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PrEP for Women

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Table of Contents

- What Is PrEP?
- How Does PrEP Prevent HIV Transmission?
- Daily Oral PrEP
- Long-Acting Injectable PrEP
- Has PrEP Been Shown to Be Effective?
- Why Are Some Research Findings Unclear?
- CDC and WHO Guidelines for PrEP Use
- The PrEP Debate
- What Does PrEP Mean for Women?
- Considering Taking PrEP?
- New Developments in the PrEP Arena

What Is PrEP?

PrEP stands for **Pre-E**xposure **P**rophylaxis. It means taking medicine **before** being exposed to something to prevent yourself from getting a disease or condition. We use several kinds of medicine this way.

In all studies, people who took the drug daily as prescribed were significantly less likely to acquire HIV when exposed to the virus during sex or injection drug use.

One example is taking anti-malaria medication when we travel to areas where we might be bitten by mosquitoes that carry malaria. When the medicine is in a person's body before getting a mosquito bite, that person is much less likely to get sick from malaria when they are bitten.

For women, another example is taking <u>contraceptive</u> (also known as "birth control") pills to avoid pregnancy. When contraceptives are already in a woman's body when she is exposed to semen during sex, she is much less likely to <u>get pregnant</u>.

PrEP here means that people who are not living with HIV take an HIV drug to reduce their risk of acquiring HIV if they are exposed to the virus. Some people use the term "topical PrEP" to describe the use of <u>microbicide</u> gels or rings (e.g., vaginal gels containing HIV drugs). However, in this article we are referring to "oral PrEP," or HIV drugs taken by mouth to prevent acquiring HIV. We will also discuss "long-acting PrEP," which became available in the US in late 2021 and is injected.

Women, PrEP, & Sexual Health (Project Inform & HIVE)

How Does PrEP Prevent HIV Transmission?

Here is how PrEP works:

- When <u>CD4 cells</u> are infected with HIV, they become little factories that make thousands of new copies of this virus each day
- HIV drugs work by blocking HIV from making copies of itself
- If an HIV-negative woman already has HIV drugs in her bloodstream when she is exposed to HIV, for example during sex without a condom, the medicine can keep the virus from making copies of itself and prevent her from acquiring HIV

Click above to view or download this fact sheet as a PDF slide presentation

Daily Oral PrEP

In July 2012, the US Food and Drug Administration (FDA) approved the daily use of Truvada (tenofovir disoproxil fumarate plus emtricitabine, or TDF/FTC), an oral (by mouth) medication, as PrEP for sexually active adults vulnerable to acquiring HIV. Truvada is also used as part of combination drug treatment for people living with HIV. This was the first time the FDA approved any medication for the prevention of HIV. The FDA has since approved Descovy (tenofovir alafenamide plus emtricitabine or TAF/FTC) for PrEP, but only for people assigned male at birth (cisgender men or transgender women). The approval was based on a clinical trial that excluded non-trans (cis) women. As a result of pressure from HIV advocates, the company that makes Descovy committed to studying the drug for PrEP in cisgender and young women.

The World Health Organization (WHO) released updated guidelines in July 2021. It recommends that tenofovir-containing daily oral PrEP be offered as an additional prevention method to all people highly vulnerable to acquiring HIV. It also recommends non-daily ("event-driven") oral PrEP for men who have sex with men, and the dapivirine vaginal ring for women in combination with other prevention methods. However, each country must individually approve the use of any drug and determine how it will provide that medicine.

Long-Acting Injectable PrEP

Some people do not want to take a pill daily, have trouble remembering to do so, or have circumstances in their lives that make it difficult to take daily medications. In late 2021, the FDA approved a long-acting injectable form of the integrase inhibitor cabotegravir for PrEP. The first two injections of Apretude (the US brand name for cabotegravir's extended-release injectable form) are given one month apart. After that, the drug is injected once every two months. Cabotegravir can also be taken as an oral medication daily for four weeks before starting injections to make sure that there are no bad reactions to the drug.

