

## OBSTETRICS

## Use of HIV pre-exposure prophylaxis during the preconception, antepartum and postpartum periods at two United States medical centers

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**BACKGROUND:** Pregnancy may increase a woman's susceptibility to HIV. Maternal HIV acquisition during pregnancy and lactation is associated with increased perinatal and lactational HIV transmission. There are no published reports of preexposure prophylaxis use after the first trimester of pregnancy or during lactation.

**OBJECTIVE:** The purpose of this study was to report the use of pre-exposure prophylaxis and to identify gaps in HIV prevention services for women who were at substantial risk of HIV preconception and during pregnancy and lactation at 2 United States medical centers.

**STUDY DESIGN:** Chart review was performed on women who were identified as "at significant risk" for HIV acquisition preconception (women desiring pregnancy) and during pregnancy and lactation at 2 medical centers in San Francisco and New York from 2010-2015. Women were referred to specialty clinics for women who were living with or were at substantial risk of HIV.

**RESULTS:** Twenty-seven women who were identified had a median age of 27 years. One-half of the women had unstable housing, 22% of the women had ongoing intimate partner violence, and 22% of the women had active substance use. Twenty-six women had a male partner living with HIV, and 1 woman had a male partner who had sex with men. Of the partners who were living with HIV, 73% (19/26) were receiving antiretroviral therapy, and 42% (11/26) had documented viral suppression. Thirty-nine percent (10/26) of partners had known detectable virus, and 19% (5/26) had unknown viral loads. Women were identified by clinicians, health educators, and health departments. Approximately one-third of the women were identified preconception (8/27); the majority of the women were identified during pregnancy (18/27) with a median gestational age of 20 weeks (interquartile range, 11–23), and 1 woman was identified in the postpartum period. None of the pregnant referrals had received safer

conception counseling to reduce HIV transmission. Twenty-six percent of all women (7/27) were eligible for postexposure prophylaxis at referral, of whom 57% (4/7) were offered postexposure prophylaxis. In 30% (8/27), the last HIV exposure was not assessed and postexposure prophylaxis was not offered. The median time from identification as "at substantial risk" to consultation was 30 days (interquartile range, 2–62). Two women were lost to follow up before consultation. One woman who was identified as "at significant risk" was not referred because of multiple pregnancy complications. She remained in obstetrics care and was HIV-negative at delivery but was lost to follow up until 10 months after delivery when she was diagnosed with HIV. No other seroconversions were identified. Of referrals who presented and were offered preexposure prophylaxis, 67% women (16/24) chose to take it, which was relatively consistent whether the women were preconception (5/8), pregnant (10/15), or after delivery (1/1). Median length of time on preexposure prophylaxis was 30 weeks (interquartile range, 20–53). One-half of women (10/20) who were in care at delivery did not attend a postpartum visit.

**CONCLUSION:** Women at 2 United States centers frequently chose to use preexposure prophylaxis for HIV prevention when it was offered preconception and during pregnancy and lactation. Further research and education are needed to close critical gaps in screening for women who are at risk of HIV for pre- and postexposure prophylaxis eligibility and gaps in care linkage before and during pregnancy and lactation. Postpartum women are particularly vulnerable to loss-to-follow-up and miss opportunities for safe and effective HIV prevention.

**Key words:** HIV prevention, lactation, postexposure prophylaxis, preconception, preexposure prophylaxis, pregnancy, transmission, safer conception

The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend offering oral preexposure prophylaxis for HIV prevention to individuals at substantial risk.<sup>1,2</sup> In 2015, the

WHO published meta-analysis data that demonstrated that oral preexposure prophylaxis (compared with placebo) effectively reduces HIV acquisition in women with a risk ratio of 0.57 (95% confidence interval, 0.34–0.94).<sup>1</sup> The same year, the CDC estimated 468,000 women in the United States were eligible for HIV pre-exposure prophylaxis, which was defined by having condomless sex in the previous 6 months with a man living with HIV, a man who has had sex with men, or a man who use intravenous drugs.<sup>3</sup>

Observational studies suggest women may have increased susceptibility to HIV during pregnancy. A meta-analysis of 5

studies found an increased, but not statistically significant, odds ratio of HIV acquisition during pregnancy (odds ratio, 1.3; 95% confidence interval, 0.5–2.1).<sup>4</sup> Biologic plausibility for increased HIV susceptibility during pregnancy has also been suggested.<sup>5</sup>

