



# Pre-Exposure Prophylaxis (PrEP)

## An Introductory Factsheet

March 2015

For more basic fact sheets in this series on emerging HIV prevention strategies visit [www.avac.org/intro](http://www.avac.org/intro).

### What is PrEP?

Pre-exposure prophylaxis, or PrEP, for HIV prevention is a strategy that involves use of antiretroviral medications (ARVs) to reduce the risk of HIV infection in people who are HIV-negative. All of the current effectiveness and follow-on trials are testing tenofovir-based regimens—using either TDF/FTC (an antiretroviral containing tenofovir (TDF) and emtricitabine (FTC) that is sold under the brand name Truvada) or TDF (an antiretroviral pill marketed under the brand name Viread). *Based on the data that have been collected to date the US Food and Drug Administration (FDA) announced its approval of daily oral TDF/FTC for PrEP in 2012.*

### What are some key developments or conclusions from PrEP effectiveness and demonstration projects so far?

- There were no significant side effects observed in trials of tenofovir-based PrEP in any of the trials.
- Adherence is essential. Each of the trials that found benefit also found that people who had high levels of adherence had high levels of protection. Lower adherence was associated with low or no protection.
- PrEP is highly protective in both men and women.
- People with high rates of HIV risk behaviors can also be highly adherent to PrEP.
- Serodiscordant couples—one HIV-positive individual and one HIV-negative individual—can use PrEP as a “bridge” during the period when the HIV-positive individual begins ART, or during the period when he or she chooses not to take ART. PrEP can also be used by serodiscordant couples for safer conception.
- Individual cases of HIV drug resistance (which could emerge if a person acquired HIV while on PrEP and went on taking the single drug during the time before diagnosis) have been observed in trials to date. These appear to have occurred in participants who were HIV-positive and in the “window period” of early infection when they began taking PrEP. These individuals tested HIV-negative on the trials’ screening tests. This reinforces the importance of regular testing for anyone initiating or taking PrEP.
- TDF/FTC and TDF are both key drugs for treating HIV in HIV-positive people. Access to tenofovir-based PrEP can only be explored in the context of sustained ART access for HIV-positive people worldwide.
- Most of what is known about oral PrEP relates to daily use of oral TDF/FTC, and thus far this dosing is the only form approved and recommended for use by regulatory bodies. In February 2015, new data from a trial of an “event-driven” dosing schedule with four pills over three days was also shown to be effective in the context of penile-anal sex, but this is not yet being recommended for regular use. It is important to note that differences in drug absorption in vaginal and rectal tissue mean that data from gay men and MSM cannot be extrapolated to women whose primary exposure is via vaginal sex—and vice versa.

### What is the status of access to PrEP today?

- PrEP access varies worldwide. National factors include whether governmental regulatory agencies have approved PrEP and/or developed policies; whether Gilead Sciences (the manufacturer of Truvada) have registered TDF/FTC for treatment and prevention in country; and, whether governments or donors have incorporated PrEP into national plans and programs and/or whether there are demonstration projects happening in the country.

### Resources

AVAC ([www.avac.org](http://www.avac.org))

PrEP Watch  
([www.prepwatch.org](http://www.prepwatch.org))

PrEP Facts  
([www.prepfacts.org](http://www.prepfacts.org))

My PrEP Experience  
([www.myprepxperience.blogspot.com](http://www.myprepxperience.blogspot.com))

- *Some developments to date include:*
  - The Southern African HIV Clinicians Society issued guidance in June 2012 for use of TDF/FTC as PrEP in gay men and other MSM.
  - In July 2012, the US FDA approved daily oral TDF/FTC as PrEP. Gilead subsequently filed for approvals in Australia, Brazil, South Africa and Thailand; these approvals are still pending.
  - In July 2012, WHO released guidance on PrEP for serodiscordant couples, MSM and transgender women in the context of demonstration projects.
  - The US CDC released US Public Health Service (PHS) guidelines for the use of TDF/FTC as PrEP in May 2014. These updated the interim guidance documents on PrEP in gay men and other MSM, heterosexual adults at risk via sexual exposure and injecting drug users.
  - In 2014, Kenya incorporated PrEP for key populations into its Prevention Revolution Road Map.
  - In July 2014, WHO released consolidated guidelines for HIV prevention, treatment and care for key populations, which include a recommendation that PrEP should be part of a comprehensive prevention package available to men who have sex with men.
  - The European Medicines Agency (Europe’s regulatory body) is updating its concept paper on the development of medicines to prevent HIV infection.

### What is the status of PrEP research today?

There are a range of types of PrEP research underway. The data from the efficacy trials of tenofovir-based PrEP that guided US FDA and WHO regulatory decisions can be found at: [www.prepwatch.org/prep-research/prep-data-to-date](http://www.prepwatch.org/prep-research/prep-data-to-date). The page includes links to published data as well as a table that reviews data from all the studies, including those that did not find evidence of benefit. There are a range of ongoing approaches to PrEP research.

**Demonstration Projects:** More needs to be learned about the safety and effectiveness of PrEP in the real world. Demonstration projects are designed to gather information on safety, efficacy and program design for new interventions. They help guide subsequent larger-scale introduction. Such projects are planned or underway in a number of countries. For an up-to-date list of ongoing and planned PrEP evaluation studies visit [www.avac.org/resource/ongoing-and-planned-prep-evaluation-studies](http://www.avac.org/resource/ongoing-and-planned-prep-evaluation-studies). The first preliminary data from a PrEP demonstration project—Partners Demonstration Project in Kenya and Uganda—was reported in February 2015 and found that PrEP was even more effective than in the earlier clinical trial in the same community.

**Research on additional PrEP agents:** Studies are underway to evaluate the safety and efficacy of other ARV-based PrEP products, both other active drugs as well as other delivery systems, such as vaginal rings and long-acting injectables. For a comprehensive review of completed and ongoing PrEP trials, visit [avac.org/pxrd](http://avac.org/pxrd), and for a list of the different products in development, visit [avac.org/infographic/arv-based-prevention-pipeline](http://avac.org/infographic/arv-based-prevention-pipeline). Long-acting injectables could potentially be used in combination as treatment for people living with HIV and as long-acting PrEP. Evaluations of both of these modalities are underway. More information is at [avac.org/infographic/introduction-long-acting-injectables](http://avac.org/infographic/introduction-long-acting-injectables).

### PrEP advocacy in AVAC Report 2014/15: Prevention on the Line

Daily oral PrEP can save lives today and learning how to implement it will lay the groundwork for new prevention options. Recommendations include:

- Implement large-scale pilots linked to national programs for oral PrEP.
- Include a PrEP recommendation for women and adolescents in the next revision of the WHO Guidance on ARVs.
- Plan and program around rollout of other ARV-based prevention options.

Read more at [www.avac.org/report2014-15](http://www.avac.org/report2014-15).

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**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.