevention within MCH)clinics. [8, 37-41] Studies focusing on non-pregnant women found that curable STIs, including CT/NG, are common among PrEP users, and STI diagnosis may motivate PrEP uptake by refining self-perceived HIV risk. [42-44] Few data exist on the burden of CT/NG among pregnant PrEP users and how CT/NG testing may influence PrEP use during pregnancy and postpartum, a period when HIV and STI acquisition has implications for both women and their infants. Moreover, studies demonstrate that CT/NG screening is feasible and acceptable at MCH clinics in Kenya and other African countries; [45] however, few data on user experiences are available. [46, 47]

This dissertation explores key epidemiologic and implementation questions on CT/NG testing to inform the integration and scale-up models for women receiving services in antenatal care settings. Below, we provide a brief overview of each research question.

Chapter 2: Burden of CT and/or NG among women initiating HIV PrEP during pregnancy

Despite the roll-out of PrEP delivery within the ANC clinics, few studies exist on the burden of CT/NG among pregnant PrEP users a period when HIV and STI acquisition has implications for both women and their infants. Studies focusing on PrEP users in Kenya found a high prevalence of CT/NG among non-pregnant women; however, there is a paucity of data among pregnant and breastfeeding PrEP users. [42, 43] MCH clinics in the WHO Africa region are integrated within a community facility and attract a significant number of women, providing a unique opportunity to generate data representative of a population with an increased risk for HIV and STIs. This data will contribute to gaps in the literature on the epidemiology of CT/NG and is crucial to developing targeted STI prevention guidelines and interventions. The objective of this analysis is to quantify the prevalence, incidence, and correlates of CT and/or NG among women initiating PrEP during pregnancy within MCH clinics.

Chapter 3: Association of STI testing and PrEP discontinuation among women in antenatal care settings

Women of reproductive age account for 56% of new HIV infections in sub-Saharan Africa, with the risk of HIV acquisition doubling during pregnancy and breastfeeding. [9, 48] To reduce the burden of HIV and work towards eliminating maternal-infant HIV transmission, the WHO recommends oral tenofovir (TFV)-based preexposure prophylaxis (PrEP) to HIV-negative people at substantial and ongoing risk for HIV acquisition in high HIV burden settings. [8] Studies in the region have found low rates of PrEP continuation, with most women citing low-risk perception as a reason for PrEP discontinuation. [49-53] Relationships based on trust, non-disclosure of extra-marital sex, and limited knowledge regarding STI risk factors are likely to lead to low-risk perception, especially when no symptoms are present. [54-57] Studies focusing on non-pregnant women found curable STIs, including CT/NG, are common among PrEP users, [42, 43] and STI diagnosis may motivate PrEP uptake by refining self-perceived HIV risk. [44] The objective of

this analysis was to evaluate the association between CT/NG testing and PrEP discontinuation among pregnant women initiating PrEP.

Chapter 4: Experiences with STI testing among women who initiated PrEP during pregnancy

Women's motivations and individual experiences with integrated POC testing and EPT (both innovative health technologies/approaches) provide valuable insights on implementation and potential scale-up in resource-constrained settings. Understanding user experiences of women offered STI testing and EPT provides valuable insights that will guide the development of CT/NG testing strategies and EPT models that can be scaled up in similar resource-constrained settings and other similar programs. Additionally results and insights from this project will inform policy decisions around implementing curable STI tests and ultimately improve the health outcomes of pregnant women and their infants. We explored participants' experiences with POC CT/NG testing and EPT among women initiating PrEP within the ANC and tested for CT/NG. We additionally explored how CT/NG testing may potentially refine the perceived risk for HIV and other STIs.

CHAPTER 2. Prevalence and incidence of *Chlamydia trachomatis* and *Neisseria gonorrhea* among women who initiated HIV pre-exposure prophylaxis during pregnancy in Kenya

ABSTRACT

Background: Limited data exist on STIs among women who initiate PrEP during pregnancy, a period when STIs pose risks to both women and infants. We evaluated the prevalence, incidence, and correlates of STIs among pregnant women initiating PrEP.

Methods: We analyzed data from an ongoing RCT that enrolled pregnant women initiating PrEP at 5 clinics in Western Kenya (NCT04472884). All women were ≥18 years, between 24-32 weeks gestation, initiating PrEP within routine antenatal care, and had high HIV risk. A subset of women were offered Chlamydia trachomatis (CT) and Neisseria gonorrhea (NG) testing using Xpert CT/NG® assays with same-day results in pregnancy and at 6- and 9-months post-delivery. Directly observed treatment (DOT) and expedited partner therapy (EPT) were offered to women diagnosed with CT/NG.

Results: All pregnant women offered CT and NG testing accepted (n=221). The median age of women was 26 years (IQR 22-30); median gestational age was 27 weeks (IQR 25-29). Prevalence of CT and/or NG during pregnancy was 19/221 (8.6%): 4.1% CT, 3.6% NG, and 1% CT and NG co-infection. Women <24 years were three times as likely to have prevalent CT/NG infection as older women (adjusted prevalence ratio [aPR]: 3.12; 95% CI: 1.24-7.85 p=0.016). Overall, 21 CT/NG infections occurred in 181.8 total person-years of follow-up (median follow-up 0.9 years, IQR 0.8-1.0), yielding an incidence of 11.6 per 100 person-years (95% CI: 7.5-17.7). Incident CT and/or NG was 7-fold higher among women <24 years compared to older women (adjusted incidence rate ratio=6.69, 95% CI 2.55-17.53, p<0.001). Same-day DOT and EPT acceptance was high (95%); at subsequent visits, 68% reported offering EPT to partners, of whom 95% confirmed partners completed EPT.

Conclusions: We found high CT/NG incidence among pregnant women initiating PrEP, indicating that routine CT/NG testing would be a high-yield strategy in this population, in addition to expanding EPT programs.

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Keywords: sexually transmitted infections, chlamydia, gonorrhea, STI prevalence, STI incidence, PrEP, pregnancy, postpartum

INTRODUCTION

Cisgender women account for 77% of new HIV infections among people aged 15-24 years in sub-Saharan Africa, with the risk of HIV acquisition doubling during pregnancy and postpartum compared to non-pregnant periods. [9, 48, 58] The World Health Organization (WHO) recommends oral HIV pre-exposure prophylaxis (PrEP) for pregnant women at substantial risk for HIV, [8] and Kenya has made tremendous strides in incorporating HIV PrEP within routine antenatal care. [8, 37-41] Cultural, economic, and social marginalization of women contributes to the risk of both HIV and other sexually transmitted infections (STIs). [59] Consequences of curable STIs, including *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG), are exacerbated in pregnancy, where infections are detrimental to both women and their infants. [60, 61] During pregnancy, untreated STIs may increase the risk of HIV acquisition among women without HIV and heighten the risk of vertical transmission during acute infection if HIV is acquired. [8, 9] Additionally, CT and NG infections during pregnancy are associated with poor perinatal outcomes. [6, 62, 63] Therefore, empirically testing for STIs within PrEP programs in antenatal care clinics presents a unique and potentially high-yield opportunity to address both HIV and STIs.

Few data exist on the burden of STIs among pregnant PrEP users, though studies from South Africa found high CT and/or NG prevalence among women initiating PrEP during pregnancy. [41] Before the era of PrEP, CT and/or NG prevalence among pregnant women in Kenya who were young, unmarried, and in new relationships was high (38.5% prevalence), with frequent asymptomatic infections. [64] A prior pilot study in Western Kenya demonstrated the feasibility of integrating CT/NG testing using Xpert® CT/NG assays within antenatal clinics offering PrEP, similar to other studies in South Africa and Botswana using Xpert® CT/NG within antenatal settings. [32, 45, 65, 66] To date, no studies have evaluated the burden or correlates of STIs among women who initiate PrEP during pregnancy in Kenya. There is a need to evaluate the context-specific STI burden among pregnant and postpartum PrEP users and to understand the

utility of STI testing within PrEP programs to inform integration of STI testing and PrEP across antenatal care settings with a high burden of HIV and STIs.

We evaluated the prevalence, incidence, and correlates of CT and/or NG among pregnant women initiating PrEP within routine antenatal care clinics in Kenya with the overall goal to inform STI testing recommendations for pregnant PrEP users in this setting.

METHODS

Study design and population

We conducted a prospective analysis nested within the ongoing mWACh-PrEP study (NCT04472884) among women initiating HIV PrEP during pregnancy. The mWACh-PrEP study is a randomized trial that began in February 2022 at five maternal child health clinics in Siaya and Kisumu, Kenya, that tests an mHealth tool to improve PrEP adherence during the peripartum period. Recruitment, data collection, and follow-up activities for the parent study are described in detail elsewhere. [67] Briefly, pregnant women were eligible to participate if they were ≥18 years old, had an HIV negative test at enrollment, had high empiric HIV risk scores - computed by estimating the likelihood of HIV acquisition based on behavioral and clinical characteristics (corresponding to 8.9 HIV infections per 100 person-years), and initiated PrEP at the study facility that day. [67, 68] Study visits aligned with antenatal and postnatal visit schedules per Kenyan national guidelines (i.e., monthly in pregnancy, 6 weeks, 14 weeks, 6 months, and 9 months postpartum). CT/NG testing was offered to a subset of participants enrolled at two of the five study sites.

Ethical approvals

The study protocol was reviewed and approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (P319/05/2021) and the University of Washington

Institutional Review Board (STUDY00010797) before study initiation. Written informed consent was obtained from all women by a study nurse.

Data collection and measures

Study nurses administered standardized questionnaires using tablet-based REDCap surveys to obtain information on sociodemographic, clinical, and pregnancy history, relationship characteristics, and sexual practices in English, Swahili, or Dholuo languages as per client's preferences. Women reported male partner characteristics (age, HIV status, and perception of other sexual partners). The 4-item Hurt, Insult, Threaten, and Scream (HITS) scale assessed intimate partner violence (IPV) with a cut-point ≥10 defining IPV. [27] Crowding ≥3 people/room was used as a proxy for low socioeconomic status (SES). [69]

Women self-reported sexual practices such as condom use, history of STI diagnosis, urogenital and vulvovaginal symptoms (i.e., abnormal vaginal discharge, foul smell, vaginal itch/burning). HIV status was ascertained using a rapid HIV antibody test administered at every visit as part of routine care among women on PrEP per national guidelines. [70] Women who tested positive for HIV at subsequent visits were not excluded from the parent study and continued follow-up through 9 months postpartum. Syphilis testing was conducted using rapid plasma reagin or SD Bioline HIV/Syphilis Duo test kits per national guidelines as part of routine antenatal care, and results were abstracted from women's medical records.