The effect of HIV acquisition during pregnancy and lactation on perinatal and lactational transmission is profound. One study demonstrated a 15-fold increased risk of perinatal transmission in the setting of HIV acquisition during pregnancy when compared with women with chronic, treated HIV (adjusted odds ratio, 15.2; 95% confidence interval,

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4.0–56.3).<sup>6</sup> When HIV is acquired during lactation, a 4-fold increase in lactational transmission has been reported, when compared with women with chronic untreated HIV.<sup>7</sup> Acute HIV occurred in 8% of US perinatal transmissions from 2005–2010.<sup>8</sup>

In the setting of potentially increased HIV susceptibility during pregnancy and well-documented increased perinatal and lactational transmission with HIV acquisition during pregnancy or lactation, HIV prevention in and around pregnancy is paramount to caring for women and eliminating perinatal and lactational transmission. HIV prevention methods include condoms, treatment of partners with HIV as prevention, postexposure prophylaxis, preexposure prophylaxis, and treatment of sexually transmitted infections (STIs). For conception, timed intercourse and assisted reproduction provide additional options. Although treatment as prevention is likely the most efficacious,<sup>9</sup> partner-dependent methods are not feasible or desirable for many women. As the only woman-controlled, discrete method to be taken in advance of exposure, preexposure prophylaxis provides a critical option for women.

In the only published studies that included women who incidentally became pregnant while receiving preexposure prophylaxis, drugs were stopped in the first trimester; no differences in pregnancy outcomes and postnatal growth were detected.<sup>10,11</sup> The Antiretroviral Pregnancy Registry contains enough data on tenofovir and emtricitabine, which are the drugs recommended for preexposure prophylaxis (co-formulated as Truvada), to detect a 1.5-fold increase in anomalies with first-trimester exposures, but no such increase has been found.<sup>12</sup> Supported by multiple studies that suggest safety in pregnancy,<sup>13–17</sup> national guidelines recommend tenofovir/emtricitabine as first-line agents for pregnant women with HIV and tenofovir for pregnant women with hepatitis B.<sup>18,19</sup> Data are very limited on lactational use, but pharmacokinetic studies suggest that infant exposure is lower through breast milk than in utero.<sup>20</sup>

The WHO and CDC suggest offering preexposure prophylaxis use during pregnancy and lactation with discussion of risks and benefits.<sup>1,2</sup> The American College of Obstetricians and Gynecologists' committee opinion on preexposure prophylaxis states tenofovir/emtricitabine has a “reassuring” safety profile in pregnancy and suggests clinicians be “vigilant” for HIV seroconversion during lactation.<sup>21</sup> However, we are unaware of published data on the use of preexposure prophylaxis during pregnancy and lactation. This study reports usage of preexposure prophylaxis and identifies gaps in referrals and services for HIV prevention among women who are at substantial risk of HIV preconception and during pregnancy and lactation at 2 US medical centers from 2010–2015.

## Methods

Two clinicians who were experienced with the provision of preexposure prophylaxis performed retrospective chart reviews at 2 academic medical centers in San Francisco, CA, and the Bronx, NY. All women identified to be at substantial risk of HIV preconception (including only women desiring to conceive), during pregnancy, or during the postpartum period (up to 1 year after delivery or the duration of lactation) and who were referred to specialty clinics for women living with or at substantial risk of HIV were included. If women had repeat pregnancies during the study period, earlier pregnancies were analyzed separately. One clinic was co-located in an obstetrics clinic, and 1 clinic was in an infectious disease clinic. Services at both clinics included multidisciplinary teams with intensive case management. Both offered full-spectrum safer conception counseling and HIV prevention options during pregnancy and lactation. If a woman took pre- or postexposure prophylaxis, both clinics generally followed CDC toxicity monitoring guidelines.<sup>2</sup>

Chart extraction included details of the referral process, demographics, medical and social histories, HIV risk factors, pregnancy and postpartum data, HIV prevention methods that had been used, HIV testing, infant outcomes, and partners' HIV status (when available). In

2008, the CDC recommended offering postexposure prophylaxis within 72 hours to all individuals, including pregnant and breastfeeding women, who had condomless sex with a person living with HIV<sup>22</sup>; women's eligibility for and use of postexposure prophylaxis according to CDC criteria was also obtained. Descriptive statistics were performed. Univariate logistic regression was used to assess for association between demographic variables and assessment of postexposure prophylaxis eligibility and use of preexposure prophylaxis, respectively.

