

## PrEP for Women <sup>[1]</sup>

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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 malaria when she or he is bitten.

For women, another example is taking [birth control](#) <sup>[2]</sup> pills (contraceptives). When contraceptives are already in a woman's body when she is exposed to semen during sex, her chances of getting pregnant are greatly reduced.

When we talk about PrEP in connection to HIV and women, we are referring to the idea of HIV-negative women taking HIV drugs to reduce their risk of becoming infected with HIV if they are exposed to it. Some people use the term 'topical PrEP' to describe the use of microbicide gels (e.g., vaginal gels containing HIV drugs). However, in this article when we talk about PrEP, we are referring only to 'oral PrEP,' or HIV drugs taken by mouth as prevention.

## How Does PrEP Prevent the Spread of HIV?

Here is how PrEP works:

- When cells 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 during unprotected sex, for example, the medicine might be able to keep the HIV from making enough copies of itself to "take hold" and prevent her from becoming infected

## Truvada Approved for Use as PrEP

Based on the findings of studies mentioned below, in July 2012, the US Food and Drug Administration (FDA) approved the daily use of Truvada (tenofovir plus emtricitabine, or TDF/FTC) as PrEP for sexually active adults at risk of HIV infection. Truvada is a drug often used as part of combination drug treatment for HIV. This is the first time the FDA has approved any drugs for the prevention of HIV.

## Has PrEP Been Shown to Be Effective?

Several recent [clinical trials](#) <sup>[3]</sup> have shown that taking Truvada as oral PrEP (one pill by mouth daily) can help prevent HIV. These studies were conducted among men who have sex with men (MSM) and transwomen (people who were born male and identify as women) in the US and Latin America, and among heterosexual women and men in several African countries. The effectiveness for Truvada as PrEP varied from 44 percent to 73 percent additional protection against HIV infection in these three studies (known as the iPrex, TDF2, and Partners studies). A study in Bangkok tested oral daily tenofovir (Viread) as PrEP among over

2,400 HIV-negative women and men who inject drugs. It showed that oral daily tenofovir reduced the risk of getting HIV by almost half (50 percent).

Other studies, however, have found these drugs not to be effective in preventing HIV. The FemPrEP study, for example, was stopped early because it did not seem to help in preventing [HIV transmission](#) [4]. FemPrEP was testing the effectiveness of oral daily Truvada in Kenyan, Tanzanian, and South African women at high risk for HIV. The VOICE study, which tested oral daily tenofovir, oral daily Truvada (tenofovir plus emtricitabine), and one-percent tenofovir vaginal gel among over 5,000 women in South Africa, Zimbabwe, and Uganda, found all three methods ineffective in preventing HIV transmission.

## Why Are the Research Findings Unclear?

For any drug or other HIV prevention tool to work, it has to be used; and research tells us that it has to be used correctly and consistently. This is true for condoms and is proving true for PrEP as well. In the studies mentioned above, the key element in PrEP's success was "[adherence](#) [5]," which means taking the drug when and how it is prescribed.

In the FemPreEP and VOICE studies, there were low levels of adherence; fewer than one in three women took the drug regularly. Additionally, many women in the FemPrEP study did not consider themselves at risk for HIV. The other studies had much higher rates of adherence. In all studies, people who took Truvada or tenofovir daily as prescribed were significantly less likely to get infected with HIV when exposed during sex or injection drug use. The US Centers for Disease Control and Prevention (CDC) reports that, in people at high risk for HIV who take PrEP consistently, the risk of HIV infection can be reduced by up to 92 percent.

We do not yet fully understand all of the reasons why people — especially women — have low levels of adherence to oral PrEP. This makes it very important to do more research looking at what issues might affect women's interest in or ability to take a drug for HIV prevention.

It is also important for women to know about and take part in the future research that will look at the unanswered questions about Truvada as PrEP. For more information about understanding, finding, and participating in research studies, see [The Well Project's article on Clinical Trials](#) [6].