Advocates are hopeful that [long-acting cabotegravir] will quickly be made available throughout the world, especially in countries with high HIV rates – and are very concerned about the extremely high cost of each dose of the drug.

The injectable is approved for adults and adolescents in the US who weigh at least 77 pounds (35 kilograms). Advocates are hopeful that the drug will quickly be made available throughout the world, especially in countries with high HIV rates – and are very concerned about the extremely high cost of each dose of the drug, which makes it impossible for most people to access. The drug also has a "long tail" – meaning it stays in people's bodies at a level that does not prevent HIV acquisition long after the person stops taking it. In studies, this was especially true for women. This means that, if a woman acquired HIV soon after stopping the injectable PrEP drug, or after missing PrEP injections, she could have a higher chance of developing <u>drug resistance</u>.

Has PrEP Been Shown to Be Effective?

Several <u>clinical trials</u> have shown that taking daily oral PrEP lowers the risk of acquiring HIV from sex by more than 90%, and from sharing injection drug equipment by more than 70%. Several studies in southern Africa did not find either oral or topical PrEP to be effective in preventing <u>HIV transmission</u> to women. However, researchers discovered that, for a number of reasons, many women enrolled in the study were not taking the medication as prescribed, which made it less effective.

Another way of taking PrEP that proved highly effective in another African study involved using it as a "bridge" until the partner living with HIV in a <u>serodifferent</u> (one partner is living with HIV, the other is HIV-negative) heterosexual couple has an undetectable viral load. Recent research has shown that people living with HIV whose viral load has been undetectable (defined as less than 200 copies of the virus and cannot be detected by standard tests) for six months and whose virus stays undetectable do not transmit HIV to their sexual partners. For more information on this exciting development, please see our fact sheet <u>Undetectable Equals Untransmittable</u>: <u>Building Hope and Ending HIV Stigma</u>.

Why Are Some Research Findings Unclear?

For any drug or other HIV prevention tool to work, it must be used – and used correctly and consistently. This is true for <u>condoms</u> and is proving true for PrEP as well. In the studies in which PrEP was not effective in women, the key to success was <u>adherence</u>, which means taking the drug when and how it is prescribed. In all studies, people who took the drug daily as prescribed were significantly less likely to acquire HIV when exposed to the virus during sex or injection drug use.

We do not yet fully understand the reasons why people – especially women – do not take oral PrEP consistently as prescribed. Research into issues that might affect women's interest in or ability to take a drug for HIV prevention is very important. To answer these questions, women need to take part in future studies about PrEP. For more information about understanding, finding, and participating in research studies, see our fact sheet on <u>clinical trials</u>.

CDC and WHO Guidelines for PrEP Use

In 2021, the US Centers for Disease Control and Prevention (CDC) updated its guidelines to encourage providers to inform all people who are having sex that PrEP can protect them from acquiring HIV, and to offer PrEP to anyone who asks for it. One desired effect of this change is that it will reduce stigma and increase awareness of PrEP, information that has reached only a small fraction of people in the US who might need it. For example, CDC has estimated that only 10 percent of women who could benefit from PrEP were prescribed the drug.

In the past, <u>guidelines</u> from the CDC on the use of PrEP in the US have been similar to the WHO guidelines recommending that daily oral PrEP be considered for HIV-negative people who are at "substantial risk" for acquiring HIV. CDC defines this as people who:

- are in a sexual relationship with a partner living with HIV
- do not regularly use condoms and who do not know the HIV status of their sexual partner(s)
- have a high number of sexual partners
- are engaged in commercial sex work
- have had a recent bacterial sexually transmitted disease
- use injection drugs and (1) share drug equipment, or (2) have an injecting partner who is living with HIV

There are also some cases when PrEP is NOT recommended. These include having:

- unknown HIV status; it is important that only people who test negative for HIV take PrEP
- signs or symptoms of acute HIV infection
- decreased kidney function

• unknown hepatitis B status and/or hepatitis B vaccination status

The guidelines also suggest that providers consider PrEP for people who live in areas or have personal networks where HIV is more common (high-prevalence areas). The guidelines provide tools to help providers identify these areas. The CDC also published a clinical providers' supplement, which includes a patient/provider checklist, counseling about using PrEP while trying to become pregnant and during pregnancy, counseling about adherence and reducing vulnerability to HIV, and information sheets for patients in English and Spanish.