STI specimen collection, testing, and treatment

In addition to parent study activities, CT/NG testing was offered to all newly enrolled women at two study sites starting in September 2022. Women who were already enrolled before the initiation of STI testing procedures were offered CT/NG testing at their next study visit. Women

were additionally offered CT/NG testing at 6 and 9 months postpartum. Women who accepted CT/NG testing were instructed on how to self-collect vaginal swabs using the Xpert CT/NG Vaginal/Endocervical Specimen Collection Kits (Cepheid, Sunnyvale, California) per manufacturer instructions. Clinician-assisted sample collection was done for women uncomfortable with self-collection at their request. Samples were then processed using the Cepheid GeneXpert® CT/NG (Xpert) assay to detect CT/NG DNA, and participants continued to receive routine services while awaiting test results. CT infections were treated with a stat dose of 400mg oral cefixime and NG infection with azithromycin 1.5g per Kenyan national guidelines at no cost. [39] Women were offered expedited partner therapy (EPT) for their sexual partners and counseled on safe sex practices to avoid re-infection. Women with a previous positive CT and/or NG were re-tested at a subsequent study visit, and EPT outcomes were collected, including partner receipt and completion of treatment. Re-testing was done at least 30 days following treatment completion to ascertain infection clearance. Clearance was defined as testing negative for CT or NG infection after a positive test and completion of directly observed treatment.

Statistical analysis

Descriptive statistics were used to summarize baseline characteristics with medians for continuous variables and proportions for categorical measures. We computed prevalence as the percentage of women with a positive test of either CT, NG, or both infections at first test and 95% confidence intervals (CIs). Poisson regression was used to evaluate factors associated with prevalent CT and/or NG infections. Incidence rates (IR) and 95% CI were calculated as the number of CT and/or NG cases following a negative baseline test over the total person-time at risk and reported as events per 100 person-years. For women who tested positive for CT and/or NG at baseline, person-time was calculated from their negative test of cure. Women with missing or persistently positive tests of cure were excluded from the incidence analysis. We also used descriptive statistics to summarize the uptake of DOT, EPT outcomes, and test-of-cure results.

Poisson regression models were used to compute prevalence ratios (PRs) and incident rate ratios (IRR) and to identify correlates (demographic, sexual partnerships, sexual behaviors, condom use, risk perception, and partnership characteristics) of CT and/or NG infection. Factors associated with CT and/or NG infection (alpha = 0.10) in univariable models were included in multivariable models. We selected age and marital status as adjustment variables based on their known association with CT and NG in this setting. [64, 71, 72] Statistical analyses were performed using STATA version 16.0 software (Stata Corp., College Station, TX).

RESULTS

Baseline characteristics

A total of 221 women initiating PrEP during routine antenatal care were enrolled in the parent study and offered CT/NG testing during pregnancy; all accepted testing **(Figure 1)**. At baseline testing, most women (99.5%) received same-day test results, while one woman received results within 2 days of testing due to personal time constraints. Among women tested for CT/NG (n=221), the median age was 26 years (interquartile range [IQR]: 22-30); 176 (80%) were married, 63 (29%) had ≤8 years of completed education, and 42 (19%) were employed **(Table 1)**. Among married women (n=172), 12 (7%) reported being in polygamous marriages. Seventy (32%) women were primigravida, and 22% of women who had been pregnant before reported a history of a previous pregnancy loss. The median gestation age at enrollment was 26 weeks (IQR 24-29). Most women (95%) reported that their partner's HIV status was unknown, and one-quarter (27%) suspected that their partner had other sexual partners. None of the women included in the current analysis tested positive for HIV during the follow-up period.

Prevalence of CT and/or NG in pregnancy

CT and/or NG prevalence in pregnancy was 19/221 (8.6%); 9 (4.1%) had CT only, 8 (3.6%) NG only, and 2 (0.9%) both CT and NG infection with only 2 women among these presenting with STI

symptoms. Women <24 years were three times more likely to have prevalent CT and/or NG than older women (14% vs. 5%, adjusted prevalence ratio: 2.59; 95% CI: 1.06-6.34; p=0.037). In univariate analyses, shorter partnership duration and larger partner age difference were also associated with CT/NG, but the associations did not remain significant after adjustment for age and marital status. We did not detect any associations between prevalent CT and/or NG and any other demographic, clinical, or relationship characteristics **(Table 2).**

Incidence of CT and/or NG

Overall, 207 women tested negative at baseline or had a negative test-of-cure and were subsequently tested postpartum at a median follow-up time of 0.9 years (IQR: 0.8-1.0); all received same-day test results and DOT. Overall, 21 new CT and/or NG infections occurred during a total of 181.8 women years, yielding an incidence of 11.6 per 100 women-years (95% CI: 7.5-17.7); CT incidence was 9.7 per 100 women-years (95% CI: 6.1-15.4) and NG incidence was 3.7 per 100 women-years (95% CI: 1.8-7.7, supplemental material).

The incidence of CT and/or NG was 7-fold higher among women <24 years compared to older women (adjusted incidence rate ratio [aIRR]=6.69, 95% CI 2.55-17.53, p<0.001). Self-reported history of STIs was also associated with a higher incidence of CT and/or NG (aIRR= 7.89, 95% CI 2.25-27.69), p<0.001). Other correlates identified in univariate analyses included having a short (<2 years) time interval since last pregnancy and having a partner with a >5 years older age difference. However, these associations did not remain after adjustment for maternal age and marital status. No other demographic, clinical, or behavioral characteristics were associated with incident CT and/or NG **(Table 3).**

EPT and test-of-cure outcomes

Of all women with a positive CT and/or NG result at any timepoint (n=41), 39 (95%) accepted EPT. Reasons for not accepting EPT included concerns of partner violence, the partner being

away, and thinking that their partner may only take EPT after testing. Of the 41 women who tested positive for CT and/or NG at any timepoint, n=13 tested positive at their final study visit and were dispensed EPT per national guidelines, but their test-of-cure results and EPT outcomes were not ascertained as part of study procedures as they exited the study. Among the n=28 with positive CT and/or NG results who accepted EPT and had study follow-up, 19/28 (68%) reported their partners accepted treatment, and 18/19 (95%) confirmed their partner had completed the EPT regimen. No cases of IPV or other social harm were reported. All women who tested positive at any timepoint returned for a test-of-cure after 30 days or more following treatment; 4/28 (14.3%) re-tested positive, including two CT-only and two CT/NG co-infections. All n=4 women who re-tested positive had received directly observed treatment at initial diagnosis and accepted EPT but were uncertain whether their partner had taken or completed the EPT at the time of test-of-cure. All women received treatment after re-testing positive.

DISCUSSION

In this prospective study of CT and/or NG prevalence and incidence among women who initiated PrEP during pregnancy in Kenya, we found universal uptake of CT/NG testing and high uptake of DOT and EPT among those testing positive for CT and/or NG, consistent with other studies in the region. [32, 73-76] Prevalence rates of CT and NG were similar in our study (4.1% vs. 3.6%), which differs from prior studies among pregnant women in Kenya which found much higher prevalence of CT than NG. [64, 71, 77] CT prevalence was lower in our cohort than among pregnant PrEP users in South Africa (25%), while NG rates were comparable (2.6%). [78] Despite the high uptake of DOT and EPT, we found high rates of incident infections during the follow-up period, especially for CT. The high incidence of CT and/or NG we observed among pregnant women on PrEP is similar to studies of STI incidence among other populations of PrEP users, including non-pregnant adolescent girls and young women (AGYW). [71, 79-81] Our results add

to the very limited data on STIs among pregnant PrEP users and support that routine testing for curable STIs would be a high-yield strategy for women who initiate PrEP during pregnancy.

Among pregnant women in the WHO Africa Region with and without HIV, pooled prevalence rates are 10.8% for CT and 3.3% for NG, supporting that CT is more common than NG. [60, 82-86] We found similar rates of prevalent CT and NG among women who were at high risk of HIV acquisition, which may suggest changing CT/NG patterns compared to previous studies. However, our study sample is relatively small, and larger surveillance studies are needed to confirm our findings. [41, 87] Limited studies have evaluated STI incidence among pregnant women on PrEP; however, data from the era prior to PrEP suggests that the overall incidence of CT and/or NG ranges from 15 to 43 infections per 100 person-years among pregnant women in this setting. [71, 88] Notably, high rates of CT and NG were found among non-pregnant AGYW PrEP users in the HPTN 082 study conducted in South Africa and Zimbabwe, with rates of 27.8 and 11.4 infections per 100 person-years for CT and NG, respectively. [77] Our findings support that STI incidence is high among PrEP users across populations, which could potentially be explained by changes in risk perception and sexual practices such as condom use after PrEP initiation. [79, 87] Overall, condom use was extremely low in our study, like prior PrEP in pregnancy studies. [52, 89, 90] Most studies observe no evidence of risk compensation following PrEP initiation yet changes in risk perception and sexual behaviors among women following PrEP initiation are common. [91, 92] Women's condom negotiation power may diminish in pregnancy due to different relationship dynamics when pregnancy prevention is not a goal or HIV risk perception may lower while on PrEP, thus changing condom use. [87, 92] Our results highlight the need for regular STI testing among women on PrEP, especially during pregnancy when STIs have consequences for women and their infants. [87]

Incidence of CT and/or NG was associated with younger age, consistent with prior research findings among pregnant and non-pregnant women with and without PrEP use in this setting. [64, 77, 93] Young women are particularly prone to STIs due to social, cultural, and economic marginalization that may limit their autonomy over sexual health and the use of condoms. [55, 56, 94, 95] Individual factors such as stigma surrounding sexuality or fear of judgment and lack of comprehensive sexual health coupled with structural factors such as limited access to healthcare, including STI services, also contribute to STI risk. [32, 96, 97] In Kenya, empiric antenatal CT/NG testing is not routine due to the absence of guidelines on laboratory CT/NG testing, inconsistent and fragmented delivery of STI services, and competing priorities such as prevention of immediate causes of maternal and child mortality. [98, 99] Implementation research to advance prenatal STI testing is necessary and may be especially high-yield for young pregnant women and those on PrEP. [100] Only one woman with a positive test in pregnancy had an incident infection, highlighting that testing only in pregnancy would potentially miss many infections. Given the high incidence rate, especially among women without prior etiological-based STI diagnosis, postpartum period is an important time for STI testing.

We observed frequent re-infections despite the high acceptance rates of DOT, EPT, and negative tests-of-cure, although the number of CT and/or NG infections was limited in our study. Moreover, most infections were asymptomatic, a finding well-documented by other studies in the region. [64, 66, 71] While most women self-reported dispensing EPT to their sexual partners, some could not ascertain EPT completion. Studies incorporating male partners are needed to fully elucidate barriers to effective EPT implementation. Additionally, more than half of women reported that their partners may have other partners, and 7% were in polygamous marriages, which may explain the high rates of re-infection despite male partners receiving EPT. This underscores the need for primary STI prevention strategies tailored to unique populations with high STI incidence, like pregnant women on PrEP.[59]

Few options for primary STI prevention are available to cisgender women beyond condoms. A recent study examined 'event-driven' doxycycline post-exposure prophylaxis (dPEP) for curable STI prevention among non-pregnant women on PrEP in Kenya. There was no benefit associated with dPEP compared to those who did not receive prophylaxis, though poor adherence may account for this finding. [101] Another study in Kenya found a low incidence of CT and/or NG among female sex workers receiving periodic presumptive treatment for both infections, signaling this approach may be an effective primary prevention strategy. [102] Although doxycycline-based strategies may be helpful as primary STI prevention, doxycycline is contraindicated in pregnancy due to possible fetal musculoskeletal and dental defects and maternal hepatotoxicity. [59, 101, 103] Intervention studies that test primary STI prevention strategies that are safe for and effective in pregnant women are urgently needed to address this maternal health challenge.

