

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

Submitted on Mar 1, 2017



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## What Is PrEP?

PrEP stands for **P**re-**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.

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 [3] pills (contraceptives). When contraceptives are already in a woman's body when she is exposed to semen during sex, her chances of getting pregnant [4] 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 HIV-positive 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 when we talk about PrEP, we are referring only to 'oral PrEP,' or HIV drugs taken by mouth as prevention.

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

## **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 during condomless 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

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## Approval for Daily Oral 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 disoproxil fumarate 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.

The US Centers for Disease Control and Prevention (CDC) estimates that meeting the testing [8], treatment, and PrEP targets established by the National HIV/AIDS Strategy could prevent 185,000 new HIV infections in the US by 2020. If testing and treatment rates remained the same over the next few years, researchers predict expanded PrEP coverage alone could reduce new infections by 20 percent.

The World Health Organization (WHO) released updated guidelines in June 2016 [9] expanding earlier recommendations that daily oral PrEP be offered as an additional prevention method for all people at substantial risk of getting HIV. The WHO approves either Viread (tenofovir disoproxil fumarate) or Truvada for daily oral PrEP.

Each country must approve the use of Truvada or Viread for use as PrEP and determine how it will provide it. As of March 2017, PrEP is available in Australia, Canada, France, Israel, Kenya, Peru, South Africa, and the US. In the UK, the National Health Service, which had been expected to approve Truvada for use as PrEP, decided in March 2016 not to provide PrEP as part of its prevention services. Instead, the National Health Service announced in December 2016 that it will conduct a three-year trial of PrEP.

Gilead, the producer of Truvada, has applied for regulatory approval in several additional countries; these approvals are pending as of March 2017.

## Has PrEP Been Shown to Be Effective?

Several recent clinical trials [10] 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 [11] (women who assigned male at birth) 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 more than 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](#) [12]. 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 more than 5,000 women in South Africa, Zimbabwe, and Uganda, found all three methods ineffective in preventing HIV transmission.

The Partners Demonstration Project showed the near elimination of HIV transmission among over 1,000 serodifferent (serodiscordant) heterosexual couples in Kenya and Uganda. The project tested a combination of PrEP and treatment as prevention. The researchers offered PrEP as a 'bridge' ? the uninfected partner took PrEP while the partner living with HIV took the first six months of antiretroviral treatment. This strategy presumably protects the HIV-negative partner with PrEP during the time it takes for the partner living with HIV to become virally suppressed.

The project was completed in December 2016 and results are forthcoming. However, preliminary results through July 2014 noted only one new infection; this represents a 96 percent reduction in infections. Importantly, this reduction in infections applies to all infections, including those from someone other than one's regular sexual partner.

## Why Are Some 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](#) [13] and is proving true for PrEP as well. In the studies mentioned above, the key element in PrEP's success was [adherence](#) [14], 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 that showed a benefit had much higher rates of adherence. In all studies, people who took Truvada or tenofovir daily as prescribed were significantly less likely to acquire HIV when exposed during sex or injection drug use. The CDC reports that, in people at high risk for HIV who take PrEP consistently, the risk of HIV infection can be reduced by 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 our fact sheet on [clinical trials](#) [10].

## CDC and WHO Guidelines for PrEP Use

The CDC's 2014 [guidelines](#) [15] for the use of PrEP in the US 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 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 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 people who test negative for HIV take PrEP
- signs or symptoms of acute HIV infection
- decreased kidney function
- unknown hepatitis B <sup>[16]</sup> 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 <sup>[17]</sup>, 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. The CDC guidelines indicate that it ought to be used in combination with other HIV prevention strategies (i.e., condoms and safer injecting practices), to further decrease risk of acquiring HIV. PrEP is not intended to be used alone to prevent the spread of HIV.

No clinical studies have yet been conducted to assess how many days of PrEP it takes to achieve protection from HIV. However, there are models based on pharmacokinetics (the study of how medications behave in and move through the body) that give scientists some good estimates. To provide high-level protection, the CDC recommends that PrEP be taken for seven days for anal sex and 20 days for vaginal sex.

It is also important that all those being prescribed Truvada as PrEP have a negative HIV test <sup>[8]</sup> 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 <sup>[18]</sup> or who are trying to become pregnant <sup>[4]</sup> talk with their health care providers about the risks and benefits of taking Truvada for 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, or serodiscordant couples when they are interested in getting pregnant.

Both Viread and Truvada, when used as PrEP for HIV-negative women, appear safe in early pregnancy. Information from the Partners PrEP study conducted among serodiscordant heterosexual couples in Africa showed that babies conceived when the mother was taking

either Viread or Truvada did not experience negative effects on birth outcomes or infant growth. Women living with HIV have been taking these HIV drugs safely during pregnancy for many years to prevent their babies from getting HIV.

## 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 [13] or other safer sex [19] 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. To date, research has not shown that the use of PrEP has led to a reduction in the use of condoms or other safer sex methods.

Some women asked about the possibility of using PrEP have expressed concerns about possible side effects [20]. 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 days to 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]. Recent studies have shown that a small, but important decrease in bone mineral density (a measure of bone strength) can be seen in men and transgender women taking Truvada as PrEP.

As a result, researchers looked at PrEP study data to see if bone loss was reversible in study participants who stopped using Truvada. The data showed that, six months after stopping PrEP, participants' bone mineral density returned to pre-PrEP levels. While this is good news, these results may not serve as a good predictor of the reversibility of bone loss in women who take Truvada as PrEP because the iPrEX study was conducted among a group of predominantly young men. Given that women are more susceptible to bone loss and fracture than men, it is important that we understand the potential long-term effects of Truvada, especially for women who are HIV-negative.