Chart review was also performed on records of women who were referred but did not attend the consultation or who had delayed referrals. Additional extracted data included circumstances under which women were identified and referred to identify missed opportunities to offer HIV prevention. Before data collection, the University of California San Francisco and Bronx Lebanon Hospital Center institutional review boards approved the study.

## Results

Twenty-seven women were identified. The median age was 27 years old; 19% of the women were black, and 44% were Hispanic. Over one-half of the women had unstable housing (52%); 22% of the women actively used substances, and 22% of them had ongoing intimate partner violence (Table). Women were identified as at substantial risk of HIV by obstetricians (n=8), midwives (n=2), primary care providers (n=8), emergency department providers (n=1), male partners' physicians (n=2), health educators (n=3), and health departments (n=3). The most common HIV risk factor was having a male partner living with HIV (26/27 women); 1 woman had a male partner with unknown HIV status who had sex with men. Notably, 15% of women (4/27) were identified when asked about their partners' HIV risk factors in the setting of syphilis diagnoses in themselves or their male partners. Of the male partners known to be living with HIV, 73% of them were undergoing antiretroviral therapy (19/26); 42% of them had

**TABLE**  
**Demographics of women identified as at substantial risk of HIV in and around pregnancy (n = 27)**

Variable	Data
Median age, y (range)	27 (18–43)
Median parity, n (range)	1 (0–4)
Race, n (%)	
Black	5 (19)
White	4 (15)
Latino	12 (44)
Asian	2 (7)
Other	4 (15)
Graduated high school, n (%)	9 (33)
Unstable housing or homeless, n (%)	14 (52)
Current intimate partner violence, n (%)	6 (22)
Current substance use, n (%)	6 (22)
History of mental health disorder, n (%)	12 (44)

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documented viral suppression (11/26); 39% of them had detectable viral loads (10/26), and 19% of them had unknown viral loads (5/26; [Figure 1](#)).

Less than one-third of women (8/27) were identified preconception, with the majority identified during pregnancy (18/27) and 1 during the postpartum period. Median time from identification to consultation was 30 days (interquartile range, 2–62). Two women were lost to follow up between identification and consultation. Of the women who were identified before conception, 1 had been referred previously for safer conception counseling to a high-risk obstetrician. Of the women who were identified during pregnancy, none reported preconception or safer conception counseling. The median gestational age at consultation among pregnant women was 20 weeks (interquartile range, 11–23).

At initial presentation, two-thirds of the records (19/27 women) documented

the assessment of postexposure prophylaxis eligibility (HIV exposure within 72 hours). No association was identified between race, age, pregnancy status, or gestational age and assessment of postexposure prophylaxis eligibility (all  $P > .1$ ). Of the 19 women whose records were assessed for postexposure prophylaxis eligibility, 37% were eligible; 57% of those were offered prophylaxis, and 50% of those chose to take postexposure prophylaxis ([Figure 2](#)).

Two-thirds of the women (16/24) who were offered preexposure prophylaxis chose to use it. This proportion was relatively consistent whether women were preconception (5/8), pregnant (10/15), or postpartum (1/1). Choosing to take preexposure prophylaxis was not associated with age, race, pregnancy status, or gestational age (all  $P > .1$ ). The median time on preexposure prophylaxis was 30 weeks (range, 4–74 weeks). One-half of the 16 women experienced adherence challenges (8/16), which included nausea and fatigue (2/8), social stressors (3/8), and difficulty adhering to a daily pill (3/8). From limited available postpartum data, no pregnancy complications or adverse infant outcomes were identified related to pre- or postexposure prophylaxis.

Approximately 40% of women chose to stop preexposure prophylaxis after conception (1/16) or delivery (6/16). Main reasons for stopping preexposure prophylaxis were not wanting to use it while breastfeeding (n=2), side-effects (n=1), adherence challenges (n=2), changes in insurance/cost (n=2), and attaining pregnancy after preexposure prophylaxis use for safer conception (n=1; [Figure 3](#)). Some women had multiple reasons for stopping preexposure prophylaxis.