Our study had few limitations. Our sample size was underpowered to detect statistically significant associations with some less frequent correlates. Nevertheless, our findings confirm the incidence of curable STIs among pregnant women. [71, 78, 88] STI testing was scaled into study procedures over time, thus creating differential timing of first tests and potentially limiting follow-up time between tests. Follow-up testing was done at 6 and 9 months post-delivery per study procedures. Women may have returned to the clinic before this period and received syndromic treatment that was not ascertained by the study, which may underestimate the true occurrence of incident infections. In future studies, serial testing during pregnancy and postpartum would more accurately estimate incidence rates during and after pregnancy. Thirteen women tested positive for CT and/or NG at their study exit visit at 9 months post-delivery, and consequently, we did not ascertain test-of-cure data. We offered EPT to women testing positive at study exit and provided the facility staff with test kits for women who returned to test after completing study activities. We did not directly ascertain EPT outcomes from partners, which may limit our ability to distinguish

between re-infection and persistence of infections among women who received DOT to treat CT and/or NG infections but tested positive at a subsequent visit.

CONCLUSION

In our study among pregnant women at high risk of HIV who initiated PrEP in pregnancy, we observed a high uptake of STI testing, moderate prevalence, and high incidence of CT and/or NG. As PrEP scales up for pregnant women in settings with a high burden of HIV and STIs, future research should focus on integrating STI testing and EPT within PrEP delivery settings. Additionally, primary STI prevention strategies that are safe and effective in pregnancy are urgently needed as this may benefit women and their infants.

CONFLICTS OF INTEREST

None declared.

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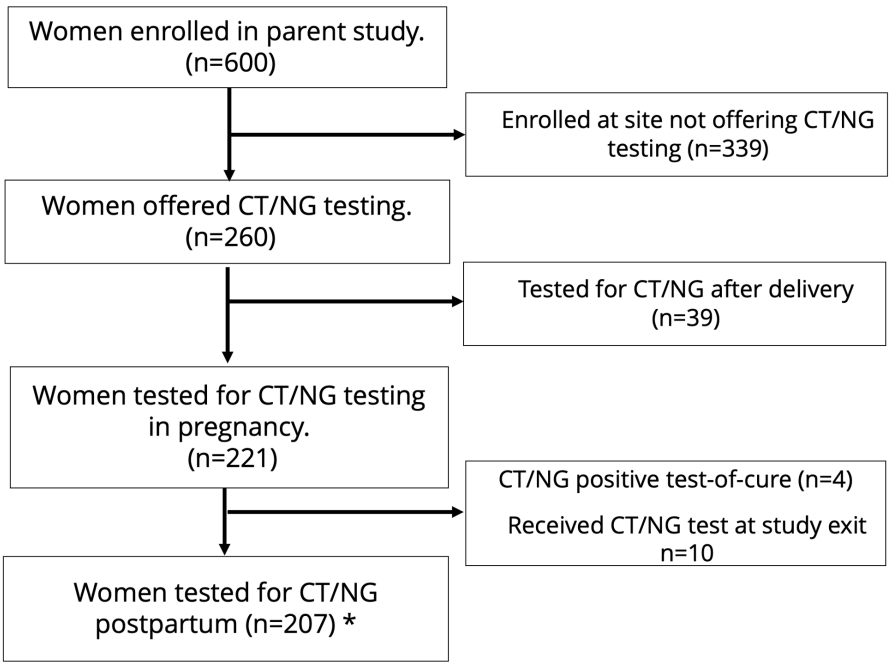
FIGURE

Figure 1. Flow diagram of participants included in the analysis



*Includes women who tested negative at baseline and those who tested positive for CT and/or NG but were subsequently CT/NG negative at test-of-cure (TOC).

TABLES

Table 1. Distribution of baseline characteristics among women enrolled at STI testing sites. (n=221)

	N	n (%) or median (IQR)
Demographic characteristics		
Age at enrollment (years)	221	26 (22-30)
Highest level of education (years)	221	12 (8-12)
Employed (vs unemployed)	221	42 (19%)
Marital status	221	
Married /co-habiting		177 (79%)
Single/ non-cohabiting		46 (21%)
Crowding (≥3 people/room)	221	53 (24%)
Distance from health facility (minutes)	221	40 (30-60)
First attendance at the antenatal care clinic [1]	221	
1st Trimester (0-13 weeks)		22 (10%)
2nd Trimester (14-26 weeks)		142 (64%)
3rd Trimester (27-40 weeks)		57 (26%)
Partner characteristics		
Currently in a relationship	221	213 (96%)
Duration of partnership (years) [2]	213	
> 5		85 (40%)
3 - 5		37 (17%)
1 - 2		67 (32%)
≤ 1		24 (11%)
Partner HIV status [2]	213	
HIV negative		8 (4%)
HIV positive		4 (2%)
Unknown status		201 (94%)
Partner age (years) [3]	190	30 (26-35)
Partner age difference ≥ 5 years (vs <5 years) [3]	190	81 (43%)
Pregnancy history and characteristics [4]		
Primigravida	221	70 (32%)
Previous pregnancy loss	151	30 (20%)
Previous premature birth (<37 weeks)	151	3 (2%)
<2 years since last pregnancy ended	151	31 (21%)
Number of living children	221	1 (0-2)
Self-reported history of STI diagnosis	221	6 (3%)
Current syphilis diagnosis in pregnancy	221	3 (1%)
Any STI symptoms [5]	221	23 (10%)
Risk assessment characteristics		
Empiric HIV risk score [6]	221	8 (8-10)
Number of lifetime sexual partners	221	3 (2-3)

Condomless sex in the past month	193	177 (92%)
Intimate partner violence [7]	221	3 (1%)
Suspicion partner has other sexual partners (last 3 months)	213	57 (27%)
Exchanged sex for money or favors	221	3 (1%)
Forced to have sex against will	221	1 (0.5%)
Alcohol use[8]	221	9 (4%)

[1] Gestation age determined by measuring the fundal height and last menstrual period as per local guidelines.
[2] Among those who are in a relationship (n=213).
[3] Among those in a relationship and were aware of their partners' age (n=190).
[4] Among those with a previous pregnancy (n=151).
[5] STI-related symptoms including abnormal vaginal discharge, sores, vulvar burn/itch and pain on urination at time of STI test.
[6] Empiric HIV risk assessment to predict HIV incidence in pregnancy and postpartum (HIV risk score ≥ 6 (translating to HIV incidence 7.3 per 100 person-years).
[7] HITS- Hurt, Insult, Threaten, and Scream (HITS) scale was used to assess history of intimate partner violence (IPV).
[8] Some alcohol use during pregnancy in the past month.

Table 2. Univariate and multivariate analyses of the correlates of prevalent CT and or NG among pregnant mWACh-PrEP maternal PrEP users (n=221)

Characteristic	N	Prevalent CT/NG (n=221)		Univariate models		Multivariate models	
		Yes (n=19)	No (n=202)	PR (95% CI)	p-value [5]	Adj PR (95% CI)	p-value [5]
Demographic							
Age at enrollment (years)	221						
<24 years		12 (14%)	76 (86%)	2.59 (1.06-6.34)	**0.037**	3.12 (1.24-7.85)	**0.016** [§]
≥24 years		7 (5%)	126 (95%)	ref			
Level of education	221						
≤8 years		3 (5%)	60 (95%)	0.47 (0.14-1.56)	0.218		
>8 years		16 (10%)	142 (90%)	ref			
Marital status	221						
Married/co-habiting		15 (9%)	161 (91%)	0.96 (0.33-2.76)	0.938		
Single/non-cohabiting		4 (9%)	41 (91%)	ref			
Duration of partnership	221						
≤2 year		12 (12%)	87 (88%)	2.11 (0.86-5.17)	**0.102**	1.62 (0.67-3.90)	0.287 [Ψ]
>2 year		7 (6%)	115 (94%)	ref			
Partner age difference [1]	190						
≥5 years older		4 (5%)	77 (95%)	0.41 (0.14-1.23)	**0.112**	0.36 (0.12-1.12)	0.079 [Ψ]
<5 years		13 (12%)	96 (88%)	ref			
Employment status	221						
Unemployed		18 (10%)	161 (90%)	4.22 (0.58-30.89)	0.156		
Employed		1 (2%)	41 (98%)	ref			
Living conditions	221						
≥3 people/room		2 (4%)	51 (96%)	0.37 (0.09-1.57)	0.178		
<3 people/room		17 (10%)	151 (90%)	ref			
Sexual behavior							
Reported condomless sex, last month [2]	193						
Any condomless sex		15 (8%)	162 (92%)	n/a	n/a		
No condomless sex		0 (0%)	16 (100%)				
Traded sex for money/items [2]	221						
Yes		0 (0%)	3 (100%)	n/a	n/a		
No		19 (9%)	199 (91%)				

Male partner HIV status [3]	213				
Unknown HIV-status		17 (8%)	184 (92%)	1.03 (0.15-7.14)	0.973
Known		1 (8%)	11 (92%)	ref	
Gynecological history					
Number of living children	221				
≤2 children		17 (10%)	161 (90%)	2.05 (0.49-8.58)	0.324
>2 children		2 (5%)	41 (95%)	ref	
Time since previous birth [4]	151				
<2 years		2 (6%)	29 (94%)	0.77 (0.18-3.37)	0.733
≥2 years		10 (8%)	110 (92%)	ref	
Self-reported STI symptoms	221				
Yes		2 (11%)	16 (89%)	1.34 (0.33-5.31)	0.689
No		17 (8%)	186 (92%)		
Self-reported history of STIs	221				
Any history of STIs		1 (17%)	5 (83%)	1.99 (0.31-12.63)	0.465
No history of STIs		18 (8%)	197 (92%)	ref	

[1] Among women reporting current relationship.
[2] Correlates analysis omitted due to zero cell count.
[3] Female partners reported HIV status of male partners.
[4] Among those with a previous birth.
[5] Poisson regression was used to identify correlates of CT and/or NG. Multivariate models were run for correlates identified in univariate models (p-value <0.1).
[§] Multivariate model adjusted for marital status *a priori*.
[Ψ] Multivariate models adjusted for age(years) and marital status *a priori.*

Table 3. Univariate and multivariate analyses of the correlates of incident CT/NG among maternal PrEP users enrolled in the mWACh-PrEP (n=207)

