

Optimizing Delivery of HIV Preexposure Prophylaxis for Women in the United States

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Abstract

Preexposure prophylaxis (PrEP) is a highly effective HIV prevention method; however, it is underutilized among women who are at risk for acquisition of HIV. Women comprise one in five HIV diagnoses in the United States, and significant racial disparities in new HIV diagnoses persist. The rate of new HIV diagnoses among black and African American women in 2015 was 16 times greater than that of white women. These disparities highlight the importance of HIV prevention strategies for women, including the use of PrEP. PrEP is the first highly effective HIV prevention method available to women that is entirely within their control. However, because so few women who may benefit from PrEP are aware of it, few women's healthcare providers offer PrEP to their patients, PrEP has not yet achieved its potential to reduce HIV infections in women. This article describes individual and systemic barriers for women related to the uptake of PrEP services; explains how providers can identify women at risk for HIV; reviews how to provide PrEP to women; and outlines client-centered models for HIV prevention services. Better access to culturally acceptable and affordable medical and social services may offer support to women for consistent and ongoing use of PrEP. This discussion may be used to inform HIV prevention activities for women and guide interventions to decrease racial/ethnic disparities in rates of HIV infection among US women.

Keywords: preexposure prophylaxis, HIV risk for women, HIV prevention for women, sexual health

Introduction

WOMEN COMPRISE ONE IN FIVE HIV diagnoses in the United States,¹ and significant racial disparities in new HIV diagnoses persist. In 2015, African and Caribbean and African American (black) women accounted for 61% of the 7,402 estimated HIV diagnoses among women; the rate of new HIV diagnosis among black women was 16 times as high of white women and 5 times as high as Hispanic women.² The proportion of black women with new HIV infections reveals a severe health disparity. Rates of new HIV infection among black women are largely attributed to heterosexual transmission, with 92% of black women acquiring HIV through

sex with a man compared with 68% for white women.² Geographically, of the 7,402 new infections diagnosed among women in 2015, 4,032 resided in the Southern region of the United States.² An estimated 22% of transgender women in the United States are living with HIV,³ and black transgender women are three times more likely than their white counterparts to have HIV.⁴ These elevated rates suggest that both the stigma of being transgender and structural racism that result in socioeconomic disparities may exacerbate HIV risk.⁴

Preexposure prophylaxis (PrEP) is a highly effective HIV prevention method for men and women; however, it is especially underutilized among women who are at risk for

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HIV. PrEP requires HIV-negative persons to take a daily pill containing two antiretroviral medications. The Food and Drug Administration (FDA) approved a PrEP indication for the fixed dose combination of tenofovir disoproxil fumarate 300 mg–emtricitabine 200 mg (TDF-FTC) in 2012⁵ and the US Public Health Service released PrEP clinical guidelines in 2014.⁶ As an individual-controlled prevention method, PrEP offers an effective, safe, and private option for women to reduce their risk of HIV acquisition.

In 2015, the US Centers for Disease Control and Prevention (CDC) estimated that 468,000 women in the United States were at significant risk of acquiring HIV⁷ and may benefit from PrEP. Identification of women who may be exposed to HIV by healthcare systems and individual providers, followed by the provision of PrEP services, is a key public health intervention that has the potential to reduce new HIV infections and reduce the racial and gender disparities in new HIV transmissions. However, data collected from 82% of US pharmacies between January 1, 2013 and March 31, 2016 demonstrated women accounted for 14% of PrEP prescriptions, and of these, only 17% were African American. In addition, one-third of all new PrEP prescriptions were dispensed in the Northeast region, suggesting a need for growth in other regions with high incidence of HIV among women such as southern states.⁸ This article is a review of literature related to PrEP, including individual and systemic barriers for women related to the uptake of PrEP services. We review how providers can assess women's risk for HIV acquisition; describe how to provide PrEP to women; and review a client-centered approach to HIV prevention care.

