



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.

What is PrEP?

Pre-exposure prophylaxis, or PrEP, for HIV prevention involves using antiretroviral medications (ARVs) to reduce the risk of infection in people who are HIV-negative. National regulatory agencies in several countries have approved the daily use of TDF/FTC (a combination ARV marketed as Truvada) by populations at high risk of HIV. In late 2015, the World Health Organization recommended PrEP as an additional prevention option for HIV-negative people at substantial risk of HIV.

Taking it as a daily oral pill is one way of using PrEP. Other strategies for using ARVs to help HIV-negative people stay negative are being developed and tested. These include a vaginal ring that releases dapivirine slowly over a month of wear, long-acting injectables, quick-dissolving 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.

What's known about oral PrEP to date?

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

- 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 there are no major safety issues seen with daily oral PrEP.
- PrEP works if you take it. Adherence is essential. Every trial that showed the effectiveness of PrEP also showed that people who took their daily pill consistently had high levels of protection from HIV. Lower adherence was associated with low or no protection.
- People with high rates of HIV risk behaviors can also be highly adherent to PrEP.
- PrEP is highly protective in people of all genders when used correctly.
- Resistance to PrEP drug(s) can arise if a person with undiagnosed HIV starts using PrEP. It can also occur if someone takes PrEP inconsistently, acquires HIV without knowing it, and continues taking PrEP. This is why providers require HIV testing before they refill PrEP prescriptions. As long as someone has a confirmed HIV-negative diagnosis, is taking PrEP consistently and correctly, and is receiving periodic HIV testing, there is little risk of getting HIV or of acquiring drug resistance.

Resources

PrEP Watch
(www.prepwatch.org)

AVAC
(www.avac.org)

PrEP Facts
(www.prepfacts.org)

- Taking PrEP daily is still recommended as the safest dosing schedule. A trial called IPERGAY tested the effectiveness of an “event-driven” dosing schedule (i.e., taking PrEP before and after sex instead of on a daily schedule). It showed that (a) oral prep is effective in the context of penile-anal sex and (b) on average, gay men in the trial used four pills on average over seven days. PrEP trials that look at daily dosing have found that four pills over seven days also happens to be the same number of pills needed per week to be protected in the context of anal sex. Nevertheless, event-driven dosing is not widely recommended.
- The World Health Organization (WHO) asserts that PrEP is fully protective after seven days of continuous use, regardless of the site of HIV exposure. The US Centers for Disease Control and Prevention (CDC), however, says that the available data show seven days as sufficient to provide anal protection but that 20 days of daily PrEP use is required to ensure full protection from HIV exposure during injection drug use and for women during vaginal sex. Because it is difficult to explain and offer one dosing regimen to one population at risk and a different regimen to other populations, most providers recommend daily dosing for at least seven days to acquire protection and do not suggest “event-driven” dosing to their patients. The differences in drug absorption in vaginal and rectal tissue also 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 oral PrEP today?

Oral PrEP access is expanding. 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 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.

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. 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.

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 a vaginal rings and long-acting injectables. For a comprehensive review of completed and ongoing PrEP trials, visit www.avac.org/pxrd, and for a list of the different products in development, visit www.avac.org/infographic/arv-based-prevention-pipeline.

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.