

Preventing HIV by Taking One Pill Once a Day: Pre-exposure Prophylaxis (PrEP) Frequently Asked Questions – updated June 2016

1. Is it true that there is a medication that can actually PREVENT someone from becoming infected with HIV?

Yes. In 2012, after a series of clinical trials, the FDA approved the use of a medication called Truvada as pre-exposure prophylaxis (PrEP) for HIV. HIV PrEP is a six-point program that includes taking one pill once a day to prevent an uninfected person from becoming infected with HIV. Clinical trials have shown that when an uninfected person takes the medication consistently, his or her chance of becoming infected with HIV is greatly reduced. The PrEP medication, Truvada, must be prescribed by a physician and people interested in PrEP should only take the medication under the guidance of a qualified medical provider.

The six-point PrEP program for people who are HIV negative includes the following:

- HIV testing - to make sure the person was not recently infected with HIV;
- Taking one Truvada pill, once a day, every day;
- Using condoms to prevent STDs;
- Periodic STD screening;
- Education about how to reduce the risk of getting HIV and STDs through sex; and,
- Counseling and support for taking the medication regularly (adherence)

2. How often are the medical appointments for PrEP?

Below is the schedule of medical appointments for people who want to take the PrEP medication:

Initial Appointment: This first appointment includes education about PrEP, a discussion about your readiness to take PrEP, HIV testing and, if ready, medication is prescribed for an initial 30-day period.

One Month Follow-Up: At the first follow-up appointment one month later, the provider will discuss your experience on PrEP including adherence, side effects and your interest in continuing. At this visit, a prescription for 60 days may be given.

Three Month Follow-Up: At this visit, HIV testing and STD screening are conducted. The provider will review the importance of adherence and provide support for taking the medication every day. At this visit, a prescription for 90 days may be given.

Every Three Months: HIV testing and other assessments are repeated every three months. If you remain HIV negative and express continued commitment to take the medication daily, a prescription for 90 days may be given every three months for as long as you prefer.

3. When I first start taking the medication, how many days do I have to take the medication in order for it to protect me from an HIV exposure?

The PrEP medication must reach and maintain a certain level in the blood and the body's mucus membranes to provide protection. The amount of time it takes may vary from person to person. For people engaging in anal intercourse, the medication must be taken each day for 7 days to reach the level needed for full protection. For the receptive partner in vaginal intercourse, it takes approximately 21 days of taking the medication consistently to reach the level of full protection in vaginal tissue.

4. How well does PrEP work?

The PrEP medication works very well at preventing HIV infection. It is most effective when taken every day. Missing only an occasional dose may not impact how well the medication works but the more days a person misses a dose, the less protective the medication will be for any exposures that occur during that time period. It is not recommended that a person start and stop the PrEP medication based on when he or she anticipates engaging in condomless sex. A person considering PrEP should only begin once he or she has made a commitment to taking the medication daily. If you are interested in more specific data regarding how well PrEP works, below is a list of links to the major clinical trials.

- iPrEX: Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. [Preexposure chemoprophylaxis for HIV prevention in men who have sex with men](#). *N Engl J Med* 2010;363(27):2587-99.
- TDF2: Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. [Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana](#). *N Engl J Med* 2012;367(5):423-34.
- Partners PrEP: Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. [Antiretroviral prophylaxis for HIV prevention in heterosexual men and women](#). *N Engl J Med* 2012;367(5):399-410.
- Bangkok Tenofovir Study: Choopanya K, Martin M, Suntharasamai P, et al; [Bangkok Tenofovir Study Group](#). [Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand \(the Bangkok Tenofovir Study\): a randomised, double-blind, placebo-controlled phase 3 trial](#). *Lancet* 2013;381(9883):2083-90.

5. How would I know if PrEP is right for me?

PrEP is one of many options for preventing HIV infection. HIV infection is passed through sharing injection drug equipment or through sexual intercourse. People can avoid HIV infection by: 1) not sharing drug injection equipment (needle, syringe, cooker, cotton, etc), and 2) having only one monogamous sex partner whose HIV status is known to be negative. If you have sex with more than one partner, consistent and correct use of condoms every time you have sex

can prevent HIV infection. New York State Clinical Guidance suggests that medical providers discuss PrEP as an HIV/STD prevention option if you:

- Are a gay man or trans-woman who has unprotected anal intercourse;
- Are in a sexual relationship with a partner who has HIV;
- Are a trans-person who has unprotected anal or vaginal sex;
- Sometimes trade sex for money, drugs or housing;
- Inject drugs or share injection equipment;
- