



Pre-Exposure Prophylaxis (PrEP)

An Introductory Factsheet

November 2020

This fact sheet provides basic information on PrEP, an HIV prevention strategy for HIV-negative individuals. For more basic fact sheets in this series on HIV prevention strategies visit www.avac.org/intro.

What is PrEP?

Pre-exposure prophylaxis, or PrEP, is another way to help HIV negative people protect themselves from getting HIV. PrEP uses antiretroviral medication (ARVs)—drugs created to treat people living with HIV—for HIV prevention. Two PrEP products, given as daily oral pills, are currently being marketed. Another ARV as PrEP, cabotegravir, was found to be safe and efficacious when administered via a long-acting injection. This finding came from two studies, known as HPTN 083 and HPTN 084.) 083 enrolled cisgender men who have sex with men and transgender women. HPTN 084 enrolled cisgender women. A vaginal ring is yet another option that may be available soon. The ring slowly releases an ARV called dapivirine. Each month, the Dapivirine Vaginal Ring would be replaced with a new one for another month of protection. The ring is undergoing regulatory review.

Other PrEP strategies under development include a quick-dissolving vaginal film (containing ARVs) that can be inserted right before sex, and a long-acting implant that could offer protection for up to a year. This factsheet focuses on oral PrEP methods. For more on the other PrEP research underway, visit www.avac.org/infographic/arv-based-prevention-pipeline.

Among the two daily oral pills, the first to be approved, in 2012, uses a two-drug combination known as TDF/FTC, brand name Truvada. It is approved for all populations at risk of HIV. Another relies on a drug combination known as TAF/FTC, brand name Descovy. Its approval by the FDA excludes those at risk of HIV from receptive vaginal sex. A trial is being planned to gather the missing data needed to approve TAF/FTC in cisgender women. The Descovy trial design and the restricted approval by the FDA sparked criticism and discussion about planning for research that includes all populations that need HIV protection. For more information on this go to avac.org/ftaf and avac.org/podcast/f-taf-fuss.

Evidence shows both of these oral products can lower the chance of getting HIV by at least 90 percent.

National regulatory agencies in many countries have agreed that using oral PrEP is a good strategy for people at high risk of HIV to stay negative. In late 2015, the World Health Organization endorsed PrEP and now recommends it as another tool that HIV-negative people can use, along with voluntary medical male circumcision (VMMC) and male and female condoms, to protect themselves from HIV.

What's known about oral PrEP for cisgender men and transgender women?

In almost all of the PrEP studies conducted to date, the participants have been cisgender men and transgender women. These studies include clinical research trials, ongoing demonstration projects and data on the use of oral PrEP collected by national PrEP programs. Here's what we know from those studies. Caution: [This information may or may not apply equally to cisgender women and transgender men:](#)

- Daily oral PrEP is safe. No significant side effects have been observed in PrEP trials to date. Every medication, including aspirin, comes with some risk. But no major safety issues have been observed with the use of daily oral PrEP.

Resources

AVAC (www.avac.org)

PrEP Watch
(www.prepwatch.org)

Please PrEP Me (provider
directory)
(www.pleaseprepme.org)

- PrEP works if you take it on schedule. Adherence is essential. In every trial in which PrEP worked well, results showed that the people who took their PrEP pill on schedule had high levels of protection from HIV. Those who did not get little or no protection from PrEP.
- People with high rates of HIV risk behaviors can also adhere very well to PrEP. This is important because it shows “safer sex” does not just mean avoiding exposure to HIV. It can also mean choosing to take PrEP for protection if you do not always use condoms.
- TDF/FTC is highly protective in people of all genders when used correctly.
- If you take PrEP when you already have HIV — but don’t know it yet — you can develop resistance to the drugs in PrEP. Drug resistance is when a drug stops working in your body, and will no longer be effective treatment for HIV infection. You must get an HIV test before starting PrEP and every time you get a refill. The test makes sure you are still HIV-negative. For PrEP to work, you need to have a negative HIV test before you start, you need to take it as directed and get re-tested for HIV every time you get a refill. This way, there is very little risk of acquiring drug resistance.
- Research in gay men and other men who have sex with men showed that “event-driven” or “on-demand” dosing schedules can also be effective. The regimen tested taking two pills at least 2 hours before having sex and at least 2 more pills in the 24-48 hours after sex — instead of taking pills daily. When trial participants (gay men and a few transgender women) took 4-7 pills per week — regardless of whether they were in the “daily dosing” group or the “on demand” group, risk of HIV was greatly reduced.

What’s known about oral PrEP for cisgender women and transgender men?

- PrEP can protect the vagina from HIV as well as it protects the rectum — but it takes longer to build up protective levels of PrEP drugs in the vagina (and it takes more regular dosing to maintain). The US Centers for Disease Control (CDC) recommends that people with vaginas take PrEP daily for 20 days *before* relying on it for protection from vaginal HIV exposure. After that, daily doses can maintain protection.
- Cisgender women and transgender men also need to be more careful about not missing PrEP doses. If you have a vagina and take fewer than 6-7 PrEP pills per week, your protection level will drop. That is why “event driven” or “on demand” PrEP use is not recommended for women and transgender men.

What is the status of oral PrEP today?

Access to oral PrEP is expanding. In 2015, WHO issued guidelines recommending, among other things, PrEP access for those at high risk of HIV. WHO’s recommendation motivated some countries to expand their PrEP program.

While some medium and low-income countries have expanded their PrEP programs, such as Kenya and South Africa, approximately 25 percent of the UNAIDS target of 3 million people have initiated. The US President’s Emergency Plan for AIDS Relief (PEPFAR) has recognized the benefits that PrEP could provide to pregnant women, men who have sex with men, high-risk heterosexuals, and other high-risk populations. They continue to support PrEP scale-up directly through country operating plans. With adequate resources and international commitment, PrEP can become a major tool for HIV prevention worldwide.

- For insights on the full scope of PrEP use around the world, [AVAC’s PrEP tracker](#) offers quarterly updates on programs delivering oral PrEP, planned, current and completed.

Status of PrEP research

- For a broad review of completed and ongoing PrEP trials, visit www.avac.org/pxrd.
- For an overview of the pipeline for next-generation PrEP, visit www.avac.org/infographic/future-arv-based-prevention.

About AVAC | AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic. This fact sheet is part of the Women’s HIV Prevention series, created to address HIV prevention strategies and the advocacy needed to bring them to reality.