PrEP needs to be taken daily as prescribed to be as effective as possible. The CDC recommends using it in combination with other HIV prevention strategies, such as condoms or safer injecting practices. PrEP is one tool that can be used to prevent the transmission of HIV.

It is also important that people have a negative <u>HIV test</u> before starting PrEP. The CDC recommends that people be tested every three months to make sure they remain HIV-negative while taking PrEP.

Lastly, it recommends that HIV-negative people who are <u>pregnant</u> or who are <u>trying to become</u> <u>pregnant</u> talk with their healthcare providers about the risks and benefits of taking PrEP. Healthcare providers should discuss PrEP as an option for protecting HIV-negative partners in serodifferent couples who want to get pregnant. Viread and Truvada have been taken by women living with HIV for many years and are safe during early pregnancy.

The PrEP Debate

While many HIV advocates believe that PrEP is a good addition to the prevention toolbox, some people disagree. Just as adherence is a factor for people living with HIV, some are worried that HIV-negative people may not take the drug as prescribed and therefore PrEP will not be effective.

There are also concerns that HIV-negative people will use PrEP instead of <u>condoms</u> or other <u>safer sex</u> measures. Although PrEP is designed to be used in addition to condoms or other HIV prevention practices, it can be taken without the agreement or knowledge of one's sex partner, for example by a woman whose male partner is not using a condom or who cannot negotiate condom use (for example, because of intimate partner violence). Since condoms, when used properly, are more effective and less expensive than PrEP in preventing HIV, some believe that allowing PrEP may affect traditional HIV prevention efforts. PrEP also does not prevent <u>sexually transmitted infections</u>, such as gonorrhea or syphilis.

Some women have expressed concerns about possible <u>side effects of PrEP</u>. The most common side effects in the studies were nausea (feeling sick to the stomach) and vomiting (throwing up), which often went away after a few days or weeks. While no serious side effects were found during the studies, Truvada can occasionally cause serious side effects, including kidney problems, liver problems, <u>lactic acidosis</u>, <u>lipodystrophy</u>, and <u>bone problems</u>. Studies in men and <u>transgender women</u> taking Truvada as PrEP have shown small decreases in bone mineral density (a measure of bone strength). Bone density does return to previous levels six months after stopping PrEP. However, these results may not apply to cisgender women who generally have lower bone mineral density than men. In the studies, another problem with Truvada was a small decrease in kidney function. This means that older people and those with kidney problems who start this drug may need to see their doctor and have lab tests more often.

Although PrEP is designed to be used in addition to condoms or other HIV prevention practices, it can be taken without the agreement or knowledge of one's sex partner, for example by a woman whose male partner is not using a condom or who cannot negotiate condom use.

If HIV-negative people take PrEP inconsistently, acquire HIV and continue to take the PrEP drug, their virus may become <u>resistant</u> to that drug and to similar HIV medications. This not only can reduce treatment options for these people but may transmit drug-resistant HIV to others.

What Does PrEP Mean for Women?

While we now have evidence that PrEP works to prevent acquiring HIV if the drugs are taken as prescribed, much more work needs to be done before PrEP becomes widely used and accepted. This includes improving healthcare systems so that people can get and afford PrEP and making HIV testing more widely available, since only people who know they are HIV-negative can use PrEP safely.

PrEP is a promising tool that women can use to prevent HIV acquisition with or without their partners' cooperation. This is particularly important when <u>intimate partner violence</u> is a factor, and a woman fears violence from her partner if she asks them to use condoms.

