HIV and PrEP among Young Women in the United States

In 2014, women accounted for nearly one in five (19%) new HIV infections in the United States.[1] Women of color, especially young women, have been especially impacted and comprise the majority of women living with the disease. Women at risk of HIV face challenges to getting needed prevention education and services. Systemic inequities perpetuate health disparities of youth; low HIV testing rates and high rates of sexually transmitted diseases (STDs) contribute to this imbalance. While multi-faceted approaches are needed to address these factors and disparities, PrEP provides another prevention option that can benefit women at high-risk of HIV acquisition.

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Women and HIV

Approximately 1 in 4 people living with HIV are women age 13 and up.[2] Of women living with HIV, about 11% do not know they are infected.[3]

In 2014, approximately 13% of new HIV diagnoses among youth aged 13–24 were young women.[4]

Women accounted for 25% (5,168) of the estimated 20,792 AIDS diagnoses among adults and adolescents in 2014 and represent 20% (246,372) of the approximately 1.2 million cumulative AIDS diagnoses from the beginning of the epidemic through the end of 2014.[5]

Among all women diagnosed with HIV in 2014, about 62% (5,128) were Black/African American, 18% (1,483) were white and 16% (1,350) were Hispanic/Latina.[6] Newly infected Black/African American women and Hispanic/Latina women are likely to be younger than white women: 23% of new infections among Black/African American women and 21% among Hispanic/Latina women were in 13–24 year olds, compared to 16% in white women.[7]

In 2014, 87% of new HIV diagnoses among women were attributed to heterosexual sex and 13% were attributed to injection drug use.[8]

Black/African American women in particular, as well as Hispanic/Latina women, continue to be disproportionately affected by HIV compared with women of other races/ethnicities.[9]

While the number of HIV diagnoses among African American women declined from 2010-2014,[10] it is still high compared to women of other races and ethnicities.[11]

PrEP and young women

As with all at-risk populations, young women can benefit from accurate HIV prevention education and condom use. Some young women at highest risk could benefit from risk reduction counseling and pre-exposure prophylaxis (PrEP). The CDC recommends that all individuals ages 13-65 be tested for HIV.

HIV prevention challenges for young women

Biological factors affect a young woman's risk for HIV infection. Most women are infected by heterosexual sex and the risk of getting HIV during vaginal sex is higher for women than for men. Anal sex is also riskier for getting HIV than vaginal sex and more so for the receptive than the insertive partner.[12] Young women are also more vulnerable to infection due to their less mature reproductive tract.[13]

Low rates of testing. Only 22% of high school students who have ever had sexual intercourse had been tested for HIV.[14] Early detection and treatment keeps people living with HIV healthy and living longer. People who know they are HIV positive can also take action to protect their sex partner(s) and drug injection partner(s) as appropriate. People who know their HIV status can take antiretroviral medications for their own health that can also reduce the spread of HIV infection by 96%.[15]

High rates of sexually transmitted diseases (STDs). Half of all STDs are in young women and men ages 15–24 even though they represent only 25% of the sexually experienced population.[16] HIV seroconversion is higher among women with STDs.[17] Furthermore, research shows that there are higher rates of STDs in some communities of color relative to whites due to social and economic conditions, posing additional risks for young people in those communities.[18]

Older male partner. Young women may be at higher risk of HIV when they have an older male sex partner. As opposed to adolescent partners, older male partners are more likely to have had multiple partners and STD, HIV, and drug exposures.[19] Furthermore, power differentials in the relationship may make it more difficult for young women to negotiate condom and contraceptive use.[20]

Intimate partner violence (IPV). More than one-third (36%) of US women have experienced rape, physical violence, or stalking by an intimate partner in her lifetime. Of these women, 69% reported experiencing IPV at age 25 or younger and 22% experienced IPV for the first time between ages 11 and 17. Women with a history of IPV are more likely to report HIV risk factors, including unprotected sex, injection drug use, and alcohol abuse, compared to women who have not experienced violence.[21]

Stigma, fear, discrimination and negative perception about HIV testing may also place young women at higher risk and discourage HIV testing and prevention efforts such as condom use.[22]

Lack of awareness of HIV status. Diagnosis late in the course of HIV infections is common in African American communities which also contributes to higher transmission rates. Later diagnosis also impacts opportunities to get early medical care.[23]

Poverty contributes to the health disparities in HIV prevalence in the US. About 46% of Blacks and 40% of Hispanics live in high poverty urban areas with high HIV prevalence compared to 10% of whites.[24] Limited access to health care including sexual and reproductive health care, housing, and HIV prevention education—among other socioeconomic factors—directly and indirectly increase the risk for HIV infection.