Materials and Methods

We reviewed a previously completed systematic collection of PrEP literature published from January 2010 through June 2017 to identify those publications related to women. Searches were conducted of MEDLINE, Embase, CINAHL, and Cochrane Library databases. The search strategy used the following criteria in the title, abstract, keyword heading word, subject heading fields: Pre-Exposure Prophylaxis/OR Chemoprevention/OR PrEP OR [topical adjacent to (prevention OR prophylaxis OR microbicide* OR gel OR pericoital OR precoital OR vaginal OR rectal OR anal)] OR chemoprophylaxis AND (exploded terms) Anti-HIV Agents/OR Anti-Retroviral Agents/OR HIV Infections/pc OR {[HIV OR human immunodeficiency virus] AND [antiretroviral* OR anti-retroviral* OR antiretrovirus* OR anti-retrovirus* OR Truvada OR tenofovir OR emtricitabine OR (TDF ADJ5 FTC)]} AND NOT animals.

Two scientists at the CDC independently reviewed the citations and removed those that were not published in English, did not contain data (e.g., editorials, reviews, news reports), or did not contain data about oral TDF/FTC for PrEP. The next step was to screen citations to remove those that did not contain new data about oral PrEP (data/analyses not previously published). Abstracts or full articles were then read, and publications were categorized into the groups listed above. The coding by the two reviewers was then compared and discrepancies were reconciled. Citations with no new data about daily oral PrEP with TDF/FTC were deleted from the updated reference file. The authors of this article received a copy of the reference file and then reviewed the citations for

those addressing risk of HIV and sexually transmitted infections (STIs) specifically for women.

Results

Individual and systemic barriers for the uptake of PrEP services for women

US women have limited knowledge of PrEP, creating a major barrier for self-referral to PrEP services. However, once informed, women express a willingness to use PrEP, and African American women are more likely than white women to consider its use.⁹ Factors that have been shown to influence women's decision-making about the use of PrEP are the following: cost, peer perspectives, having a woman-controlled prevention strategy, physician input, and ease of accessing services and medication near to their homes.^{10–13} Women express concern that medical providers who are unaware of the guidelines for PrEP use in women will be less willing to offer and prescribe PrEP.¹³

A major barrier to PrEP uptake by women is the lack of perception of risk for HIV acquisition.¹⁴ Black women, for example, who may not perceive themselves at risk for HIV have a higher probability of exposure to HIV, despite practicing the same sexual behavior (condom use, number of partners) as other women.¹⁵ Being in a sexual network with higher rates of HIV and STIs coupled with low awareness of partners' status or risk factors, increase the risk of HIV acquisition even with protective sexual behavior.¹⁶ Aholou et al. found that black women were more likely to have partners who they perceived to be nonmonogamous and were more likely than women of other racial groups to report protective behaviors such as condom use at last vaginal or anal sex.¹⁵ This is consistent with other studies that have described higher rates of condom use among black women,^{17,18} suggesting that other social and structural factors contribute to HIV acquisition risk for these women.¹⁶

Specifically, sexual networks, partner selection practices,¹⁹ incarceration,^{20,21} low awareness of HIV status or partner's status,²² low male-to-female sex ratios,¹⁶ poverty,^{16,23} low educational attainment,^{16,23} and lack of access to healthcare²⁴ may contribute to increased risk of HIV acquisition among black women. Racial segregation along with mass incarceration of black men may limit the number of available partners to black women and thus may contribute to the formation of insular sexual networks with overlapping concurrent partners. As a result, many black women in these communities face greater exposure to HIV acquisition with each sexual encounter, and may underestimate this consequence.¹⁶

Knowledge of a partner's HIV status can lead to reductions in risky sexual behaviors.^{25,26} However, women are significantly less likely than men to know their partners' HIV status.²⁷ In addition, men living with HIV who have sex with both men and women less often notify female sex partners of their seropositivity.²⁸ The Women's HIV SeroIncidence Study (HPTN 064) examined the prevalence and characteristics associated with knowledge of partner's serostatus among a cohort of African American women in the United States.²⁹ The study found that 43% of the African American women living in high poverty and high HIV prevalence areas were unaware of their most recent male partner's HIV status. The women with lower knowledge of partner serostatus was associated with having

TABLE 1. ASSESSMENT TO IDENTIFY WOMEN WHO MAY BENEFIT FROM DAILY ORAL ANTIRETROVIRAL PREEXPOSURE PROPHYLAXIS

Ask

- Has she ever had an HIV test? If yes, does she know the result? If never tested, or doesn't know the result, or hasn't been tested in >1 year, offer and provide HIV test.
- Has she been sexually active in the past 6 months? If sexually active, ask:
 - About gender of partner(s)
 - About what body parts she uses for sex (will help guide education re: protective levels and also which body parts to screen for gonorrhea and chlamydia trachomatis)
 - If she knows the HIV status of her partner(s);
 - if partner is positive, whether she knows their HIV treatment and viral load status
 - if they are aware of partner's concurrency, partner drug use, partner recent incarceration history, and if significantly older age.
 - About methods she currently uses/prefers for HIV and STD prevention
 - If diagnosed with a bacterial STD in the last 6 months
- Is she interested in/intending to become pregnant?
 - If interested in pregnancy, discuss safe conception methods
 - If not interested in pregnancy, ask about contraceptive methods she is using; if none, discuss contraceptive options
- Has she ever injected drugs that were not prescribed for her?
 - If yes, when did she last inject? What drug(s)? Is she using clean injection equipment? Is she sharing injection equipment?

two or more sex partners, suggesting that women most at risk for HIV are least likely to know of their infection risk. Other factors identified were food insecurity, partner age >35, intimate partner violence (IPV), partner's sexual concurrency with multiple women, prevalence of substance abuse, and sex exchange for financial and in-kind resources in their communities.³⁰

Transgender women, women who inject drugs, and women who exchange sex for money or commodities juggle a multitude of priorities in the face of formidable barriers to care. Although HIV incidence is high among these communities, prevention efforts specifically for these populations have been minimal. Such interventions would require attention to the structural, social, and individual factors influencing HIV risk in these groups, including unemployment, stigma, discrimination, criminalization, homelessness, sexual assault, physical abuse, and lack of familial support.³¹

An estimated 18% (115,000) of persons in the United States who inject drugs have indications for PrEP use.⁷ Women who inject drugs are more likely to engage in sex with partners who inject drugs.³² In addition, women who share needles are most likely to do so with their sexual partners, and women are frequently injected by their sexual partners.³³ PrEP offers a unique prevention tool for this population as it protects against HIV transmitted through both sexual contact and injection drug use.³⁴ Other risk reduction methods include the following: destigmatizing injection drug use, ensuring women's access to syringe programs, opioid substitution therapy, and supervised injection facilities. Women who exchange sex for money or commodities face barriers to care, which include facing stigmatization at medical care facilities.

Identifying women who may benefit from PrEP

Factors associated with vulnerability to HIV include a history of inconsistent or no condom use; recent diagnosis of an STI; exchange of sex for commodities (such as money, shelter, food, or drugs); use of intravenous drugs and/or alcohol dependence; having a partner(s) with HIV; having had a partner(s) of unknown HIV status with any of the factors previously listed; women living in communities with high

HIV prevalence; and being in a high-risk sexual network with low awareness of partners' status or risk factors. Partner characteristics such as prior incarceration, injection drug use, concurrent partnerships with women and/or men, and those partners who are unaware of their HIV infection represent a substantial risk factor to women. Women who have condomless sex with a partner living with HIV and whose viral load is not suppressed are at significant risk of HIV acquisition. Longitudinal studies among women have shown that a diagnosis of gonorrhea or syphilis is highly associated with the risk of HIV acquisition in a mean subsequent time of 3.6 years.³⁵ However, while population-based risk factors would make screening women for PrEP eligibility easier, the nuances of a woman's vulnerability to HIV likely go beyond scripted screening questions. Careful history taking around sexual health and trauma experiences, informed by a keen understanding of social determinants of health, may provide the opportunity to discuss expanded HIV prevention options with women who are at risk for HIV exposure.³⁶ Table 1 is an example of an assessment to identify potential candidates for PrEP.