Characteristic	CT/NG infections/ person-years	Incidence (per 100 person-years)	Univariable Analysis		Multivariable Analysis	
			IR (95% CI)	**p-value** [3]	IRR (95% CI)	**p-value** [3]
Demographic						
Age at enrollment (years)						
<24 years	15/67.27	22.29 (13.44-36.99)	4.26 (1.65–10.97)	**0.003**	6.69 (2.55-17.53)	**<0.001** [§]
≥24 years	6/114.53	5.24 (2.35-11.66)	ref			
Level of education						
≤8 years	6/53.83	11.15 (5.01-24.81)	0.95 (0.37–2.45)	0.917		
>8 years	15/127.97	11.72 (7.07-19.44)	ref			
Marital status						
Married/co-habiting	19/144.67	13.13 (8.38-20.59)	2.44 (0.57–10.47	0.231		
Single/non-cohabiting	2/37.13	5.39 (1.35-21.54)	ref			
Partner age difference [1]						
≥5 years older	13/70.39	18.47 (10.72-31.80)	2.66 (1.01–7.00)	**0.047**	1.30 (0.46-3.70)	0.619 [Ψ]
<5 years	6/86.49	6.94 (3.12-15.44)	ref			
Employment status						
Unemployed	18/145.41	12.38 (7.79-19.65)	1.50 (0.44–5.09)	0.515		
Employed	3/36.39	8.24 (2.66-25.56)	ref			
Crowded living conditions						
≥3 people/room	19/137.23	13.85 (8.83-21.71)	3.09 (0.72–13.25)	0.130		
<3 people/room	2/44.57	4.49 (1.12-17.94)	ref			
Sexual behavior						
Reported condomless sex, last month						
Any condomless sex	18/145.85	12.34 (7.78-19.59)	1.73 (0.23-12.93)	0.595		
No condomless sex	1/13.98	7.15 (1.01-50.76)	ref			
Gynecological history						
History of pregnancy loss						
No	15/100.09	14.99 (9.03-24.86)	3.91 (0.52-29.58)	0.187		
Yes	1/26.07	3.84 (0.54-27.23)	ref			

Time since previous birth [2]							
	<2 years	6/23.09	25.99 (11.68-57.85)	2.68 (0.97-7.37)	**0.056**	1.79 (0.64-5.02)	0.271 [Ψ]
	≥2 years	10/103.07	9.07 (5.22-18.03)	ref			
Self-reported STI symptoms							
	Yes	1/4.75	21.04 (2.96-149.36)	1.86 (0.25-13.88)	0.544		
	No	20/177.05	11.29 (7.29-17.51)	ref			
Self-reported history of STIs							
	Any history of STIs	3/1.94	154.77 (49.92-479.87)	15.46 (4.56-52.49)	**<0.001**	7.89 (2.25-27.69)	**0.001** [Ψ]
	No history of STIs	18/179.86	10.01 (6.31-15.88)	ref			
CT/NG detected at baseline							
	Yes	1/7.73	12.93 (1.82-91.79)	1.13 (0.15-8.38)	0.908		
	No	20/174.06	11.49 (7.41-17.81)	ref			

[1] Among women reporting current relationship.
[2] Among women who had previously given birth. Poisson regression model p-value < 0.1 included in the adjusted model.
[3] Poisson regression was used to evaluate correlates of CT/NG p-value <0.1 considered significant in the unadjusted model.
[§] Multivariate model adjusted for marital status *a priori*.
[Ψ] Multivariate models adjusted for age(years) and marital status *a priori.*

Table 4. Supplementary Table on CT and/or NG incidence among women all in pregnancy or post-delivery(n=207).

STI type	Pregnancy and post-delivery (n=207)	
	cases per women years	Incidence Rate (95% CI) *
CT only	18/185.80	9.69 (6.10-15.38)
NG only	7/189.62	3.69 (1.76-7.74)
CT and/or NG	21/181.9	11.55 (7.53-17.72)

* Assuming 100% cure rate of CT/NG following treatment of a positive test.

CHAPTER 3. Co-delivery of STI testing for women who initiate PrEP in pregnancy is associated with lower PrEP discontinuation through the postpartum period

Abstract

Background: Few studies evaluate how testing for sexually transmitted infections (STIs) influences PrEP use during pregnancy and postpartum.

Methods: We analyzed data from an RCT that enrolled women between February 2022 and July 2023 who were newly initiating PrEP in pregnancy then followed through 9-months postpartum in Western Kenya (NCT04472884). Starting in September 2022, all participants were offered *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG) testing at a subset of study sites. Women already enrolled before the initiation of STI testing procedures were offered CT/NG testing at their subsequent study visit. PrEP discontinuation was compared between women who first tested for CT/NG in pregnancy compared to those who did not test in pregnancy.

Results: A total of 260 women enrolled in the parent study at sites that offered CT/NG testing at a median of 26 weeks gestation (IQR 24-29). Of the 260 women, all accepted CT/NG testing when offered; 221 (85%) were first tested for CT/NG during pregnancy and 39 (15%) were first tested postpartum. By 6 months postpartum, the median time to first PrEP discontinuation was 252 days (95% CI: 140-286), and women who tested for CT/NG in pregnancy less frequently discontinued PrEP compared to those who did not test in pregnancy (41% vs. 69%, p=0.001). After adjustment for partner HIV status, testing for CT/NG in pregnancy was associated with 39% lower PrEP discontinuation by 6 months postpartum (adjusted hazards ratio 0.61, 95% CI 0.37-0.99, p=0.049).

Conclusions: Co-delivery of STI testing for women who initiate PrEP in pregnancy could promote PrEP use through the postpartum period**.**

Keywords: PrEP, sexually transmitted infections, STI testing, pregnancy, postpartum

INTRODUCTION

Scale-up of HIV pre-exposure prophylaxis (PrEP) is ongoing in East and Southern Africa, with young cisgender woman as a priority population. [104, 105] Other curable sexually transmitted infections (STIs), such as *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG), are commonly detected among women who use PrEP in the region. [70, 106] Studies among non-pregnant women using PrEP in Zimbabwe and South Africa enrolled in HPTN 082 found high incidence of CT and NG (rates ranging from 11-28 infections per 100 person-years). [77] Similarly, studies among PrEP users in Kenya found a high prevalence of CT and NG among non-pregnant women. [42, 43] Data suggest that testing for STIs may increase PrEP uptake, [65, 107] potentially by refining risk perception. Yet, studies are needed to evaluate whether testing for STIs promotes continued PrEP use after initiation. Further, there is a paucity of data on STI testing and PrEP use among women who initiate PrEP during pregnancy, when changes in risk perception, sexual practices, and condom use may influence how STI testing impacts PrEP use. [79, 87]

Our team recently found high rates of CT and/or NG among women who initiated PrEP during pregnancy in Kenya. [108] A qualitative evaluation in the same cohort found that STI testing encouraged sustained PrEP use, even when STI results were negative, as testing made women feel proactively involved in preventing HIV/STI complications for themselves and their infants. [109] Additionally, women suggested the need for routine STI screening within antenatal care to reduce stigma, similar to routinizing 'opt-out' antenatal HIV testing. Therefore, co-delivery of STI testing and PrEP presents a potentially high-yield opportunity to address STIs and HIV among pregnant women in high-burden settings, a population disproportionately affected by STIs and HIV. [45, 110, 111] Studies among pregnant women without HIV in South Africa found that having an STI diagnosis and/or symptoms is associated with higher PrEP uptake. [65, 112] However, no studies to date evaluate PrEP continuation following STI testing among women who initiate PrEP in pregnancy, and none have included postpartum STI testing among PrEP users. We sought to

evaluate the relationship between CT/NG testing in pregnancy and postpartum and PrEP discontinuation among women initiating PrEP within antenatal clinics in Western Kenya.

METHODS

Study design, population and procedures

We analyzed data from an ongoing randomized trial among women initiating daily oral PrEP during pregnancy within five public antenatal clinics in Siaya and Kisumu, Kenya (mWACh-PrEP Study; NCT04472884). The mWACh-PrEP Study evaluates the effectiveness of an mHealth tool in improving PrEP adherence during pregnancy through the postpartum period. The parent study's enrollment, data collection, and follow-up procedures are described elsewhere.[67] Briefly, women were eligible to participate if they were pregnant, at least 18 years old, had a negative HIV test at enrollment, had a high empiric HIV risk score (corresponding to 8.9 HIV infections per 100 person-years), and were newly initiating PrEP that day. [67, 68] Enrollment occurred between February 2022 and July 2023, and study visits align with antenatal and postnatal visit schedules per Kenyan national guidelines (i.e., monthly in pregnancy, 6 weeks, 14 weeks, 6 months, and 9 months postpartum).

Trained nurses collected information on sociodemographic characteristics, pregnancy history, partner and relationship information, and characteristics associated with HIV acquisition. HIV risk perception was assessed by asking "*Based on your sexual activities with this partner during the past 3 months (or past 12 months if last reported sexual contact with this partner was between 3-12 months ago), how much do you feel at risk of becoming infected with HIV?* and dichotomized as low ("no/small/moderate risk") versus high-risk perception ("high risk/very high risk").[109, 111, 113]

PrEP discontinuation was assessed at each visit by asking participants whether they had stopped taking PrEP since their last study visit and if PrEP refills were dispensed. Women additionally received health education on HIV risk reduction strategies, clinical assessment, and safety monitoring while on PrEP, and adherence counseling on the benefits of continued use of PrEP in line with the national guidelines. At every study visit, nurses ascertained participants' HIV status using a rapid HIV antibody as per PrEP per national guidelines.[70]

At a subset of two sites, participants were additionally offered CT and NG testing using Xpert CT/NG® assays with same-day results. Starting in September 2022, CT/NG testing was offered to all women at enrollment in pregnancy, and 6 and 9 months postpartum at the two sites. Women already enrolled before the commencement of STI testing were offered CT/NG testing at their subsequent study visit. Women testing positive were additionally offered directly observed treatment and expedited partner therapy per Kenyan national guidelines on STIs at no additional cost. [114] A detailed description of CT/NG outcomes is described elsewhere. [108] Participants from the two sites offering CT/NG were included in the current analysis.

Ethical approvals

Before initiating study activities, we obtained approval from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (P319/05/2021) and the University of Washington Institutional Review Board (STUDY00010797). A written informed consent was obtained from all participants.

Statistical analysis

We used Chi-square tests for proportions to assess differences in baseline characteristics between women at the two sites who continued and discontinued PrEP by 6 weeks and 6 months postpartum and whether the frequency of PrEP discontinuation differed between women who first

tested for CT/NG in pregnancy vs. postpartum. We used Kaplan–Meier survival plots to estimate the median time to first PrEP discontinuation overall and stratified by timing of STI testing (pregnancy vs. postpartum). We then examined the association of STI testing with time to PrEP discontinuation using Cox proportional hazards regression.