## CDC and WHO Guidelines for PrEP Use

In May 2014, the CDC released updated [guidelines](#) [7] for the use of PrEP in the US. These guidelines recommend that PrEP with daily, oral Truvada be considered for HIV-negative people who are at substantial risk for HIV. This includes people who:

- are in a sexual relationship with an HIV+ partner
- 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 injections drugs and (1) share drug equipment, or (2) were recently in a drug treatment program

There are also some reasons that PrEP is NOT recommended. These include having:

- unknown HIV status; it is important that only HIV-negative people take PrEP
- signs or symptoms of acute HIV infection
- decreased kidney function
- unknown hepatitis B [8] status and/or vaccination status

The guidelines also suggest that providers consider PrEP for those persons living in areas or 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 [9], 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.

It is important to note that PrEP needs to be taken daily as prescribed to maximize its effectiveness and that it needs to be used in combination with other HIV prevention strategies (i.e., condoms and safer sex and injecting practices). PrEP is not intended to be used alone to prevent the spread of HIV, because it is not 100 percent effective. It is also important that all those being prescribed Truvada as PrEP have a negative HIV test before starting the medication and that they get tested regularly while taking it. The CDC guidelines recommend that people be tested every three months to make sure they remain HIV-negative while taking PrEP.

Lastly, the CDC recommends that HIV-negative women who are pregnant [10] or who are trying to become pregnant [11] talk with their health care providers about the risks and benefits of taking Truvada for PrEP. While the information we have to date does not show negative effects among infants exposed to Truvada during pregnancy, this information comes from HIV+ women taking Truvada. There is very little data on HIV-negative women using Truvada during pregnancy.

The World Health Organization (WHO) has also issued guidance for heterosexually active women and men. It recommends that, in countries where HIV is spread in couples in which one partner is living with HIV, both tenofovir (Viread) and Truvada be considered as possible additional prevention choices for the HIV-negative partner. Further recommendations for oral PrEP are expected from the WHO in 2015.

## The PrEP Debate

While many HIV advocates believe that Truvada as PrEP is a good addition to the prevention toolbox, some people disagree.

Just as adherence is a factor for people living with HIV, there are concerns that HIV-negative people may not adhere to the drugs and therefore PrEP will not be effective.

There are also concerns that HIV-negative people will use PrEP in place of condoms [12] or other safer sex [13] measures. Although PrEP is designed to be used **in addition to** condoms or other safer sex measures or safer injection practices, one of the benefits of PrEP is that it can be taken without the agreement or knowledge of one's sex partner. Since condoms, when

used properly, are more effective and less expensive than PrEP in preventing HIV, some believe that the approval of Truvada as PrEP may have a negative effect on these prevention efforts, and lead to additional HIV infections.

Some women asked about the possibility of using PrEP have expressed concerns about possible side effects [14]. The studies of Truvada as PrEP have found that the most common side effects were nausea and vomiting. These side effects often occur among people taking a new HIV drug and often go away after a few weeks. While no serious side effects were found during the studies, Truvada can occasionally cause serious effects, including kidney problems, liver problems, lactic acidosis [15], lipodystrophy [16], and bone problems [17]. In addition, the long-term effects of many HIV drugs are not well understood, especially for those who are HIV-negative. Therefore, it is important to weigh the benefits of preventing HIV infection against the possibility of side effects from Truvada when considering whether to take Truvada as PrEP.

In addition, if HIV-negative people taking PrEP become HIV+, do not know it, and continue to take Truvada, there is the possibility that their HIV will become resistant [18] to Truvada and other similar HIV drugs. This not only can reduce treatment options for the individuals who become HIV+, but also can have serious consequences for public health, as Truvada-resistant HIV could then be spread to others.