A history of trauma has been identified as a significant risk factor for HIV acquisition.³⁷ Women living with HIV have disproportionate rates of exposure to trauma, defined as experiencing or witnessing sexual or physical violence resulting in an intense emotional response, compared to those without HIV.³⁸ Women in violent relationships have few feasible HIV risk reduction options since traditional prevention methods, male and female condoms, are dependent on a partner's cooperation. PrEP has critical advantages for women in violent relationships, including potential use without their partners' active involvement, knowledge, or consent, coital independence, dual protection against sexual and injection HIV risk, and an opportunity for connection to primary care and social services.³⁴ Caring for and counseling women affected by trauma require specific approaches that foster a therapeutic clinical environment, routine screening for trauma, and a comprehensive response program that promotes safety and healing.³⁹ However, some women may not disclose experiences of violence,⁴⁰ just as some women may choose not to disclose vulnerabilities to HIV. Thus, it is

TABLE 2. IDENTIFYING GENDER AND SEXUAL ORIENTATION

What sex were you assigned at birth?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Decline to State
What is your sex or current gender?	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Transmale/Transman <input type="checkbox"/> Tansfemale/Transwoman <input type="checkbox"/> Prefer to self-describe _____ <input type="checkbox"/> Prefer not to say
Questions about your sexual health and sexuality	<ul style="list-style-type: none"> ● Are you sexually active? ● When was the last time you had sex? ● When you have sex, do you do so with men, women, or both? ● How many sexual partners have you had during the last year? ● Do you have any desires regarding sexual intimacy that you would like to discuss?

critical to provide education and information about PrEP to all women as part of comprehensive HIV preventive care so as not to miss women who do not disclose specific vulnerabilities to HIV.

Adherence

The efficacy of PrEP is dependent on adherence for effective drug concentration to reach vaginal, cervical, and anal tissues. Maximum intracellular concentration of tenofovir varies with specific tissues: cervicovaginal tissue penetration takes up to 20 days, rectal tissue takes up to 7 days, and serum penetration takes up to 20 days to reach maximum intracellular concentration.⁶ To assure effective protection, it is important to emphasize the use of additional HIV prevention strategies (e.g., condoms) during the time frame when drug concentration may not yet achieve protective concentration (20 days for vaginal exposure and 7 days for rectal exposure). Pharmacokinetic studies suggest that PrEP requires a minimum adherence of 6 of 7 doses/week (85% adherence) to protect cervicovaginal tissue from HIV, and adherence of 2 of 7 doses/week (28% adherence) to protect colorectal tissue.³⁹ The efficacy of PrEP in women varied widely across clinical trials from 26% to 81% and corresponded with adherence.⁴¹ PrEP was nonefficacious when adherence was low⁴² and was most efficacious when adherence was high.^{43,44}

PrEP may not be suitable for all persons at risk of HIV for reasons such as inability to adhere to a daily pill regimen and fear of partner violence. However, PrEP may be desirable for persons during “seasons of high risk,” that is period of times when a person is more vulnerable to HIV. Perception of risk has demonstrated an important facilitator of adherence.⁴⁵ This was demonstrated in the FEM-PrEP study done in Kenya, South Africa, and Tanzania, where 70% of women perceived little risk for acquiring HIV; thus, adherence and efficacy were low.⁴⁵ Strategies that providers can use to promote adherence include facilitating accurate knowledge and understanding of medication benefits and requirements, reminder calls or text messages, promoting self-efficacy for adherence, providing a formal support program that includes peer support, and providing resources to address mental health, substance use problems, economic and housing constraints.⁴⁶ Trust and the support of a partner have been shown to reinforce adherence with participants in the African Partners PrEP trial reporting that partners living with HIV often

