PrEP for Women [1]

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What Is PrEP?

PrEP stands for Pre-Exposure Prophylaxis. 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.

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 birth control pills (contraceptives). When contraceptives are already in a woman's body when she is exposed to semen during sex, she is much less likely to get pregnant.
PrEP here means that HIV-negative women 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 microbicide [5] gels (e.g., vaginal gels containing HIV drugs). However, in this article we are referring only to 'oral PrEP,' or HIV drugs taken by mouth to prevent getting HIV.

How Does PrEP Prevent the Spread of HIV?

Here is how PrEP works:

- When CD4 cells [6] are infected with HIV, they become little factories that make thousands of new viruses 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 enough copies of itself to "take hold" and prevent her from getting HIV

Approval for 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) as PrEP for sexually active adults at risk of getting HIV. Truvada is often used as part of combination drug treatment for HIV. This was the first time the FDA approved any medication for the prevention of HIV. The World Health Organization (WHO) released updated guidelines in June 2016 that expand earlier recommendations. It now recommends that daily oral PrEP be offered as an additional prevention method to all people at substantial risk of getting HIV. The WHO has approved the use of either Viread (tenofovir disoproxil fumarate) or Truvada for this purpose. However, each country must individually approve the use of Truvada or Viread as PrEP and determine how it will provide the drug.

Has PrEP Been Shown to Be Effective?

Several clinical trials [8] have shown that taking Truvada as oral PrEP (one pill by mouth daily) lowers the risk of acquiring HIV from sex by more than 90%. That risk is reduced by more than 70% among people who inject drugs. In past years, several studies in southern Africa did not find either oral or topical PrEP to be effective in preventing HIV transmission [9] 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. These findings are discussed in the section below.

Another way of taking PrEP that proved highly effective in another African study involved using PrEP as a "bridge" until the partner living with HIV in a serodifferent [10] (one partner is living with HIV, the other is HIV-negative) heterosexual couple has an undetectable viral load. As of February 2015, this strategy had reduced the risk of acquiring HIV by 96%.

Recent research has shown that people living with HIV whose viral load is undetectable (cannot be detected by standard tests) do not transmit the virus to their sexual partners. For more information
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 condoms and is proving true for PrEP as well. In the studies mentioned above, the key to PrEP's success was adherence, 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. This makes more research into issues that might affect women's interest in or ability to take a drug for HIV prevention 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 clinical trials.

CDC and WHO Guidelines for PrEP Use

The 2017 guidelines from the US Centers for Disease Control and Prevention (CDC) on the use of PrEP in the US recommend that daily oral Truvada be considered for HIV-negative people who are at substantial risk for acquiring HIV. This includes 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 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 HIV risk reduction, 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 HIV test 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 women who are pregnant or who are trying to become pregnant talk with their health care providers about the risks and benefits of taking Truvada for...
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PrEP. In 2014, the US Public Health Service released clinical practice guidelines suggesting that health care providers now discuss PrEP as one of several options 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 appear to be 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 condoms [12] or other safer sex [18] 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. Since condoms, when used properly, are more effective and less expensive than PrEP in preventing HIV, some believe that allowing Truvada to be used as PrEP may affect traditional HIV prevention efforts. PrEP also does not prevent sexually transmitted diseases [19], such as gonorrhea or syphilis.

Some women have expressed concerns about possible side effects of PrEP [20]. The most common side effects in the studies were nausea and vomiting, 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 effects, including kidney problems, liver problems, lactic acidosis [21], lipodystrophy [22], and bone problems [23]. Studies in men and transgender women [24] taking Truvada as PrEP have shown small decreases in bone mineral density (a measure of bone strength). Density returned to previous levels six months after stopping PrEP. However, these results may not apply to 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.

If HIV-negative people take Truvada for PrEP, acquire HIV and continue to take Truvada, their virus may become resistant [25] to that drug and to similar HIV medications. This not only can reduce treatment options for these people but may transmit Truvada-resistant HIV to others.

What Does PrEP Mean for Women?

While we now have evidence that PrEP works to prevent getting 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 health care systems so that people can get and afford PrEP, and making HIV testing [16] 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 without their partners' cooperation. 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 interactions 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 internal 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 sexually transmitted infections or diseases (STIs or STDs) [19].

**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 bone loss [23]. Two alternatives to TDF are under development:

- Descovy, which combines a different form of tenofovir called TAF (tenofovir alafenamide) with emtricitabine was approved for men and trans women in October 2019. The approval was based on a clinical trial that excluded non-trans 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.
- 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.

Some people do not want to take a pill daily, or have trouble remembering to do so. Two long-acting forms of PrEP are under development:

- An injectable form of an integrase inhibitor, cabotegravir, is being studied to both treat and prevent HIV. One clinical trial investigated the drug among women and another among men and trans women.
- Islatravir is a new type of antiretroviral that could be used as an implant (similar to a contraceptive patch) or monthly pill for HIV prevention, or a weekly pill for HIV treatment. A clinical trial of the monthly pill in women is expected to start in early 2021.

**Tags:**

- PrEP [27]
- Pre-exposure prophylaxis [28]
- Truvada PrEP [29]
- Tenofovir PrEP [30]
- Guidelines PrEP [31]
- PrEP women [32]
- HIV drugs HIV-negative [33]
- Clinical trials PrEP [34]
- Research PrEP [35]
Additional Resources

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

- What Is PrEP? (PrEP REP Project, video; also available in Spanish)
- US PrEP Locator (Greater than AIDS, interactive map)
- Find a PrEP Provider (PleasePrePMe, interactive map)
- Prevention for Women: Resources (HIVE)
- Women and PrEP (coalition of organizations in the United Kingdom)
- Knowledge & Attitudes of US Women of PrEP (HIVE)
- PrEP (US Centers for Disease Control and Prevention)
- HIV PrEP Safe for Breastfeeding Women, Infants (OB GYN News)
- Hormone Levels Not Affected by PrEP in Trans Women (San Francisco AIDS Foundation)
- Pre-Exposure Prophylaxis (AVAC)
- Pre-exposure prophylaxis (PrEP) (aidsmap)
- Women and PrEP: A Q&A with Dr. Judy Auerbach (BETA, via TheBody)
- The Questions About PrEP (San Francisco AIDS Foundation)
- New Campaign, Toolkit Gets Providers PrEP’d for Women (TheBodyPro)
- Spreading the Word about HIV Prevention for African-American Women (National Public Radio)
- D.C. PrEP for Women Initiative (Washington AIDS Partnership)
- Black Women and PrEP Toolkit (The Black AIDS Institute)
- This World AIDS Day, Let's Talk About PrEP (Black Women's Health Imperative)
- FOR PROVIDERS: Family Planning Provider PrEP Toolkit (HIVE)
- Merck Launches Major Trial of Monthly Islatravir PrEP Pill for Women (POZ)
- Long-Acting Injectable Cabotegravir (AVAC)
- Side-by-side comparison: Truvada and Descovy for PrEP (San Francisco AIDS Foundation)
- Having More Options Makes PrEP More Viable (TheBody)

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[8] https://www.thewellproject.org/hiv-information/understanding-clinical-trials
[12] https://www.thewellproject.org/hiv-information/talking-your-partner-about-condoms
[16] https://www.thewellproject.org/hiv-information/hiv-testing
[18] https://www.thewellproject.org/hiv-information/safer-sex
[19] https://www.thewellproject.org/hiv-information/sexually-transmitted-infections-or-diseases-stis-or-stds
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