Given the results of the FemPrEP and VOICE studies, it is clear that there is more to learn about the effectiveness of Truvada as PrEP in women. Some people believe we have enough knowledge to go ahead and begin using PrEP now, while others think we should wait until we have more proof that it is effective for women.

## **What Does PrEP Mean for Women at Major Risk of Becoming HIV-Infected?**

While we now have evidence that PrEP works in preventing 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 access and afford PrEP and making HIV testing [19] more widely available, since **only people who know they are HIV-negative can use PrEP safely**. If people use PrEP when they are already HIV+, they are much more likely to develop drug-resistant HIV, which they may then pass on to others. Having drug-resistant virus can also make it harder to treat HIV infection (see The Well Project's article on Resistance [18]).

PrEP is a promising tool that women can use to prevent HIV infection without their partners' cooperation. However, many questions remain. How will taking PrEP affect pregnancy and breastfeeding? How will women get HIV testing, especially if their partners refuse to get tested? Will they be able to get PrEP if they do not know their partners' HIV status? Will a man be more likely to refuse to use a condom if he knows his partner is taking PrEP? Will women be able to keep the PrEP drugs given to them? Some women worry that the drugs given to them might be taken away and given to another family member who is viewed as "needing them more." These and other questions are currently being explored in both research and advocacy efforts in the US and worldwide.

## Considering Taking Truvada as PrEP?

If you think PrEP may be a good option for you, here are a few questions you may want to talk over 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 Truvada's likely side effects and how will 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 Truvada a less-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 [20] with Truvada?
- What should I do if I become pregnant while on PrEP?

There is also a good checklist available at How to Talk to Your Doctor about PrEP [21]. You may also want to discuss the pros and cons of taking Truvada as PrEP compared to using condoms or other safer sex [13] techniques to reduce the risk of getting HIV. 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 in place 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 diseases [22].

***Adapted and updated from "PrEP: What Does It Mean for Women?" [23] with permission from Global Campaign for Microbicides and AIDS United.***

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## Additional Resources

Select the links below for additional material related to resistance.

What is PrEP? (video; whatisprep.org) [35]

Additional Layer of Love (SF AIDS Foundation) [36]

[Preservar la Pasión \(SF AIDS Foundation\)](#) [37]

[New guidelines recommend daily HIV prevention pill for those at substantial risk \(CDC\)](#) [38]

[PrEP Watch](#) [39]

[Pre-Exposure Prophylaxis \(CDC\)](#) [40]

[PrEPared to Fight: A Woman-Centered Approach to HIV Prevention \(BETA\)](#) [41]

[Pre-Exposure Prophylaxis \(AVAC\)](#) [42]

[WHO Guidance on PrEP](#) [43]

[Is PrEP the Right Choice for You? \(for men and transgender women who have sex with men; Project Inform\)](#) [44]

[Women and PrEP Using Daily Oral TDF/FTC or TDF ? What the Science Tells Us \(AVAC\)](#) [45]

[Is PrEP Right for Me? \(for women; BAPAC\)](#) [46]

[Bangkok Tenofovir Study \(CDC\)](#) [47]

[VOICE Trial?s Disappointing Result Poses Big Questions for PrEP \(AIDSmap\)](#) [48]

[PrEP Wars \(AIDSmap\)](#) [49]

[PrEP and PEP Patient Assistance Program \(NASTAD\)](#) [50]

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- [15] <http://www.thewellproject.org/hiv-information/lactic-acidosis>
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- [22] <http://www.thewellproject.org/hiv-information/sexually-transmitted-diseases-stds>
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- [47] <http://www.cdc.gov/nchhstp/newsroom/docs/PrEP-IDU-factsheet-508.pdf>
- [48] <http://www.aidsmap.com/VOICE-trials-disappointing-result-poses-big-questions-for-PrEP/page/2657862/>
- [49] <http://www.aidsmap.com/PrEP-wars-debating-pre-exposure-prophylaxis-in-the-gay-community/page/2572027/>
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