reminded, supported, and reinforced medication adherence.⁴⁷ Providers can encourage partner support if the woman has disclosed her interest in PrEP to her partner, to help achieve adherence. However, if partner trust and support are not possible, providers can reinforce that PrEP provides a method of HIV prevention that does not require partner knowledge.

For young women who have limited experience with healthcare utilization and lack of experience with long-term medications adherence, daily PrEP presents additional challenges. This has been demonstrated by low adherence rates to oral contraception, resulting in high rates of unintended pregnancy. PrEP adherence support can focus on practical issues: medication storage, reminders for carrying doses when away from home, pill taking behaviors based on daily routines, and partner/family/peer support.

Discussion

PrEP is the first highly effective HIV prevention method available to US women that is entirely within their control. However, due to lack of awareness of PrEP by women who would benefit from its use, and insufficient knowledge of PrEP by women’s healthcare providers, PrEP is not yet achieving its potential to reduce the number of new diagnoses occurring among women. With strong evidence for the effectiveness and safety of PrEP, it becomes essential to deliver PrEP services to women in ways that meet their needs.

PrEP is now a standard prevention option and should not be presented hesitantly. Providers briefly describe to the patient how it works, its effectiveness and safety, what ongoing care is required, resources available to cover the cost, answer any questions, and, if she is interested, initiate PrEP care.³⁶ See Fig. 1 which describes how to prescribe PrEP.

Facilitators for provision of PrEP for women

Black women, who comprise 62% of new HIV diagnoses among all women, are more likely than white women to have concurrent sex partners and partners who they perceived to be nonmonogamous, yet, use protective behaviors more frequently, such as condom use at last vaginal or anal sex. This suggests that other social and structural factors (e.g., higher community baseline HIV and STD prevalence, inequality of health resources due to poverty, racism, gender power imbalance, and incarceration) likely contribute to HIV acquisition