All women who were offered preexposure prophylaxis were also counseled regarding other HIV prevention methods. Eight women chose not to use preexposure prophylaxis: 5 women reported condom use; 5 women considered their partner's HIV treatment adequate prevention, and 2 women reported planning on abstinence during pregnancy and lactation. Of the women who were planning to use treatment

exclusively as prevention, all had partners with documented viral suppression. Women who chose not to use preexposure prophylaxis had uncomplicated pregnancies and remained HIV-free through delivery.

One-half of the women (10/20) in care at delivery did not attend a postpartum visit, despite significant outreach. At delivery, 7 women planned to continue preexposure prophylaxis, 4 of whom planned to breastfeed. Of the 11 women who planned to not use preexposure prophylaxis after delivery, 8 women planned to breastfeed. [Figure 3](#) presents available information about each woman's decisions regarding preexposure prophylaxis before conception, during pregnancy, and after delivery and lactation status.

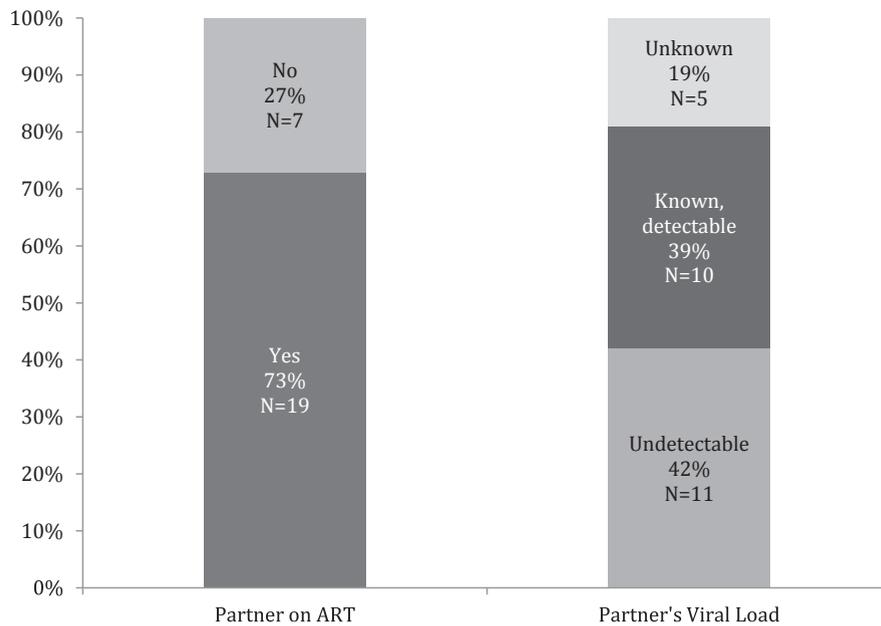
In the postpartum period, most women who used contraception chose 1 that could be initiated in the hospital (20% (4/20) chose depo medroxyprogesterone acetate; 15% (3/20) chose postpartum tubal ligation; 10% (2/20) chose condoms). Thirty percent of the women (6/20) received an interval postpartum intrauterine device, and 40% of the women (5/20) had no documented postpartum contraception plan.

Three women had repeat pregnancies during the study period. All were identified and offered preexposure prophylaxis during their first pregnancies; 2 women chose to use it and discontinued during the postpartum period. These women's subsequent pregnancies were unplanned but continued. Both women used preexposure prophylaxis again during pregnancy. The woman who planned a repeat pregnancy was counseled before conception and used treatment as prevention, as she had in her first pregnancy.

Three women were not offered preexposure prophylaxis. Two interacted with clinicians only in the emergency department or obstetrics triage where both disclosed their partners' status. Neither was counseled about pre- or postexposure prophylaxis, and both were lost to follow up before consultation. One woman subsequently was diagnosed with HIV.

Her story highlights missed opportunities: A woman sought care at 30 weeks

**FIGURE 1**  
Partner's treatment status and viral load (n = 26)



Twenty-six women reported having partners living with HIV, of whom 27% were not on antiretroviral therapy and 58% had known detectable or unknown viral loads.