One study found that urban minority female adolescents living in poverty reported high levels of worry about AIDS, but also reported equal or greater concerns about having enough money to live on, general health, doing well in school, getting pregnant, and getting hurt in a street fight. These women may prioritize taking care of their housing, food, child care, and transportation needs ahead of HIV risk reduction behaviors.[25]

Prevalence of HIV in Black/African American communities may affect a young woman's risk of infection. The higher prevalence of HIV in Black/African American communities and the fact that African Americans tend to have sex with partners of the same race/ethnicity mean that Black/African American women face a greater risk of HIV infection with each new sexual encounter.[26]

Historic injustices. Unethical experimentation, such as the Tuskegee syphilis study, have affected the Black/African American community's, and other communities of color's, trust of public health messages and may contribute to an unwillingness for some to be tested or treated for HIV.[27]

About PrEP

PrEP stands for **Pr**e-**E**xposure **P**rophylaxis. PrEP can be used by those at substantial risk of HIV exposure through sexual contact or injectable drug use to prevent acquisition of HIV infection.

To date, the FDA has approved one drug, Truvada, for PrEP in adults (18 and older) in 2012. Truvada is a combination of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) in one daily pill. It was FDA-approved for HIV treatment in 2004. In March 2016, the FDA approved low strength TDF-FTC for *treatment* for those under 18 years of age.

Evidence from clinical trials conducted among multiple high-risk populations suggests that oral TDF-FTC reduces the risk of HIV infection—by up to 92%—among those who regularly take their medications.[28] When taken daily, TDF-FTC is safe and highly effective in preventing HIV infection.[29]

TDF-FTC should be used as part of a comprehensive prevention plan that also includes adherence and risk reduction counseling, HIV prevention education, and behavioral interventions such as drug abuse treatment and correct and consistent condom use.

TDF-FTC is for individuals who are at ongoing substantial risk of HIV infection. For those who need to prevent HIV after a single high-risk event of potential HIV exposure—such as condomless sex, sexual assault, or needle-sharing injection drug use—there is post-exposure prophylaxis (PEP). PEP must begin within 72 hours of exposure.

Indications for PrEP use for women

Per the CDC PrEP Guidelines,[30] PrEP may be appropriate for the following populations:

	Men who have sex with men (MSM)	Heterosexual women and men	Injection Drug Users (IDU)
Recommended Indicators for PrEP Use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use (with MSM, IDU, other high risk partner)	HIV+ injecting partners Sharing injection equipment or needles Risk of sexual acquisition (see columns on left)

Advantages of PrEP for women

TDF-FTC is the first HIV prevention tool that women can fully control. A woman does not have to negotiate or rely on her partner's condom use. Also, women in abusive relationships may be able to discreetly take PrEP to protect themselves as needed.

PrEP effectiveness in young women

Both the FEM-PrEP and VOICE clinical studies failed to find efficacy in women at high-risk on daily TDF-FTC.[31] However, other studies of heterosexual populations including both women and men found higher efficacy where higher levels of adherence were achieved.[32]

Research indicates that adherence needs to be greater to achieve high levels of efficacy in women. Some studies have found that women need daily doses of TDF-FTC to prevent HIV acquisition while men need only two doses per week.[33] Furthermore, according to the CDC PrEP guidelines, data suggest that maximum intracellular concentrations of tenofovir diphosphate are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervico-vaginal tissues at approximately 20 days.[34]

Some research also suggests that PrEP may not be as effective in women younger than 25 and particularly younger than 21.[35] Further research is needed.

PrEP safety

TDF-FTC has been used to treat HIV for over a decade with a good safety profile. In prevention studies to date, TDF-FTC for PrEP has not caused serious short-term safety concerns. TDF-FTC has caused renal toxicity and decreased bone mineral density when used for HIV treatment for months and years. TDF-FTC is considered safe for women of child-bearing age. Decisions about possible use during **pregnancy** must be individualized. While available data suggests that TDF-FTC does not increase the risk or birth defects, there are not enough data to exclude the possibility of harm (Pregnancy Class B). TDF-FTC is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high as in a serodiscordant partnership and because pregnancy itself is associated with an increased risk of HIV acquisition.

Since TDF-FTC is actively eliminated by the kidney, it should be co-administered with care in patients taking medications that are eliminated by active tubular secretion (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valganciclovir, aminoglycosides and high dose of multiple NSAIDs). Drugs that decrease renal function may also increase concentrations of TDF-FTC.

