



# Pre-Exposure Prophylaxis (PrEP)

## An Introductory Factsheet

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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 involves use of antiretroviral medications (ARVs) to reduce the risk of infection in people who are HIV-negative. Daily TDF/FTC (a combination ARV marketed as Truvada) has been approved for use in populations at high risk of HIV by a number of national regulatory agencies. In late-2015, the World Health Organization recommended PrEP as an additional prevention option for HIV-negative people at substantial risk of HIV.

Daily oral PrEP is one type of PrEP strategy. Other formulations of ARVs for prevention in HIV-negative people under investigation include a vaginal ring containing dapivirine, long-acting injectables, vaginal films and more. This factsheet focuses on developments in oral PrEP. For more on the wider pipeline of PrEP research, visit [www.avac.org/infographic/arv-based-prevention-pipeline](http://www.avac.org/infographic/arv-based-prevention-pipeline).

### What's known about oral PrEP to date?

These lessons come from the clinical research trials, ongoing demonstration projects and from data collected via national programs.

- Daily oral PrEP is safe. There were no significant side effects observed in PrEP trials to date. Every medication, including aspirin, comes with some risk. But there are no major safety issues seen with daily oral PrEP.
- PrEP works if you take it. Adherence is essential. Each of the trials that found a 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.
- Resistance to PrEP drug(s) can arise if the person starts PrEP with undiagnosed HIV and/or if he or she acquires HIV and keeps on taking PrEP afterwards. As long as someone has a confirmed HIV-negative diagnosis and is taking PrEP consistently and correctly, along with periodic HIV testing, there is little risk of getting HIV and of acquiring drug resistance.
- Daily dosing is recommended. Data from IPERGAY, a trial of an “event-driven” dosing schedule (i.e., before and after sex), showed oral prep to be effective in the context of penile-anal sex. Data from Ipergay showed, on average, gay men who participated in the trial used four pills over seven days. According to trials looking at daily dosing, four happens to be the same number of pills needed per week to be protected in the context of anal sex. But, it is difficult to explain and offer a dosing strategy for one population (e.g. MSM engaged in anal sex) and not for others, so “event-driven” dosing is not widely recommended. 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.

### Resources

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

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

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

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

Oral PrEP access is expanding, albeit slowly. One catalyst is the expanding adoption of the WHO consolidated guidelines on ARVs for treatment and prevention. These guidelines recommend immediate initiation of ART for people living with HIV and PrEP for those at substantial risk. Most countries are primarily focused on implementing the ART component of these guidelines. However, once a national guideline indicates support for PrEP, access work can accelerate—this includes developing guidance for PrEP delivery, ensuring drug supply for PrEP programs, piloting programs and more. Various countries are at various stages of expanding PrEP access. You can visit [www.prepwatch.org](http://www.prepwatch.org) to learn more.

For a comprehensive look at the steps involved in securing PrEP access in country, check out our “access roadmap” at [www.prepwatch.org/policies-and-programs/access-roadmap](http://www.prepwatch.org/policies-and-programs/access-roadmap).

## What is the status of PrEP research today?

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 publications as well as a table that reviews data from all the studies, including those that did not find evidence of a benefit.

*Implementation and demonstration studies:* These projects gather information on safety, efficacy and program design for new interventions. They help guide subsequent larger-scale introduction. For an up-to-date list of ongoing and planned implementation and demonstration studies looking at PrEP visit [www.avac.org/resource/ongoing-and-planned-prep-evaluation-studies](http://www.avac.org/resource/ongoing-and-planned-prep-evaluation-studies).

*Research on additional PrEP agents:* Studies are underway to evaluate the safety and efficacy of other ARV-based PrEP products, including other active drugs and other delivery systems, such as vaginal rings and long-acting injectables. For a comprehensive review of completed and ongoing PrEP trials, visit [www.avac.org/pxrd](http://www.avac.org/pxrd), and for a list of the different products in development, visit [www.avac.org/infographic/arv-based-prevention-pipeline](http://www.avac.org/infographic/arv-based-prevention-pipeline).

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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.