ART, antiretroviral therapy.

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of gestation and was diagnosed with significant fetal anomalies. At this visit, she disclosed that her partner was living with HIV; this information was listed in

her medical record. Although her partner received care in the same institution, a release of information was never obtained, and his viral load was never documented. She attended all antenatal appointments including multiple specialty referrals and biweekly antenatal testing. Her obstetrician performed frequent HIV testing but never discussed pre- or postexposure prophylaxis or referred her for consultation. At delivery, maternal viral load was undetectable. Her infant died immediately after delivery because of anomalies, and the patient was lost to follow up. She was represented to care 10 months after delivery when she was diagnosed with HIV. She then attended the same clinic where she would have been cared for during pregnancy had she been referred originally.

### Comment

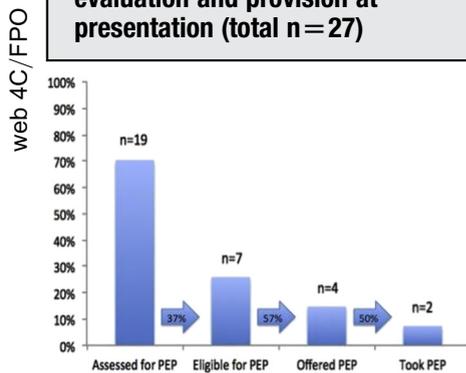
Women at 2 US medical centers frequently chose to use preexposure prophylaxis for HIV prevention when offered in and around pregnancy. Women's choices around preexposure

prophylaxis use changed before conception and during pregnancy and lactation, which highlights the importance of regularly assessing HIV vulnerabilities, offering a variety of HIV prevention options, and eliciting women's preferences around HIV prevention strategies.<sup>23,24</sup> No women seroconverted who were offered preexposure prophylaxis in this study. One woman who self-identified as at substantial risk of HIV was not offered pre- or postexposure prophylaxis and was diagnosed with HIV within 10 months of being under intensive obstetrics care. Her case highlights the importance of offering comprehensive HIV prevention services to women who are most vulnerable to HIV, including in and around pregnancy, which is the only time some women access care.

Limitations of this study include its being a retrospective review from 2 centers with long-standing interdisciplinary obstetrics and HIV clinics. Data were obtained solely from medical records, some of which may incompletely reflect nuanced conversations about HIV vulnerability and prevention. Furthermore, practice patterns changed over time, as data on preexposure prophylaxis in women emerged and normative guidance developed. Critically, records were reviewed only of women who were identified as at substantial risk of HIV who were referred to specialty clinics. Although it is unlikely that other pregnant or lactating women received preexposure prophylaxis within these centers, it is highly likely that there were other women at substantial risk of HIV who were not referred to care who managed their vulnerability in a variety of ways, with and without their providers' knowledge. Consequently, this study provides a very specific review of women who knew and disclosed their HIV vulnerability to someone in the health care system who then informed a specialty clinic about the woman and her pregnancy status.

The CDC recommends offering preexposure prophylaxis to women who recently had condomless sex with a man at substantial risk of HIV.<sup>2</sup> Challenging the feasibility of this screening approach, 1 study in San Francisco demonstrated

**FIGURE 2**  
Postexposure prophylaxis evaluation and provision at presentation (total n = 27)



Among 27 women, 19 were assessed for postexposure prophylaxis eligibility, of whom 37% were eligible. Of these women, 57% were offered prophylaxis, and 50% of those offered to chose to take postexposure prophylaxis.