RESULTS

Participants characteristics

A total of 261 women who initiated PrEP during routine antenatal visits were enrolled in the parent study at sites that offered CT/NG testing. One participant completed follow-up prior to CT/NG testing procedures commencing and, therefore, was not tested. Of the 260 women, 221 (85%) were first tested for CT/NG during pregnancy, of whom 183 were tested at enrollment when they initiated PrEP, and 38 at a subsequent visit during pregnancy. Among the 38 women who tested for CT/NG in pregnancy after enrollment, the median time since PrEP initiation at the time of CT/NG testing was 33 days (IQR 29-62). Overall, 39 women enrolled in the parent study prior to implementation of CT/NG testing procedures and were only tested postpartum (45% at 6 weeks, 30% at 6 months, and 23% at 9 months). There were no differences in demographic, clinical, or relationship characteristics between women who were first offered CT/NG testing in pregnancy compared to postpartum (*data not shown*).

STI testing and PrEP discontinuation

Overall, 109/260 (42%) women who initiated PrEP in pregnancy discontinued PrEP by 6 weeks postpartum, and 118/260 (45%) women discontinued by 6 months postpartum. There was a trend towards lower PrEP discontinuation when comparing women whose partner's HIV status was unknown versus those who knew their partner's HIV status at 6 weeks (42% vs. 63%, p=0.085) and 6 months postpartum (44% vs. 69% p=0.053). PrEP discontinuation at 6 weeks and 6 months was also higher among women who were unmarried, had lower education, and had shorter

partnership duration **(Table 5)**. There were no significant differences in other demographic, clinical, or relationship characteristics comparing those who discontinued to those who continued PrEP by 6 weeks and 6 months postpartum **(Table 6)**.

Women who tested for CT/NG in pregnancy less frequently discontinued PrEP by 6 weeks postpartum compared to those who tested for CT/NG only in the postpartum period (39% vs. 59%, p=0.019). Similarly, PrEP discontinuation by 6 months postpartum was also less frequent among women who tested for CT/NG in pregnancy compared to those tested postpartum only (41% vs. 69%, p=0.001). Among women who tested for CT/NG in pregnancy (n=221), those who tested positive for CT and/or NG (n=19) had similar frequency of PrEP discontinuation compared to those who tested negative (n=202) at 6 weeks (68% vs. 60%, p=0.493) and 6 months postpartum (58% vs. 59%, p=0.931).

Among women who were tested for CT/NG during pregnancy (n=221), the median time on PrEP was 130 days (IQR 88-161) compared to 101 days (IQR 57-149) among those who did not test for CT/NG in pregnancy (n=39). Testing for CT/NG in pregnancy was associated with a 39% longer time to PrEP discontinuation by 6 months postpartum (hazard ratio 0.58, 95% CI 0.37-0.93, p=0.023). Testing positive for CT/NG in pregnancy was not associated with time to PrEP discontinuation (hazards ratio 0.71, 95% CI 0.31-1.63, p=0.421), though statistical power was limited.

DISCUSSION

In this prospective study among women who initiated PrEP during pregnancy, we found lower PrEP discontinuation among women who tested for CT/NG at or near the time of PrEP initiation

in pregnancy compared to women who only tested postpartum. Almost half of women discontinued PrEP by 6 months postpartum, consistent with other studies among women in the region who initiated PrEP during or after pregnancy that found discontinuation rates ranging from 30%-60%. [49-53] Importantly, we found that testing for CT/NG during pregnancy was associated with lower PrEP discontinuation postpartum, regardless of the CT/NG results. Our results add to the limited data on the influence of STI testing on risk refinement and PrEP use among women in the peripartum period and support the potential positive impact of co-delivering CT/NG testing and PrEP within antenatal care. [65]

These data support findings from our qualitative evaluation on STI testing experiences where women reported that STI testing encouraged using PrEP despite negative STI results (*manuscript in progress*).[109] Our results add to prior studies in Kenya which found that a recent STI diagnosis or syphilis diagnosis in pregnancy is associated with PrEP continuation among women who initiate PrEP in pregnancy. [49] Our study also contributes to growing evidence that suggests that STI testing and diagnoses may motivate PrEP use beyond initial uptake. [65, 112] Several studies among pregnant women in South Africa, Botswana, and Kenya demonstrate consistently high feasibility and acceptability (85-99%) of CT/NG within routine antenatal settings. [32, 34, 45] Our current findings suggest an added benefit to antenatal CT/NG testing for promoting continued PrEP use among women who initiate PrEP within antenatal care. Women with unknown partner status or a partner living with HIV also less frequently discontinued PrEP compared to those with HIV-negative partners, similar to prior studies in Kenya. [115] Future studies that improve knowledge of partner HIV status, in addition to CT/NG testing, may be beneficial for PrEP delivery.

Our study has limitations. CT/NG testing was only conducted at two sites. The parent RCT was not designed to evaluate CT/NG testing as an intervention, and participants were not randomized to receive testing, although the timing of testing in pregnancy vs. postpartum was not purposive

and only related to administrative procedures. We did not detect differences in baseline characteristics between women who tested in pregnancy vs. postpartum, though the number of women who only tested postpartum was modest (n=39), which limits our power to detect differences. Our sample size was limited in evaluating associations between CT/NG testing and PrEP discontinuation; however, despite the small sample size, we found significant results supporting the association between CT/NG testing and lower PrEP discontinuation. [65] We did not include any biomarkers for PrEP adherence, and some PrEP continuation may have been misclassified due to inaccurate self-reports. Larger randomized trials with objective measures of PrEP adherence are needed to rigorously evaluate whether CT/NG testing is associated with PrEP use in this population, ideally with serial CT/NG testing.

In summary, our study found that STI testing in pregnancy was associated with lower PrEP discontinuation in the postpartum period. Co-delivery of STI testing with PrEP within antenatal care is a potential ‘high yield’ strategy to address HIV and other STIs, with STI testing also encouraging sustained PrEP use.

TABLES

Table 7. Distribution of participants' characteristics comparing PrEP discontinuation by 6 weeks and 6 months among women enrolled at study sites offering CT/NG testing (n=260)

Characteristic	N (%) or Median (IQR)						
		Discontinued PrEP by 6 weeks			Discontinued PrEP by 6 months		
	Overall n=260	Yes (n=109)	No (n=151)	p-value	Yes (n=118)	No (n=142)	p-value
Demographic							
Age at enrollment (years)							
<24 years	105	54 (51%)	51 (49)	0.074	54 (51%)	51 (49%)	0.107
≥24 years	155	97 (63%)	58 (37%)		64 (41%)	91 (59%)	
Level of education							
≤8 years	74	24 (32%)	50 (68%)	0.050	26 (35%)	48 (65%)	**0.036**
>8 years	186	85 (46%)	101 (54%)		92 (49%)	94 (51%)	
Marital status							
Married/co-habiting	207	79 (38%)	128 (62%)	**0.015**	87 (42%)	120 (58%)	**0.032**
Single/non-cohabiting	53	30 (57%)	23 (43%)		31 (59%)	22 (42%)	
Duration of partnership							
≤2 year	111	54 (49%)	57 (51%)	0.058	59 (53%)	52 (47%)	**0.030**
>2 year	149	55 (37%)	94 (63%)		59 (40%)	90 (60%)	
Partner age difference [1] n=224							
≥5 years older	91	34 (37%)	57 (63%)	0.206	36 (40%)	55 (60%)	0.111
<5 years	133	61 (46%)	72 (54%)		67 (50%)	66 (50%)	
Employment status							
Unemployed	212	90 (42%)	122 (58%)	0.716	96 (45%)	116 (55%)	0.945
Employed	48	19 (40%)	29 (60%)		22 (46%)	26 (54%)	
Living conditions							
<3 people/room	200	85 (43%)	115 (58%)	0.731	26 (43%)	34 (57%)	0.716
≥3 people/room	60	24 (40%)	36 (60%)		92 (46%)	108 (54%)	
Sexual behavior							
Reported condomless sex, last month [1] (n=227)							
Any condomless sex	204	85 (42%)	119 (58%)	**0.031**	94 (46%)	110 (54%)	0.579
No condomless sex	23	15 (65%)	8 (35%)		12 (52%)	11 (48%)	
Traded sex for money/items							
Yes	3	2 (67%)	1 (33%)	0.382	1 (33%)	2 (67%)	0.673
No	257	107 (42%)	150 (58%)		117 (46%)	140 (54%)	

Male partner HIV status [2]							
Unknown HIV-status	240	99 (41%)	141 (59%)	0.057	106 (44%)	134 (56%)	0.114
HIV negative	16	10 (63%)	6 (37%)		11 (69%)	5 (31%)	
Partner with HIV	4	0(0%)	4 (100%)		1 (25%)	3 (75%)	
Gynecological history							
Number of living children							
≤2 children	212	94 (44%)	118 (56%)	0.097	104 (49%)	108 (51%)	**0.012**
>2 children	48	15 (31%)	33 (69%)		14 (29%)	34 (71%)	
Time since previous birth [3] (n=175)							
<2 years	33	12 (36%)	21 (64%)	0.721	11 (33%)	22 (67%)	0.516
≥2 years	142	47 (33%)	95 (67%)		56 (39%)	86 (61%)	
Self-reported STI symptoms							
Yes	19	8 (42%)	11 (58%)	0.937	8 (42%)	11 (58%)	0.766
No	241	101 (42%)	140 (58%)		110 (46%)	131 (54%)	
Self-reported history of STIs							
Any history of STIs	7	4 (57%)	3 (43%)	0.408	3 (43%)	4 (57%)	0.892
No history of STIs	253 (97%)	105 (42%)	148 (58%)		115 (45%)	138 (55%)	
Timing of CT/NG testing							
Tested for CT/NG at enrollment in pregnancy							
Yes	183	65 (36%)	118 (64%)	**0.001**	68 (37%)	115 (63%)	**<0.001**
No	77	44 (575)	33 (43%)		50 (65%)	27 (35%)	
Tested for CT/NG any time in pregnancy							
Yes	221	86 (39%)	135 (61%)	**0.019**	91 (41%)	130 (59%)	**0.001**
No	39	23 (59%)	16 (41%)		27 (69%)	12 (31%)	

[1] Gestation age determined by measuring the fundal height and last menstrual period as per local guidelines.
[2] Among those who are in a relationship.
[3] Among those in a relationship and were aware of their partners' age
[4] Among those with a previous pregnancy
[5] STI-related symptoms, including abnormal vaginal discharge, sores, vulvar burn/itch, and pain on urination at time of STI test.