Adapted from: NYC Health, PrEP Provider FAQs[36]

PrEP safety for women under 18 years of age

In March 2016, the United States Food and Drug Administration (FDA) updated the TDF-FTC tablet label to expand the indication to include treatment for pediatric patients weighing at least 12 kilograms and the addition of the following strength tablets (100/150 mg, 133/200 mg and 167/250 mg). See the **full changes** for more information.

The CDC PrEP guidelines suggest that prior to initiating TDF-FTC as PrEP for adolescents that clinicians consider:

- Lack of data on safety and effectiveness of TDF-FTC taken by patients under age 18;
- Possibility of bone or other toxicities among youth who are still growing; and
- Safety evidence available when TDF-FTC is used in treatment regimens for HIV-infected youth.

These factors should be weighed against the potential benefit of providing TDF-FTC for an adolescent at substantial risk of HIV acquisition.[37]

Unless contraindicated for an adolescent's safety, parent/guardian involvement is advised. In addition, the individual patient's ability to comply with daily dosing given developmental stage, family and social support, housing situation and other life circumstances should also be considered.

Supporting PrEP adherence

Research indicates that the efficacy of TDF-FTC depends upon patient adherence to the regimen as well as the benefits of the medication itself.[38] Therefore PrEP education, assessment of a patient's ability to adhere, follow up safety monitoring visits, and additional social supports as needed by individual patients given their life circumstances are all critical to successful TDF-FTC use.[39] Adherence is also critical to reducing the risk of developing a drug resistant virus.

Patients with chronic diseases have reported that the most important factors in medication adherence were incorporating medication into their daily routines, knowing that the medications work, believing the benefits outweigh the risks, knowing how to manage side effects, and low out-of-pocket costs.[40]

When initiating TDF-FTC, PCPs must educate patients to ensure they understand:

- How to take their medications (e.g., when, how many pills);
- What to do if they experience problems (e.g., what to do if they miss a dose, what constitutes a missed dose);
- What the most common side effects are and help patients develop a plan for handling them; and
- The importance of using condoms, especially if they decide to stop taking TDF-FTC.[41]

Additional tools such as providing reminder systems (e.g., texts, emails) have also proven effective. Furthermore, addressing financial, substance abuse, and mental health needs that may interfere with adherence and facilitating social supports are also recommended and may be key to maintaining adherence over time in high-risk youth. The Clinical Reference Sheet in this toolkit outlines key components of medication adherence counseling.

Research in this area continues to explore mechanisms for encouraging adherence, as well as novel formulations of PrEP that can help overcome adherence barriers such as long acting vehicles or intermittent PrEP.

Hormonal contraception and PrEP

Studies have found that TDF-FTC has no adverse impact on hormonal contraceptive effectiveness for pregnancy prevention.[42] Injectable contraceptives (Depo-Provera) have been associated with a 2–4 fold increased risk of HIV acquisition in some observational studies.[43] Research has demonstrated that TDF-FTC could mitigate the potential increased HIV-1 acquisition and transmission risks that have been associated with DMPA use.[44]

Conception, pregnancy and breastfeeding

Please refer to the CDC's **Provider Information Sheet-PREP During Conception, Pregnancy and Breastfeeding** for more information.

HIV and intimate partner violence

Women with a history of intimate partner violence (IPV) are more likely to report HIV risk factors, including unprotected sex, injection drug use, and alcohol abuse, relative to women who have not experienced violence.[45]

The National Domestic Violence Hotline (**www.thehotline.org/help/**) is available to all who suffer from intimate partner violence.

As of April 29, 2015, survivors of domestic violence may apply for health insurance under the Affordable Care Act at any time. They do not need to wait for Open Enrollment.

Exposure to IPV can increase a woman's risk for HIV infection through:

- forced sex with an HIV positive partner
- limited or compromised negotiation of safer sex practices
- increased sexual risk-taking[46]

Source: Suzanne Maman, et al., "The intersections of HIV and violence: directions for future research and interventions," Social Science and Medicine 50, no. 4 (2000):459-478, DOI: 10.1016/S0277-9536(99)00270-1.

As survivors of domestic violence, they qualify for a Special Enrollment Period (SEP). Survivors can contact the call center at 1-800-318-2596 and explain, "I am a survivor of domestic violence. I want a Special Enrollment to apply for health care." The call center will grant the SEP and the survivor will have 60 days to choose a health care plan. More details are available at **healthcare.gov** or the **Health Cares About IPV: Intimate Partner Violence Screening and Counseling Toolkit** (Futures Without Violence).

Other PrEP methods being studied

A number of studies are underway to look at different delivery mechanisms as well as medications for use as PrEP, including:

- multipurpose technologies (MPT) which would deliver contraception and PrEP, such as a vaginal ring;
- microbicides; and
- long acting antiretrovirals delivered by implant or injection.

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