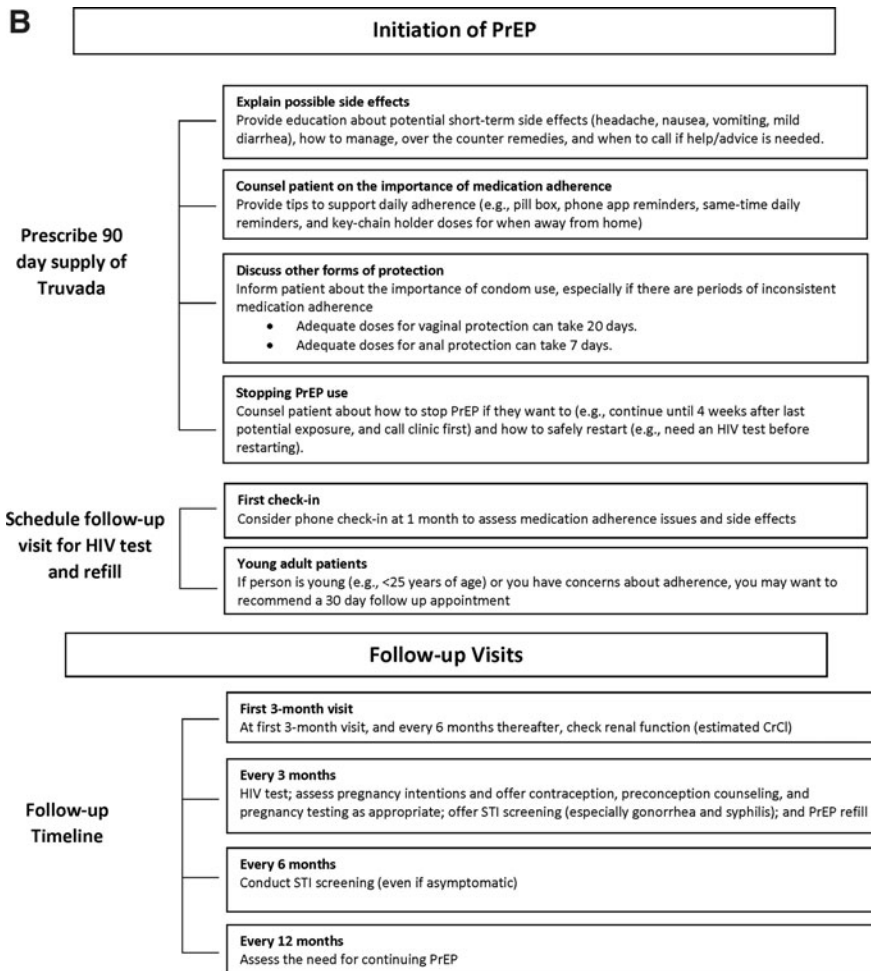
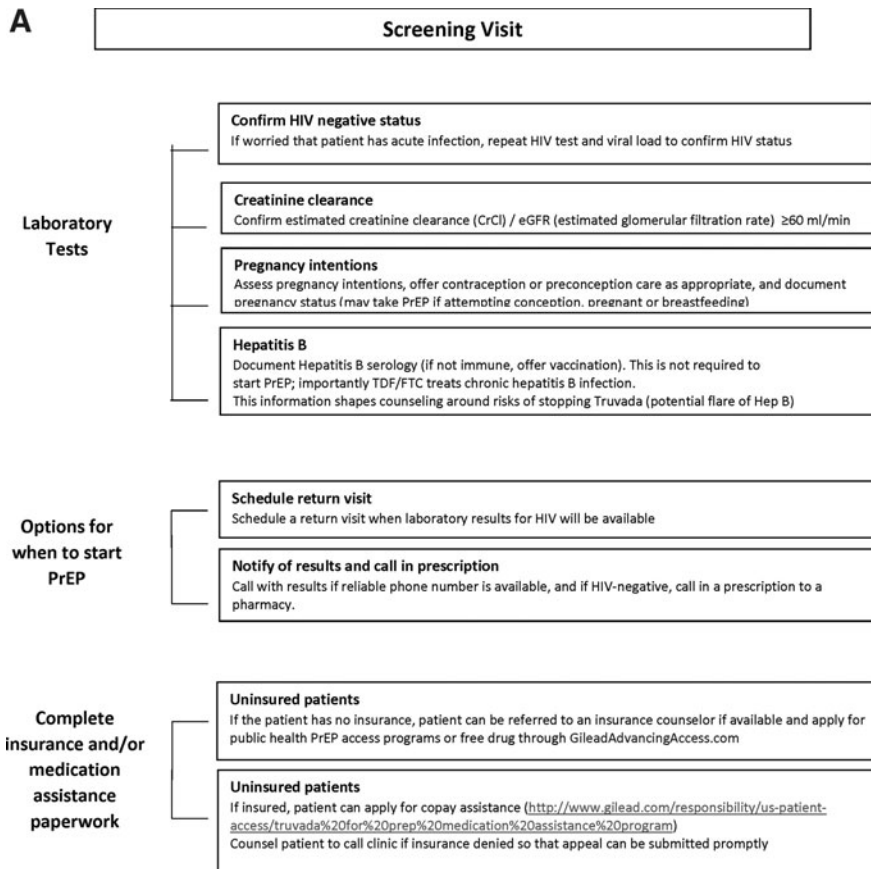


FIG. 1. A and B: Prescribing PrEP for women. PrEP, preexposure prophylaxis.

risk for black women.¹⁶ Awareness of factors impacting women's HIV acquisition risk allows clinicians to tailor their history taking and shared decision-making practices to increase women's access to PrEP. Medical providers can help raise awareness of PrEP among potential users through clear positive messaging that are culturally sensitive, engaging partners when appropriate, integrating HIV prevention services with the delivery of other services that meet women's needs such as family planning, pregnancy care, emergency contraception, postexposure prophylaxis, and IPV counseling.