Table 8. Timing for CT/NG testing and PrEP discontinuation

STI testing timing	PrEP discontinuation					
	6 weeks (n=260)		6 months (n=260)		9 months (n=260)	
	Yes (n=109)	No (n=151)	Yes (n=118)	No (n=142)	Yes (n=158)	No (n=102)
Tested pregnancy only (n=12)	9	3	9	3	10	2
Tested postpartum only (n=39)	23	16	27	12	30	9
Tested pregnancy and postpartum (n=209)	77	132	82	127	118	91
Total	**109**	**151**	**118**	**142**	**158**	**102**

CHAPTER 4: *“It gives me the strength and courage to take care of myself ”:* **experiences with STI testing among women who initiated PrEP during pregnancy in Western Kenya**

ABSTRACT

Background: Sexually transmitted infections (STIs) in pregnancy contribute to poor perinatal outcomes and increased HIV acquisition risk, underscoring the importance of delivering STI/HIV services within antenatal care. Few studies evaluate women's perspectives on co-delivery of antenatal STI testing and HIV pre-exposure prophylaxis (PrEP). We sought to understand motivations for and experiences with STI testing among pregnant women who initiated HIV PrEP.

Methods: We conducted in-depth interviews (IDI) among a subset of women enrolled in a randomized trial in Western Kenya (NCT04472884) who initiated PrEP within antenatal clinics and tested for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG) in pregnancy and/or postpartum as part of parent study procedures. Deductive and inductive methods were used to analyze transcripts and debrief memos. The Health Belief Model guided exploration of STI testing experiences, motivations for testing, and the impact of testing on PrEP use.

Results: Overall, 39 women who initiated PrEP during pregnancy and tested for CT/NG participated in IDIs; 6 tested positive for CT and/or NG. Median age was 26 (IQR 21-29), 23% of participants had ≤8 years of education, 15% were employed, and 72% were married. Most (86%) did not know their partner's HIV status, and 82% persisted with PrEP use at 9 months postpartum. Perceived vulnerability to STI/HIV acquisition, fear of adverse outcomes from untreated infections (e.g. pregnancy loss or harm to baby), and desire to alleviate symptoms (e.g., abnormal discharge) all motivated STI testing uptake when offered during antenatal visits. Provision of STI-related education, availability of STI services like immediate treatment and expedited partner therapy, and supportive interactions with providers promoted positive experiences with STI testing. STI testing encouraged health-promoting behaviors, including sustained PrEP use, even when STI results were negative, as testing made women feel proactively involved in preventing HIV/STI complications for themselves and their infants.

Conclusions: In this qualitative evaluation among women who initiated PrEP in pregnancy, STI testing encouraged PrEP use, even when results were negative. Incorporating STI testing within PrEP delivery in antenatal care represents an opportunity for addressing HIV/STI in this priority population.

Word count: 338 (limit 350)

Keywords: PrEP, user experiences, sexually transmitted infections, STI testing, risk perception

INTRODUCTION

The burden of curable sexually transmitted infections (STIs) remains high among pregnant women in East Africa and contributes to poor pregnancy and birth outcomes in this setting. [116, 117] Additionally, STIs increase the risk of HIV acquisition during pregnancy among women without HIV and the risk of vertical HIV transmission among women who acquire HIV during pregnancy. [8, 9] Therefore, simultaneously addressing HIV and STIs represents an important opportunity for improving global maternal and infant health. PrEP does not protect against curable STIs commonly detected among pregnant PrEP users, such as *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG),[70, 106] and studies to address CT and NG in this population are few. Syndromic STI management is the standard of care in Kenya, resulting in delayed or missed treatment opportunities. [12] Integrating empiric STI testing within antenatal clinics offering PrEP services could address both STI and HIV prevention and is a potentially high-yield strategy for women at high risk for both. STI testing may also motivate PrEP use by clarifying one's self-perceived HIV risk, making co-delivery of STI testing with PrEP particularly attractive. [100]

Several quantitative pilot studies among pregnant women living with and without HIV in South Africa, Botswana, and Kenya demonstrate consistently high feasibility and acceptability (85-99%) of 'near-patient' Xpert® testing for CT, NG, and *Trichomonas vaginalis* within routine antenatal settings. [32, 34, 45] Yet, few qualitative data exist from end-users on STI testing service delivery integrated within antenatal care settings. Prior to the era of PrEP, existing studies in the region among general populations of pregnant women explored barriers and facilitators of STI testing and expedited partner therapy (EPT). These studies identified testing characteristics (e.g., ease of use, results turnaround time, integration of service delivery, and EPT availability), client factors (e.g., STI knowledge, attitude and beliefs, relationship dynamics, pregnancy status, risk perception, and self-efficacy), and structural factors (e.g., access to services and resources and availability of guidelines) as important for implementation. [28, 31-36] However, no studies to date

have evaluated STI testing experiences among pregnant PrEP users who may have unique perspectives on STI testing, given their behavioral profiles and adoption of HIV preventive strategies. Understanding experiences with STI testing among pregnant women who initiate PrEP is helpful to refine co-delivery strategies in this unique population. [44]

Our team conducted a prospective study exploring the burden of CT and/or NG among women who initiated PrEP during pregnancy in Western Kenya. [108] We found a prevalence of CT and/or NG at enrollment in pregnancy of 8.6% and a high incidence (11 infections per 100 person-years) through 9 months postpartum, highlighting the burden of CT/NG among women who initiate PrEP. [108] We conducted this qualitative evaluation to understand women's experiences with CT/NG testing within antenatal clinics delivering PrEP and the impact of CT/NG testing on PrEP continuation among women who initiated PrEP during pregnancy. Our overall objective was to gather experiences and perspectives to inform co-delivery of CT/NG testing within antenatal care settings, offering PrEP for future implementation and scale-up.

METHODS

Study design and population

We conducted a qualitative evaluation informed by the Health Belief Model. [118] We invited a subset of women enrolled in the ongoing mWACh-PrEP study (NCT04472884) who were offered *Chlamydia trachomatis* (CT) and *Neisseria gonorrhea* (NG) testing using Cepheid GeneXpert® CT/NG assays as part of parent study procedures to participate in in-depth interviews (IDIs). The parent study, including STI testing activities, is detailed elsewhere. [67, 110] Briefly, the mWACh-PrEP study is a randomized trial that tests a mHealth tool to improve PrEP adherence among pregnant women not living with HIV who newly initiate PrEP at five routine antenatal clinics in Siaya and Kisumu, Kenya. At a subset of two sites, we offered CT/NG testing at enrollment or at any point during pregnancy and at 6 and 9 months postpartum. Women who had already enrolled

in the trial prior to the initiation of STI testing procedures were offered CT/NG testing at their next study visit. Women testing positive for CT or NG were offered treatment at no cost. mWACh-PrEP study participants were eligible for the current qualitative analysis if they were offered and accepted CT/NG testing at least once at any point during the parent study, either during pregnancy or postpartum. All women offered CT/NG testing accepted. [110] PrEP use status was dichotomized (continued or discontinued) based on self-report at 9 months postpartum.

Data collection

Participant Recruitment

Nurses affiliated with the mWACh-PrEP study but not associated with or offering STI testing services informed participants about the qualitative study during parent study follow-up visits. A subset of women was purposively selected after completion of follow-up in the parent study at 9 months postpartum. We sought a heterogeneous group of women, including those who tested for CT/NG during pregnancy and/or postpartum and those diagnosed with either CT and/or NG, to represent varied experiences with the STI services offered. Qualitative interviewers invited participants to join IDIs from September 2023 to April 2024.

Qualitative team and data collection

The coding team comprised five Kenyan cisgender women, including qualitative interviewers (HA, and SO), a study coordinator (EA), a data manager (SW), and a project director (JN) — all of whom had prior research experience among pregnant women. Additionally, a Ph.D. student (TC) based in the United States with expertise in qualitative data analysis coded transcripts. Based on published literature and previous experience working with this population and region, JN, TC, HA, CO, and SO collaboratively created semi-structured interview guides. EA, HA, CO, and SO translated the interview guides into Swahili and Dholuo and then back-translated them into English for quality control and to maintain the intended meaning.

Based on domains of the Health Belief Model, interview guides were developed to capture user experiences and motivations for STI testing, including individual factors (perceived threats and benefits), modifying factors (*psychosocial*), self-efficacy (*competence*), and cues to actions (*triggers for change*). The domains were organized into the main topic areas of (1) individual motivations for CT/NG testing, (2) impact of CT/NG testing on PrEP use, and (3) recommendations for improving STI testing and treatment in antenatal care. [118] EA, TC, and trained qualitative interviewers (HA, CO, and SO) working within the region and familiar with the local context piloted the interview guides between August and September 2023. Qualitative interviewers conducted audio-recorded IDI sessions in a private room within the study clinic, using the participant's preferred language (English, Kiswahili, or Dholuo), with each interview taking approximately 40 minutes, followed by verbatim transcription into English.

An initial set of transcripts was independently verified against the audio recording by EA and JN, both fluent in the local languages. The qualitative team evaluated all transcripts for completeness and accuracy, while a random sample of 7 (18%) transcripts were back-translated into Swahili and Dholuo for accuracy as part of the QA/QC checks. At least two analysts independently conducted data cleaning and translation processes.

Data analysis

A codebook was developed by randomly selecting 10 transcripts and using both deductive and inductive thematic analysis approaches to test and iteratively generate potential codes related to CT/NG testing motivators and user experiences. We generated codes deductively based on the topic area guides and research questions, while inductive codes emerged from the transcript data. The coding process began with open coding and discussion within the core team, leading to a list of potential codes refined with subsequent discussions and review of additional transcripts iteratively. Consensus coding of a similar transcript was conducted by the whole coding team,

followed by further discussions to refine the finalized codebook. Dedoose was used for data management and analysis. Primary coding of the IDIs was conducted by JN, TC, EA, HA, and SO. Each transcript was coded independently using the final revised codebook to ensure the rigor and reliability of findings per the consolidated criteria for reporting qualitative research (COREQ) guidelines. Memos facilitated discussions while reviewing divergent codes. [119]

Secondary coding, which entailed a review of each other's codes to evaluate any disagreements, followed by discussions to review any divergent codes, was guided by the memos. After completion of the coding process, we generated initial themes by running a query to extract data and formulated a thematic map that was used to connect related concepts and further refine the themes.

Ethical considerations

Study activities are approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (P319/05/2021) and the University of Washington Institutional Review Board (STUDY00010797). All study participants received Kshs. 500 (approximately USD 5) to compensate for transportation to the study clinic and for time participating in study activities.

RESULTS

Participant characteristics

In total, 39 women who initiated PrEP in pregnancy, enrolled in the parent study, and tested for CT/NG participated in IDIs. Six participants tested positive for an STI (4 for CT, 1 for NG, 1 for both); all received directly observed treatment and accepted EPT for their sexual partners. The median age was 26 years (interquartile range [IQR]: 21-29), 28 (72%) were married, 9 (23%) had ≤8 years of completed education, and 6 (15%) were employed. At 9 months postpartum, 82% persisted with PrEP use. **(Table 7)**

Overall, key themes emerged from the IDIs related to domains of the Health Belief Model (**Figure 1**), including positive experiences with STI testing and factors that facilitated testing (*perceived benefits and health motivation domains*), contextualizing HIV/STI risk through STI testing (*perceived vulnerabilities*), and how STI testing influenced PrEP use (*cues to action*). We additionally summarized experiences with EPT due to the unique circumstances of these participants.