However, many questions remain. For example: Will women be able to keep the PrEP drugs they receive? Some women worry that their drugs might be taken away and given to another family member who is seen as "needing them more."

Considering Taking PrEP?

If you think PrEP may be a good option for you, here are a few questions you can discuss with your health care provider:

- How often—and for how long (i.e., days, weeks)—do I need to take PrEP if I am trying to protect myself from HIV? What happens if I miss a dose or several doses?
- What are likely side effects and how can I manage them?
- How often will I need to be tested for HIV?
- How much will the drug cost me? Will it be covered by my insurance? Will the HIV tests also be covered by my insurance?
- Do any of my current medical conditions make PrEP drugs not a good choice for my health overall?
- Do any of my other prescription medications, over-the-counter drugs, street drugs, herbs, vitamins, or supplements have <u>interactions</u> with the drug?
- What should I do if I become pregnant while on PrEP?

While PrEP is designed to be used in combination with condoms or other safer sex measures, women who cannot or do not use condoms may want to use PrEP instead of condoms. It is important to understand the overall risks and benefits of using PrEP to reduce one's HIV risk, as well as to consider methods of protection from other <u>sexually transmitted infections or diseases (STIs or STDs)</u>.

New Developments in the PrEP Arena

Clinical trials of several other PrEP products are ongoing.

Studies have shown that the tenofovir disoproxil fumarate (TDF) in Truvada can lead to a reduction in kidney function and <u>bone loss</u>. Alternative drugs being considered include:

- Maraviroc (Selzentry) has already been approved as an HIV drug and is being studied for PrEP.
 Both oral (by mouth) and vaginal gel formulations of the drug are being tried.
- A very long-acting form of PrEP, lenacapavir, is being studied as a single injection every six

months. The study is expected to be completed in 2027.

 A vaginal ring containing the drug dapivirine has been approved in South Africa and other countries, but not in the US.

Additional Resources

Select the links below for additional material related to PrEP for Women.

- ¿Qué es PrEP? (PrEP REP Project; video in Spanish)
- PrEP Services Locator (PleasePrEPMe; interactive map)
- Find HIV Services Near You HIV PrEP (HIV.gov)
- Pre-Exposure Prophylaxis (PrEP) (aidsmap)
- PrEP for Women: Is It Effective? (TheBody)
- HIV PrEP Safe for Breastfeeding Women, Infants (MDedge/ObGyn)
- Hormone Levels Not Affected by PrEP in Trans Women (San Francisco AIDS Foundati...
- PrEP (Pre-Exposure Prophylaxis) (US Centers for Disease Control and Prevention)
- New Campaign, Toolkit Gets Providers PrEP'd for Women (TheBodyPro)
- PrEP (profilaxis prexposición) (Centros para el Control y la Prevención de Enfe...
- New Campaign, Toolkit Gets Providers PrEP'd for Women (TheBodyPro)
- HIV and Women: PrEP Coverage (US Centers for Disease Control and Prevention)
- El VIH y las mujeres: Cobertura de PrEP (Centros para el Control y la Prevenció...
- Black Women and PrEP Toolkit (The Black AIDS Institute)
- SisterLove's Dazon Dixon Diallo: Our Language Around Risk Perception, PrEP & Wo...
- Women and PrEP (Sophia Forum, United Kingdom)
- Cabotegravir for Women: A Potential Game Changer (International Workshop on HIV...
- Injectable PrEP and COVID Show We're All in This Together (aidsmap)
- Side-by-side Comparison: Truvada and Descovy for PrEP (San Francisco AIDS Found...
- Having More Options Makes PrEP More Viable (TheBody)
- WHO Recommends the Dapivirine Vaginal Ring as a New Choice for HIV Prevention f...
- US Regulator's Decision on Vaginal Ring Denies Choice to Women Who Need HIV Pre...
- Clinicians' Quick Guide: What Is HIV PrEP? (US Centers for Disease Control and ...



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