A perceived barrier to PrEP use is that medication cost is formidable. This has fortunately been addressed through coverage by most public and private insurers and several state health departments offer PrEP-assistance programs to support access for uninsured people (CA, IL, MA, NY, WA). In addition, the PrEP medication assistance plan through Gilead Sciences provides free medication to those who are uninsured and low income (<500% of federal poverty level); for those who are insured, this plan offers coverage of insurance copays up to \$4800 per year (GileadAdvancingAccess.com).

Addressing patients' sexual health is integral to assuring successful implementation of PrEP services for lesbian, gay, bisexual, and transgender (LGBT) persons. Medical providers can facilitate open conversations about their patient's sexual orientation and gender identity and ensure that there are messages that LGBT people are welcome in their medical offices. When patients feel that they are respected, they are likely to respond accurately and honestly to sensitive questions, which may facilitate discussions of risk reduction interventions. Intake forms and provider-initiated medical history questions should include how patients self-identify their sexual orientation and gender identity. Patient histories should address sexual behavior, sexual health, sexual orientation (including identity, behavior, and attraction), and gender identity.⁴⁸ Clinical prevention interventions for transgender persons include routine screening for STIs and HIV, cultural competency training directed at provider attitudes and behavior toward transgender patients, mutual patient-provider trust, and the bundling of comprehensive HIV prevention services with medical and psychosocial services.⁴⁹ See Table 2 to help identify gender and sexual orientation.

Understanding unique motivations and barriers to care of sex workers, including stigmatization at medical care facilities, can contribute to successful uptake of PrEP for women who exchange sex for money or commodities. This can be facilitated by cultural competency training for healthcare providers, collocation and integration of services such as STI, reproductive health, family planning, HIV and prevention care, gender affirming care, coupled with peer training to provide outreach, one on one counseling, and group discussions.

A client centered approach

The goal of PrEP implementation is to ensure that clients are well informed about PrEP, and are empowered to access and utilize it if they choose to use this method of HIV prevention. A way for providers to achieve this goal is by using a client-centered approach that considers women's preferences, needs, and values. Shared decision-making provides one such approach, which can be appropriately applied to clinical scenarios, in which there are multiple options. In the realm of HIV prevention, options include condoms, postexposure

prophylaxis, regular partner testing, treatment as prevention of a partner living with HIV, and STI testing and treatment. The clinician shares evidence-based information, while the client offers her preferences and values; together, they arrive at a patient-centered choice.^{36,50} This process cannot be a one-time endeavor. Rather, early PrEP studies indicate the importance of assessing and reassessing vulnerabilities to HIV exposure and interest in and/or satisfaction with PrEP, as clients' life situations, values, and preferences regarding HIV prevention change over time.⁵¹ Building trust has been identified as an evidence-based best practice in family planning counseling, to both acknowledge a history of mistreatment and distrust, and to promote effective shared decision-making and client-centered care.⁵²

Altering the risk perception, historical, social, environmental, and structural determinants of health and healthcare access for women at substantial risk for HIV and subsequent infection are daunting but necessary long-term tasks. Raising awareness of PrEP among potential users, using messages that are culturally sensitive, and training healthcare providers to deliver PrEP effectively are achievable in the near term if we focus our efforts appropriately. If we successfully link the clinical delivery of PrEP with wrap-around services to support medication adherence by helping women juggle competing life issues, such as access to insurance, substance abuse treatment, mental health services, and social service support, PrEP will contribute to the goal of making new HIV infections rare in women.

Author Disclosure Statement

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