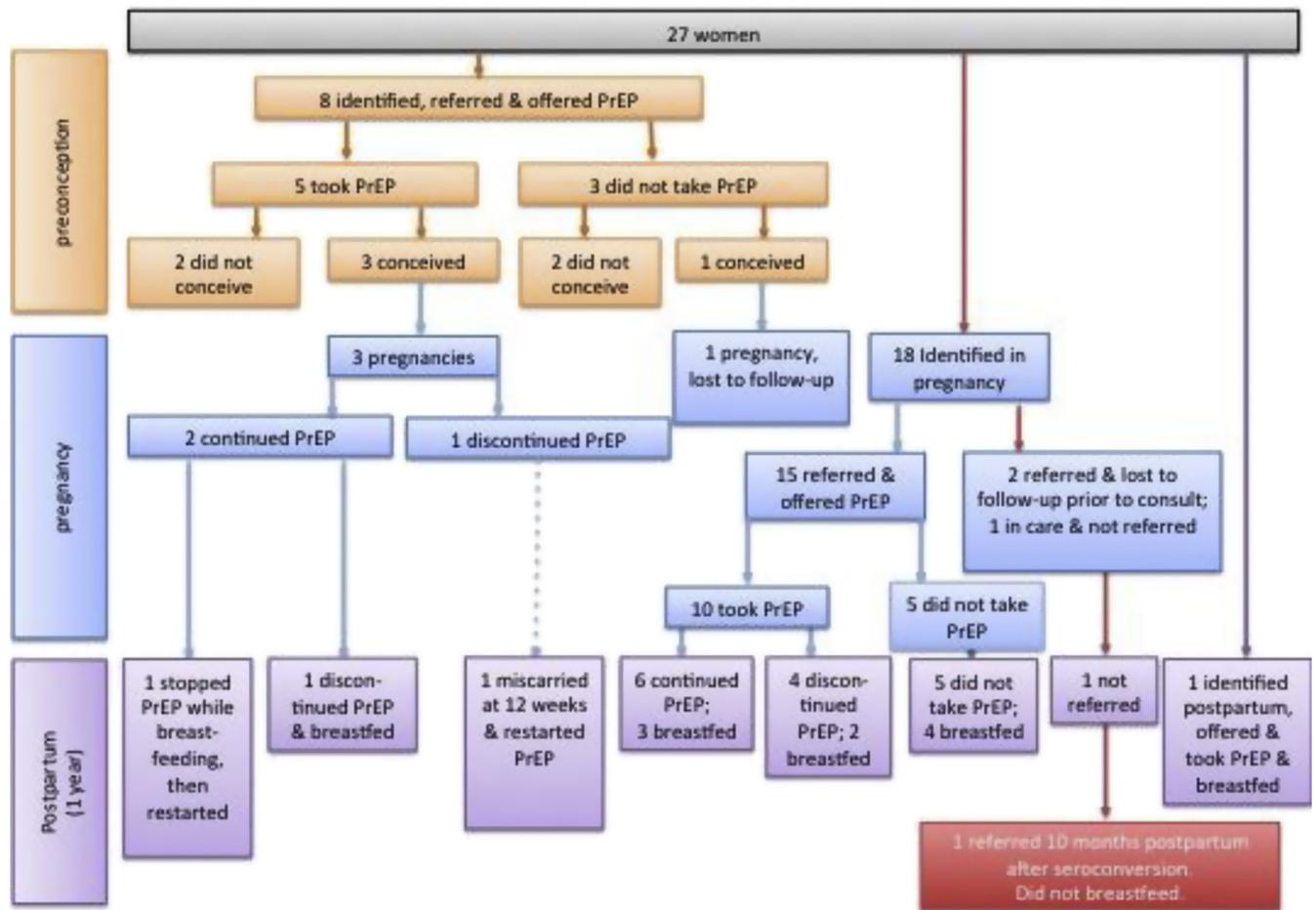
PEP, postexposure prophylaxis for HIV prevention.

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FIGURE 3

Women identified as “at substantial risk” of HIV acquisition preconception, during pregnancy, and after delivery at 2 medical centers in the United States

web 4C/FPO



Twenty-seven women were identified as at substantial risk of HIV; 8 were identified prior to conception, 18 were identified during pregnancy, and 1 was identified postpartum. Of the 24 women who were offered pre-exposure prophylaxis, 16 (67%) chose to take it. Choices around pre-exposure prophylaxis use changed over the course of preconception, pregnancy and postpartum periods. One seroconversion was identified in the study; this woman was not offered pre-exposure prophylaxis.

PrEP, preexposure prophylaxis.

