

Pre-exposure Prophylaxis (PrEP) for HIV Prevention

May 2014

Fast Facts

- Pre-exposure prophylaxis, or PrEP, is a way to help prevent HIV by taking a pill every day.
- People who are at substantial risk for HIV should talk to their doctor about PrEP.
- PrEP must be taken every day to be most effective.

Pre-exposure prophylaxis, or PrEP, is a way for people who do not have HIV to help prevent HIV infection by taking a pill every day. The pill contains two medicines that are also used, in combination with other medicines, to treat HIV. When someone is exposed to HIV through sex or injection drug use, PrEP can help stop the virus from establishing a permanent infection.

When used consistently, PrEP has been shown to greatly reduce the risk of HIV infection in people who are at substantial risk. PrEP is much less effective when it is not taken consistently.

PrEP is a powerful HIV prevention tool, and can be combined with condoms and other prevention methods to provide even greater protection than when used alone. People who use PrEP must commit to taking the drug daily and seeing their health care provider every 3 months for HIV testing and other follow-up.

PrEP Medicines

Most PrEP clinical trials have tested a combination of two antiretroviral drugs, tenofovir disoproxil fumarate (also called TDF, or tenofovir) and emtricitabine (also called FTC), taken in a single pill daily for HIV prevention. This combination pill (brand name **Truvada**) was approved by the US Food and Drug Administration (FDA) for use as an HIV treatment in 2004, and was approved as PrEP in July 2012. Some clinical studies have also evaluated the use of tenofovir on its own as a preventive drug, but this drug alone is not FDA-approved for PrEP.

Research Supporting PrEP Use

On May 14, 2014, the US Public Health Service released the first comprehensive clinical practice guidelines for PrEP (www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf). This follows the earlier publication of brief interim guidelines that were based on findings from several large national and international clinical trials. These trials evaluated PrEP among gay and bisexual men, heterosexual men and women, and injection drug users. All participants in these trials received pills containing either PrEP or placebo, along with intensive counseling on safe-sex behavior, regular testing for sexually transmitted diseases (STDs), and a regular supply of condoms.

In all of these studies, the risk of getting HIV infection was lower—up to 92% lower—for **participants who took the medicines consistently** than for those who did not take the medicines. (See our PrEP web page at www.cdc.gov/hiv/prevention/research/prep/ for a brief description of the clinical trials, with links to the published studies.)

Guidelines for PrEP Use

The new federal guidelines for health care providers recommend that PrEP be considered for people who are HIV-negative and **at substantial risk for HIV infection**.

For sexual transmission, this includes anyone who is in an ongoing relationship with an HIV-positive partner. It also includes anyone who 1) is not in a mutually monogamous relationship with a partner who recently tested HIV-negative, and 2) is a

- gay or bisexual man who has had anal sex without a condom or been diagnosed with an STD in the past 6 months; or
- heterosexual man or woman who does not regularly use condoms during sex with partners of unknown HIV status who are at substantial risk of HIV infection (e.g., people who inject drugs or have bisexual male partners).

For people who inject drugs, this includes those who have injected illicit drugs in past 6 months and who have shared injection equipment or been in drug treatment for injection drug use in the past 6 months.

Health care providers should also discuss PrEP with heterosexual couples in which one partner is HIV-positive and the other is HIV-negative as one of several options to protect the partner who is HIV-negative during conception and pregnancy.

For a summary of clinical indications and treatment recommendations for PrEP, see the Table on the next page.



Summary of Guidance for PrEP Use			
	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection:	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network 	<ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible:	<ul style="list-style-type: none"> Documented negative HIV test before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function, no contraindicated medications Documented hepatitis B virus infection and vaccination status 		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply		
Other services:	<ul style="list-style-type: none"> Follow-up visits at least every 3 months to provide: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment At 3 months and every 6 months after, assess renal function Every 6 months test for bacterial STDs 		
	<ul style="list-style-type: none"> Do oral/rectal STD testing 	<ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months 	<ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

Because no prevention strategy for sexually active people is 100% effective, patients taking PrEP are encouraged to use other effective prevention strategies to maximally reduce their risk, including:

- Using condoms consistently and correctly.
- Getting HIV testing with partners.
- Choosing less risky sexual behaviors, such as oral sex.
- For people who inject drugs, getting into drug treatment programs and using sterile equipment.

The more prevention options patients choose, the greater their protection. Some HIV prevention strategies, such as using condoms, can also provide protection against other STDs, which PrEP does not prevent.

PrEP is only for people who are at ongoing substantial risk of HIV infection. For people who need to prevent HIV after a single high-risk event of potential HIV exposure—such as unprotected sex, needle-sharing injection drug use, or sexual assault—there is another option called postexposure prophylaxis, or PEP. PEP must begin within 72 hours of exposure.

See our PEP Q&A (www.cdc.gov/hiv/basics/pep.html) for more information.

Supporting PrEP Uptake

To support the new guidelines and provider's supplement, CDC is leading efforts on multiple fronts to improve PrEP awareness and delivery in community settings. For example, the agency is implementing a pilot study examining practical requirements, costs, and impact of PrEP delivered at four federally qualified health centers, and will support state and local health departments by providing webinars and program guidance on using CDC funds to support PrEP implementation.

Many other groups will also play a vital role in achieving the full promise of PrEP. Health care providers can prescribe PrEP to those patients with indications for its use and increase awareness and uptake of PrEP for their patients who are at substantial risk. Advocates can raise PrEP awareness in at-risk populations, and groups implementing HIV prevention efforts can integrate PrEP education into existing programs.

Resources

- Basic PrEP Q&As (www.cdc.gov/hiv/basics/pep.html)
- Clinical Practice Guidelines (www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf)
- Clinical Practice Guidelines—Providers' Supplement (www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf)
- Basic PEP Q&As (www.cdc.gov/hiv/basics/pep.html)

Additional Resources

CDC-INFO
1-800-CDC-INFO (232-4636)
www.cdc.gov/info

CDC HIV Website
www.cdc.gov/hiv

CDC Act Against AIDS Campaign
www.cdc.gov/actagainstaids