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U.S. Guidelines that empower women to prevent HIV with pre-exposure prophylaxis

Julia Raifman, ScD and

Department of Health Law, Policy, and Management, 715 Albany Street, Room Talbot 242 West, Boston, MA 02118, USA

Susan G. Sherman, PhD, MPH

Department of Health, Behavior, and Society, Johns Hopkins Bloomberg School of Public Health

Empowering women to prevent HIV

Since the early days of the human immunodeficiency virus (HIV) epidemic, healthcare providers have sought methods of preventing HIV that empower women to protect their health.^{1,2} Now pre-exposure prophylaxis (PrEP), a daily pill that prevents HIV, can empower women with a method of HIV prevention that they can control and do not need to negotiate with male partners,³⁻⁶ in contrast to male condoms.⁷ In the United States (U.S.), the first country to approve PrEP for HIV prevention, the U.S. Centers for Disease Control and Prevention (CDC) Clinical Practice Guidelines emphasize evaluation of patients' risk based on sexual behavior and epidemiological context and recommend PrEP for those at substantial risk of the Guidelines suggests considering a number of factors for detecting substantial risk, including a recent bacterial sexually transmitted infection (STI), a high number of sex partners, low condom use, sex work, and being in a high-prevalence area or network. However, the Guidelines then define "recommended indications for PrEP use by heterosexually active women (Box B2)" solely based on the characteristics or behaviors of their male sexual partners. Specifically, the Guidelines recommend that women are indicated for PrEP if they have male sexual partners who are men have sex with men, who inject drugs, or who are living with HIV – indications that entirely dependent on the disclosures of women's male sexual partners.⁸ Defining women's eligibility for PrEP based on their male partners' disclosures is unrealistic and has the effect of diminishing women's empowerment to protect themselves from HIV. We recommend that the CDC PrEP Guidelines include in "Box B2: Recommended indications for PrEP use by heterosexually active [men and] women" women's characteristics that the Guidelines identify as associated with substantial risk of HIV, such as low condom use combined with sex work or being in a high-prevalence area or network.

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juliaraifman@gmail.com, (919) 593-0738.

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HIV among U.S. women

Nearly a quarter of Americans living with HIV are women, and women accounted for 19% of newly diagnosed HIV cases in the U.S. in 2015.⁹ The Centers for Disease Control and Prevention (CDC) estimates that 468,000 U.S. women have indications for PrEP,¹⁰ but a study of women from six U.S. cities found that less than 10% were aware of PrEP in 2012,¹¹ and a 2013 study of women living with HIV in Philadelphia found that just 7% were aware of PrEP.¹² Further, there is limited research in the US that examines the interest, familiarity, or nature of PrEP uptake among cisgender women.^{13,14} Reducing HIV among women at risk is a critical component of achieving an AIDS-free generation in the U.S., and PrEP could play a major role in achieving reductions in HIV incidence.

Oral PrEP can prevent 92% of HIV transmission among adherent individuals,¹⁵ and trials have demonstrated that PrEP can have high efficacy among women who adhere to it.^{16,17} In the Partners PrEP Study, oral tenofovir-emtricitabine (TDF-FTC) reduced new HIV infections by 66% relative to a placebo among Kenyan and Ugandan women in serodiscordant relationships.¹⁶ In a CDC study of PrEP among serodiscordant couples in Botswana, oral TDF-FTC for women had 49% efficacy.¹⁷ PrEP trials have also underscored the importance of adherence to effectively protect against HIV, with a number of studies among women ending early due to poor adherence.¹⁷⁻¹⁹ Based on trial results demonstrating the efficacy of oral PrEP, the U.S. Food and Drug Administration approved oral PrEP for women and men who are part of high-risk populations in 2012.²⁰

Guidelines that give women agency

Women should be empowered to use PrEP without needing to know their male partners' HIV status, sex of other sexual partners, or injection drug behaviors. Research indicates that many men do not disclose their HIV status or MSM or injection drug behaviors to female sexual partners,^{21,22} and this may be especially true as mobile phones and social media increasingly facilitate casual sexual encounters.^{23,24} At the same time, PrEP is only effective for women if healthcare providers understand how to identify women at risk and inform and support their ability to use PrEP, especially given high rates of non-adherence among high-risk women in efficacy trials.

As the CDC PrEP Guidelines recommendations for assessing substantial risk suggest, there are subgroups of women in the U.S. for whom PrEP could be indicated based on elevated rates of HIV incidence. The World Health Organization recommends PrEP for populations with estimated HIV incidence of 3% or greater.²⁵ Although evidence suggests that female sex workers (FSWs) likely meet this definition, there are limited data regarding HIV incidence and prevalence among U.S. FSWs.^{26,27} The National HIV Behavioral Surveillance (NHBS) system may also inform indications for PrEP that are based on women's characteristics. The NHBS estimates HIV prevalence among high-risk heterosexuals, defined as those who live in areas where 20% or more of residents live below the federal poverty line, every three years.²⁸ In the 2010 heterosexual wave of the NHBS, women in the sample had an HIV prevalence of 2.5%,²⁹ relative to 0.16% of heterosexual women across the United States.³⁰ These findings suggest that characteristics that define women's

eligibility for the NHBS may be able to inform indicators for women's PrEP eligibility that are based on women's characteristics rather than those of their sexual partners. Cost effectiveness and balancing risks and benefits will also be an important consideration for any guidelines on PrEP use by women.

In addition to the need for research on which U.S. women should be eligible for PrEP, there is a need for PrEP implementation research among U.S. women.¹¹ Demonstration trials among U.S. women at substantial risk of HIV will be important for understanding how to best support women's PrEP uptake and adherence.

Conclusions

PrEP could play an important and empowering role in reducing HIV incidence among U.S. women. The CDC presents evidence-based guidelines on detecting substantial risk for HIV among patients based on patient factors such as a recent STI, participation in sex work, being in a high HIV prevalence area or network, and low condom use. To further empower those at risk of HIV to protect themselves, the CDC should include in "Box B2: Recommended indications for PrEP use by heterosexually active [men and] women" indications that are based on women's characteristics, rather than exclusively those of their sexual partners. PrEP Guidelines in countries around the world should also ensure that indications for PrEP are based on individuals' characteristics and not only those of their sexual partners. Researchers should contribute to defining evidence-based PrEP guidelines for women by evaluating PrEP indications based on women's characteristics and behaviors, including sex work, that are most associated with high HIV incidence. There is also a need for PrEP demonstration trials among U.S. women to understand how to best support PrEP uptake and persistence among those most at risk.

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