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that women infrequently know the risk profiles of their partners.<sup>25</sup> Nevertheless, our study highlights several potential screening techniques. First, women presenting for preconception, pregnancy or postpartum care can be asked, “Are any of your male sexual partners living with HIV?” Affirmative responses initiate a review of comprehensive HIV prevention options that include pre- and postexposure prophylaxis and rapid referral, if comprehensive services are not available on-site. When an HIV test is ordered on a preconception, pregnant, or postpartum patient, she could also be

asked about her partner(s)’ risk factors and offered education materials about preexposure prophylaxis. One of the clinical sites in this study included this line of questioning in their electronic record during the study period, in conjunction with an immediate referral for those who answered affirmatively. Women who were unsure of their partner(s)’ status were given information about where to obtain partner testing. Although further implementation research is needed, this study supports the practice of screening women in and around pregnancy for vulnerabilities to

HIV and offering HIV prevention education and methods whenever and wherever they contact the health care system.

STI, and particularly syphilis, screening provides an additional opportunity for comprehensive HIV prevention education: 1 in 6 women in this study were identified as at substantial risk of HIV through a syphilis diagnosis. STI screening is already part of routine obstetrics care; any positive result should prompt a review of vulnerabilities to HIV and the offer of comprehensive HIV prevention strategies. A study of women

in Florida demonstrated that those with a history of syphilis had 20 times the HIV incidence rate and that those with a history of gonorrhea had 6 times the HIV incidence rate when compared with women without a history of STIs<sup>26</sup>; diagnosis of an STI provides an important opportunity to identify women who are vulnerable to HIV.

This study also highlights missed opportunities for safer conception counseling—techniques to prevent HIV acquisition while attempting conception. No women in this study who were identified as at substantial risk of HIV during pregnancy had received safer conception counseling. Not only does HIV risk screening need to be integrated into obstetrics care, but pregnancy intentions must be elicited and integrated into HIV risk assessments outside of pregnancy to educate women about safer conception methods.<sup>23</sup> Two women had unplanned, but desired, repeat pregnancies, which highlights the importance of both contraception and safer conception counseling during pregnancy and after delivery. Moreover, men who are living with HIV should be asked about reproductive intentions with referrals for partners to testing and counseling regarding HIV prevention options, family planning, or safer conception.

Multiple additional missed opportunities were found: women were identified but not referred, women were lost to follow up before presentation to a specialty clinic for counseling, and women were not offered comprehensive HIV prevention methods. These gaps highlight the importance of training providers across the health care system to offer time-sensitive, comprehensive counseling and prevention options. In particular, women presenting to emergency rooms or obstetrics triage provide opportunities to engage them in care and review comprehensive HIV prevention services. Although same-day initiation of preexposure prophylaxis may not be feasible, postexposure prophylaxis (for eligible patients) should be. This simple and effective intervention prevents HIV acquisition and may facilitate a woman's entrance into regular care. Although

preexposure prophylaxis in the form of a daily pill that is highly dependent on adherence for effectiveness may not be feasible for all women, all women deserve, at a minimum, to learn about this important prevention option.

Identifying and caring for women at substantial risk of HIV requires nuanced conversations about risks and benefits of each HIV prevention option and allowing room for a woman's vulnerabilities and preferences to change over time.<sup>23</sup> Although the counseling may be complicated, the medical care is straightforward: the CDC published simple guidelines for toxicity and STI screening.<sup>2</sup> Consequently, although this study focuses on specialty clinic care, much of the effort in these cases focused on social stressors and adherence support, which are services that can be provided by generalist practices.

As preexposure prophylaxis knowledge disseminates, key implementation questions remain regarding where women access HIV prevention services. Most likely, service provision will vary depending on local resources and HIV incidence. Research is needed on how to best provide support services and the frequency and timing of HIV testing in pregnancy and lactation among women who are vulnerable to HIV. Given women's complex social histories in this study, many of which are mirrored in women who are living with HIV, support services for women challenged by adherence may be modeled after multidisciplinary care for women living with HIV.

Finally, this study is consistent with obstetrics literature regarding frequent postpartum loss to follow up. For breastfeeding women, supporting retention in care is critical to prevent maternal HIV acquisition and lactational transmission. Moreover, much of the HIV prevention work in pregnancy is negated if support wanes after delivery and a woman is diagnosed with HIV in her next pregnancy. Therefore, it is critical to further understand not only how to best support women's retention in care during the postpartum period, but how to engage women in ongoing

care, supporting both their future pregnancies and long-term health. ■

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