Perceived benefits of STI testing and health motivation

Women demonstrated a varied level of STI knowledge, with most women being familiar with examples such as chlamydia, gonorrhea, chancroid, and syphilis and their related symptoms such as vaginal itching and abnormal vaginal discharge. Women acknowledged that untreated STIs could potentially lead to complications, including difficulty in conception, stillbirths/miscarriages, and preterm births, although the depth of awareness was varied.

> *"…Gonorrhea, syphilis, are the ones that I know…If a pregnant woman gets it, that would be very bad… It can cause miscarriage, you can also give birth to unhealthy baby. That disease [STI] is bad, it can be good luck if the baby comes out alive since it can cause stillbirth. The fetus might not have good health in the womb"* –***Age 28, CT/NG negative, discontinued PrEP.***

> *"When it [STI] progresses, you will have a smelly discharge and itching, you won't feel comfortable. It can also infect the unborn child if it progresses. It can cause a miscarriage."* – ***Age 32, CT/NG negative, discontinued PrEP.***

> *"With pregnant women, you can transmit it [STI] to the fetus, and it will affect the baby. It may cause miscarriage, or the mother may develop some complications…The baby may be born*

prematurely, stillbirth, or a child may be born with a mental disorder or any form of disability." – ***Age 21, CT/NG negative, continued PrEP.***

Availability of CT/NG testing within the antenatal clinics, coupled with health education from providers motivated women to test. While most women were aware of syphilis testing for pregnant women, they were unaware that testing for other STIs was possible. Discussions held with the providers sensitizing women on the importance of testing, implications for delayed testing, and the availability of treatment if a test result was positive were motivators for women to test.

"I knew if I tested, then I would be free because I had never tested for [STIs], so when I came here and found that they were testing, I found it to be good. Now you live knowing your status. You might be infected and you don't know, they [STIs] can eat someone from inside until it reaches a point where they cannot even give birth... So that was the reason why I decided to take the test." – ***Age 33, CT/NG negative, continued PrEP.***

"I decided to test because I was informed that it was important to know my status, especially now that I was pregnant. They even offered treatment in case one turned positive for [an STI] to protect the child. That is why I agreed to be tested." – ***Age 27, CT/NG positive, continued PrEP.***

Having a positive interaction with providers was highlighted as a motivator for testing, as providers within the maternal and child health clinics were friendly, welcoming, and non-judgmental. One participant had symptoms but feared to talk about it at the general outpatient clinic; however, providers at the antenatal clinic seemed warm and approachable, prompting her to disclose her symptoms and agree to test.

"In outpatient, I was afraid because I didn't have someone I can tell my problems. When I joined the study, they [providers] were friendly and …. I told them I had some itching and some yellowish discharge, and they asked if I would agree to be tested. Which I accepted, so that is how I accepted to be screened." – ***Age 20, CT/NG positive, continued PrEP****.*

Some women feared that collecting the sample for STI testing would hurt their baby; however, following reassurances from providers that the process was simple and painless, receipt of a detailed description of sample collection procedures, and options for provider-assisted sample collection, women became at ease. Women also recognized the importance of early detection and treatment of STIs to prevent poor outcomes.

"Before I got tested, she told me not to fear because STI can be cured. In case I test positive for STI, I will be put on drugs and I will get well when detected in early stage. So, I was eager to know… I was very comfortable because the nurse was very free [non-judgmental]…. she told me how to do it [sample collection]. After I had collected the sample, I could just take to her then she could take to the laboratory, and she could come back with results." – ***Age 21, CT/NG negative, continued PrEP.***

"Before she gave me the sample collecting tube, [the nurse] took me through STIs, how they manifest and what would happen in case you could be having one, and how I would be helped in case I have one…this made me become courageous while undergoing these procedures. …because in case I tested positive, then I could get immediate help… that is why I decided to take all these initiatives. If I tested positive, then I can get help early enough." –***Age 27, CT/NG negative, continued PrEP.***

Perceived vulnerabilities to STI and HIV

Women expressed a desire to know their STI status and saw testing as a means of protecting themselves and their unborn infants. Some women sought treatment upon experiencing symptoms related to CT/NG, such as vaginal itch and abnormal discharge.

> *"I accepted [testing] because refusing wasn't going to benefit me; after all, they [the nurses] wanted to help me…I felt comfortable because it [testing] was going to motivate me to maintain or reduce the chances of getting the STI. Knowing my status was important so that I can get treatment if [an STI was] found. It was all about the desire to know my STI status."* –***Age 23, CT/NG negative, continued PrEP.***

Some women perceived themselves to be at a higher risk for contracting STI based on being in polygamous marriages, a suspicion that their partners had other sexual partners, or women themselves having multiple sexual partners, thus putting them at high risk for contracting CT/NG infection.

> *"So, I had three different sexual partners, all of them knew that the pregnancy was theirs [giggles]… I didn't know their sexual behaviors too. So, I had to test to find out whether I was infected [with STIs] or not."* – ***Age 28, CT/NG negative, continued PrEP.***

Cues to action: STI testing and PrEP use

Most women stated that testing for CT/NG did not negatively influence their PrEP adherence since they still considered themselves to be at risk for HIV, regardless of their CT/NG test result. Some women expressed that negative STI results encouraged health-promoting behaviors,

including sustained PrEP use, even when STI results were negative, as testing made women feel proactively involved in preventing HIV/STI complications for themselves and their infants.

> *"You know any time you do a [STI] test, the results can either come that you have it or you do not have it…After I knew that I didn't have HIV or even the STI, it gives me the strength and the courage to take care of myself so that I don't get those things."* – ***Age 33, CT/NG negative, continued PrEP.***

> "*It motivated me because when I realized that I am not infected with STI, I was trying hard not to get HIV, so from that point, I made a decision to continue with the PrEP; I did not leave [stop taking PrEP], even after the results [STI] came out negative."* – ***Age 21, CT/NG negative, continued PrEP.***

Women who tested positive for CT/NG expressed a heightened perception of risk for other STIs, including HIV, and the test results motivated them to continue PrEP

> *"Yes, I felt I was at risk. Because now that I have this STI, chances are high that I also get infected with other STIs. For example, if I have sex with another man and I don't know their status. I can contract it again. This showed that I could be at risk of getting HIV and other STIs, and that is why I made a decision to change my behavior…."* – ***Age 20, CT/NG positive, continued PrEP***

One participant in a polygamous marriage still considered themselves at risk despite testing negative for CT/NG due to the added risk of infection from the other partners, thus motivated to continue PrEP.

"...I would have wished that my spouse and my co-wife all get tested [for STI]... I can be [negative], but one of them [sexual partner or co-wife] has it [STI]… without knowing the other people's status would make my chances of contracting it [STI] higher. Because… I was [tested] negative [for STI], this really encouraged me to continue taking PrEP… to be [HIV-negative] and give birth to an infection-free baby" – ***Age 27, CT/NG negative, continued PrEP.***

Experiences with EPT

Women expressed disappointment, feelings of shame, and perceived stigma following a positive STI result. Some feared their partner's responses to their positive test, while others felt they had been betrayed by their partners. All women testing positive were offered and accepted directly observed therapy and EPT; however, most were anxious regarding delivering EPT to partners.

"I felt bad because I didn't expect that I shall have an STI. I didn't understand where it came from, was it an infection from my husband or... It worried me. He was also not comfortable and asked me what was the cause. The challenge that I had was convincing him to take the drugs…" – ***Age 20, CT/NG positive, continued PrEP****.*

"I hated myself, I asked myself so many questions. I wondered where the STI could have come from, because if someone found out you have the STIs [perceived stigma]… I thought of such things." ***– Age 27, CT/NG positive, continued PrEP.***

"I was scared because I was asking myself if I go with these drugs, how will I tell him for him to also agree and take, so I feared. He just asked me, 'how did you contract it [STI]?' and I told him I am the one who is supposed to ask you." – ***Age 22, CT/NG positive, discontinued PrEP.***

While women recognized the importance of treating their sexual partners before the resumption of sex to prevent re-infection, some encountered challenges in relaying the test results and dispensing EPT, often employing a variety of options such as persuasive language, deception or confrontational language to induce uptake and completion of EPT.

> *"… I told him that since I am pregnant and we can still be intimate, I don't want to affect my baby in case he or I have other partners. I took the first drug in his presence, and he also did so."* – ***Age 20, CT/NG positive, continued PrEP****.*

Recommendations for improving STI testing user experience and EPT

Some women were uncomfortable with sample collection, citing a lack of prior experience and fear of inserting the swab into the vagina. However, following support from a provider, they successfully collected the sample.

> *"I was not comfortable because it involved insertion of items in the vagina. I had no prior experience with it and feared a little bit."* – ***Age 27, CT/NG positive, continued PrEP.***

> *"For me, I don't like things associated with inserting objects in my vagina. But it was not painful."* – ***Age 19, CT/NG negative, continued PrEP.***

Several women suggested provider-assisted services, including guided sample collection instructions or providers collecting samples for those fearful or unable to collect samples. Satisfaction was high among women who used private rooms for sample collection, while those using facility toilets had mixed reactions, some citing concerns about privacy, cleanliness, and long queues.

"I can say it's better you collect the sample by yourself so that you can learn, like next time when you go back again, the nurse will not have a lot of work, so it's you who will do for yourself." ***Age 22, CT/NG positive, discontinued PrEP.***

Most women agreed that routine STI testing should be 'opt-out', similar to routinized HIV testing in antenatal care. Testing all women was encouraged since some women might be fearful to request a test, and others might lack symptoms. While some women were comfortable with testing at enrollment and after delivery, some suggested more frequent testing would be beneficial to ensure treatment before complications ensue.

"They should perform [STI testing] for all women who are pregnant. Even after delivery, testing should... continue. They should make [testing] mandatory so that everyone knows their status. They should copy the way they always do for HIV testing. When you come to the facility, they direct you to the screening room where they collect our samples, if they can copy that." – ***Age 31, CT/NG positive, continued PrEP.***

"It is important that all women get tested because when pregnant, there is an increase in vaginal discharge, and [you] cannot tell the cause… if you are infected, you will spread it to others. Frequently testing will allow me to find out about my status before it gets worse. …One improvement would be frequent testing, we should be tested after every month." – ***Age 32, CT/NG negative, discontinued PrEP***

In contrast, a few suggested that women should be asked before testing and that the test should only be given to those who accept. Some women were not aware of the STI testing services until they were offered the test as part of the study activities and recommended health education to all

women seeking routine services within the clinic. Some women suggested the provision of free treatment services as a motivation for routine screening.