Researchers also recently reported that people taking Truvada can experience modest reductions in kidney function. While Truvada is safe and well-tolerated in most people who use it for PrEP, those who are older [24] and/or who already have reduced kidney function when they begin using Truvada may benefit from more frequent monitoring. It is important to note that the reported studies included only transgender women and men who have sex with men.

In addition, if HIV-negative people taking PrEP acquire HIV, do not know it, and continue to take Truvada, there is the possibility that their HIV will become resistant [25] to Truvada and

other similar HIV drugs. This not only can reduce treatment options for the individuals who acquire HIV, but also can have serious consequences for public health, as Truvada-resistant HIV could then be spread to others. Having drug-resistant virus can also make it harder to treat HIV infection.

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?

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](#) <sup>[8]</sup> 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 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 can 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 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 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](#) <sup>[26]</sup> 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](#) <sup>[27]</sup>. You may want to discuss the pros and cons of taking Truvada as PrEP compared to using condoms or other [safer sex](#) <sup>[19]</sup> 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 infections or diseases (STIs or STDs) [28].

## New Developments in the PrEP Arena

Because studies have shown that the tenofovir (specifically tenofovir disoproxil fumarate, or TDF) in Truvada can lead to a reduction in kidney function and bone loss [23], researchers have begun testing another form of tenofovir called TAF (tenofovir alafenamide) for use as PrEP. Treatment with TAF, which can be given at lower doses than TDF while achieving the same level of HIV suppression, appears to produce less bone loss and less reduction in kidney function.

In April 2016, the FDA approved the use of Descovy, a combination of emtricitabine and TAF, in treating HIV. Gilead sponsored a clinical trial in November 2016 to evaluate whether TAF will be as safe and effective as Truvada when used as PrEP.

Researchers have also found promise in using the HIV drug maraviroc (Selzentry) as PrEP. A clinical trial of 188 US women found that the drug was safe and well-tolerated as PrEP, and that no new HIV infections occurred during the study. Maraviroc is an entry inhibitor, and does not negatively affect bone or kidney health in the way that the tenofovir in Truvada sometimes does.

Because some people do not want to take a pill daily, or have trouble remembering to do so, researchers have looked at a long-acting injectable form of cabotegravir (an integrase inhibitor). In the ÉCLAIR study, a phase IIa trial looking at safety, tolerability, and pharmacokinetics [29] (how medications behave in and move through the body), HIV-negative men at low risk for HIV were given three shots in the buttocks ? one every three months. Their satisfaction with the injectable treatment was high, and participants reported preferring the shots to once-daily oral PrEP. Based on the pharmacokinetics, an eight-week dosing schedule may be more appropriate. Nevertheless, the results are encouraging, as long-acting injectables may reduce the burden of adherence and improve HIV prevention [30].

***Adapted and updated from "PrEP: What Does It Mean for Women?" [31] 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 PrEP for Women.

[What Is PrEP? \(video; whatisprep.org\)](#) [51]

[US PrEP Locator \(Greater than AIDS; interactive map\)](#) [52]

[PrEP for Women in the US: A Collection of Resources \(for women, clinicians, advocates; HIVE\)](#) [53]

[SisterLove's Dazon Dixon Diallo: Our Language Around Risk Perception, PrEP & Women \(YouTube video\)](#) [54]

[US Women & PrEP Working Group \(PrEP Watch\)](#) [55]

[Knowledge & Attitudes of US Women and PrEP \(HIVE\)](#) [56]

[PrEP \(CDC\)](#) [57]

[Transcending Barriers for Safer Pleasure \(Project Inform\)](#) [58]

[Truvada as PrEP Medication Resource Guide \(HIVE\)](#) [59]

[Additional Layer of Love \(SF AIDS Foundation\)](#) [60]

[Preservar la Pasión \(SF AIDS Foundation\)](#) [61]

[PrEPared to Fight: A Woman-Centered Approach to HIV Prevention \(BETA\)](#) [62]

[Pre-Exposure Prophylaxis \(AVAC\)](#) [63]

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[Is PrEP Right for Me? \(for women; HIVE\)](#) [65]

[Women and PrEP: A Q&A with Judy Auerbach \(BETA\)](#) [66]

[PrEP Navigation Resources \(AIDSsource\)](#) [67]

[PrEP: A New Option for Women for Safer Loving \(Project Inform\)](#) [68]

[PleasePrEPMe.org - Find a PrEP provider, or add one to the locator](#) [69]

[The Questions about PrEP \(women.prepfacts.org\)](#) [70]

[Spreading the Word about HIV-Prevention for African-American Women \(NPR\)](#) [71]

[D.C. PrEP for Women Initiative](#) [72]

[10 Things Black Women Need to Know about PrEP \(The Black AIDS Institute\)](#) [73]

[Maraviroc Shows Potential for HIV PrEP in Women \(MDEdge\)](#) [74]

[Let's Talk about PrEP \(Black Women's Health Imperative\)](#) [75]

[FOR PROVIDERS: Billing Coding Guide for HIV Prevention - PrEP, Screening, and Linkage Services \(NASTAD\)](#) [76]

[FOR PROVIDERS: Family Planning Provider PrEP Planning Toolkit \(HIVE\)](#) [77]

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