> *"…one might turn positive for STI but don't have money to treat it. They [hospitals] should offer [free] treatment to motivate us to get tested. During physical clinic visits, they [providers] should create time to offer health education in a group, not only individually."* – ***Age 32, CT/NG negative, discontinued PrEP***

> *"…when sensitizing people on STI, … consider that some people are shy and will not accept testing. Some don't know how to collect the sample but wish to be tested. But if you sensitize them well, they will accept even if it is the nurse collecting samples."* – ***Age 23, CT/NG negative, continued PrEP.***

DISCUSSION

This qualitative study evaluated women's experiences with CT/NG testing within antenatal clinics delivering PrEP and the impact of CT/NG testing on PrEP use. Factors that motivated testing included perceived vulnerabilities to STIs and benefits of testing, similar to studies on screening for other conditions (e.g., diabetes, hypertension, and breast cancer). [120-122] These findings underscore the importance of educating pregnant women on the risks of STIs and benefits of screening to promote STI testing uptake, highlighting an opportunity for antenatal education. Positive interactions with providers and availability of STI treatment also motivated STI testing. STI testing refined risk assessment and encouraged PrEP use, even when STI results were negative. Our results complement prior pilot evaluations which found high acceptability of antenatal STI testing assessed quantitatively by adding qualitative perspectives from end-users

and identifying opportunities for strengthening co-delivery of STI and HIV prevention services for pregnant women. [45, 110, 111]

In our study, STI testing encouraged health-promoting behaviors, including sustained PrEP use, even when STI results were negative, as testing made women feel proactively involved in preventing HIV/STI complications for themselves and their infants. Moreover, women in polygamous marriages and those who had multiple partners (or partners with multiple partners) remained motivated to continue PrEP as a means of protection, even after negative STI results. For those who tested positive, STI testing confirmed self-perceived risk and further motivated PrEP use. Relationship dynamics and power imbalances may lead to an inability to negotiate safer sex practices, thus influencing perceived risk and utilization of HIV/STI prevention strategies that are within one's reach and control. [56, 123, 124] Serial STI testing during periods of PrEP use could allow women to re-evaluate and/or recognize their risks to proactively make informed decisions about STI/HIV prevention. [125] Studies among pregnant women in South Africa and Kenya suggest STIs are common during pregnancy, and STI diagnosis motivates PrEP initiation. [110, 112, 126] For instance, recent findings among pregnant women not living with HIV in South Africa found that having an STI diagnosis and/or symptoms was associated with higher proportions initiating oral PrEP compared to lack of an STI diagnosis or symptoms. [65, 112] These findings indicate that STI testing may influence PrEP use in pregnancy. Yet, there is paucity of data on serial STI testing in pregnancy through the postpartum period to promote sustained PrEP use. Future studies are needed to examine if serial STI testing promotes consistent PrEP use through pregnancy and postpartum.

Positive interactions with providers, receipt of comprehensive STI education, and availability of STI services, including immediate treatment and EPT, all promoted STI testing in our study. Providers play a pivotal role in the uptake of new STI services or strategies since they are the

main contact with patients. [111, 127, 128] Social norms reinforcing stigma, discrimination, or perceived hostility from providers associated with being diagnosed with STIs may lead some women to avoid testing services, thus limiting uptake. [31, 97] Creating safe spaces can empower patients to prioritize their health and uptake STI testing and other reproductive health interventions. [111, 127, 128] Prior studies demonstrate the effectiveness of incorporating informed decision-making in disease management. [129] In our study, women knew the risks associated with STIs in pregnancy, but fewer were aware of strategies to address STIs, including diagnostic testing. Health education to increase awareness of STI complications and management in pregnancy may facilitate informed decision-making on utilization of STI services among antenatal care attendees. Increasing availability of STI testing within antenatal care, coupled with immediate treatment and offer of EPT, would also facilitate addressing STI burden in this population. To date, cost greatly limits availability of empiric STI testing services beyond HIV and syphilis. Low-cost point-of-care diagnostics for other STIs are urgently needed to scale up availability of STI testing in antenatal care.

Routinizing STI testing as ‘opt-out’ could increase coverage and potentially address the stigma attached to the current standalone STI services delivery approach. [31] ‘Opt-out’ testing is a CDC recommendation for HIV testing that presumes an individual has consented unless they explicitly decline and is often used in regions of high HIV burden. [130] Studies in Kenya consistently show universal ‘opt-out’ testing is acceptable and increases HIV testing. [131, 132] The WHO recommends incorporating STI services alongside other routine health services to reduce cost, increase access and uptake. [100] Integrating point-of-care STI testing into antenatal care settings has the potential for rapid turnaround time and ensure same-day treatment of both women and their sexual partners, thus disrupting the cycle of reinfections. [32, 35, 133]

Limitations

The parent study enrolled pregnant women with high HIV risk scores who initiated PrEP within routine ANC, who may experience STI testing differently compared to general populations of pregnant women or those who decline PrEP. Our sample did not include women who initiated PrEP in settings outside of antenatal clinics, though >80% of women in Kenya attend public antenatal clinics. [134] A dedicated team of nurses and laboratory technicians provided health education and guided the sample collection process. We did not conduct any IDIs to assess baseline STI knowledge before testing; therefore, unable to disentangle prior knowledge from that gained during the study. Service provision by the study staff may be different from routine staff in the public clinics. Additionally, women were not purposively selected based on STI results; therefore, our ability to synthesize perspectives on STI positivity and EPT was limited.

Conclusion

Our qualitative evaluation found that STI testing is highly acceptable when co-delivered with PrEP for pregnant women. Factors that motivated STI testing among women who initiated PrEP in pregnancy included positive interactions with providers, receipt of STI education that reinforced benefits of testing, and availability of STI treatment and EPT. Additionally, STI testing encouraged PrEP use, even when STI results were negative. Incorporating STI testing into PrEP delivery in antenatal care represents a potential ‘high yield’ opportunity for addressing HIV/STI in pregnancy.

Figure 2. Key themes based on the Health Belief Model, adapted from Rosenstoch Becker Maimann 1974

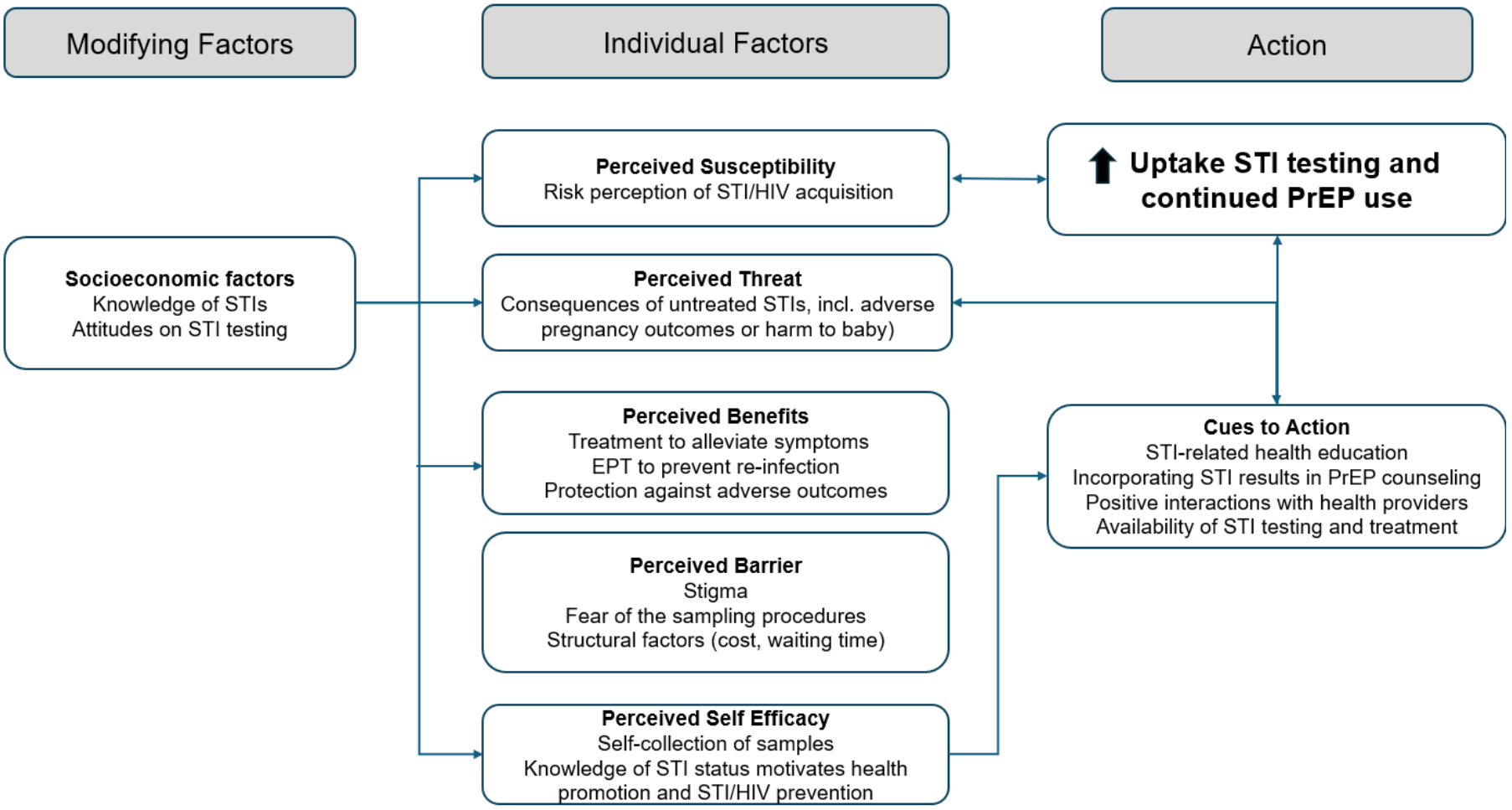


Table 9. Characteristics of participants who initiated PrEP during pregnancy, tested for CT/NG, and participated in in-depth interviews (n=39)

	n	n (%) or median (IQR)
Demographic characteristics		
Age (years)	39	26 (21-29)
Highest level of education (years)	39	12 (10-13)
Employed (vs unemployed)	39	6 (15%)
Relationship characteristics		
Currently in a relationship	39	38 (97%)
Marital status	39	
Married /co-habiting		28 (72%)
Single/ non-cohabiting		11 (28%)
Marriage type polygamous (vs monogamous)		4 (14%)
Partner characteristics		
Partner age difference ≥ 5 years (vs <5 years)	32	13 (41%)
Partner HIV status	39	
HIV negative		5 (14%)
Unknown status		34 (86%)
Clinical characteristics		
Positive CT and/or NG test	39	6 (15%)
Partner accepted EPT[1]	6	6 (100%)
PrEP status at 9 months postpartum	39	
Continued		32 (82%)
Discontinued		7 (18%)
Risk assessment characteristics		
Empiric HIV risk score [2]	39	9 (8-9)
Number of lifetime sexual partners	39	3 (2-3)
Partner has other sexual partners [3]	38	11 (29%)

[1] Among those testing positive and accepting EPT (n=6).
[2] Empiric HIV risk assessment to predict HIV incidence in pregnancy and postpartum (HIV risk score ≥ 6 (translating to HIV incidence 7.3 per 100 person-years). EPT- Expedited partner therapy.
[3] Among those in a relationship (n=38)

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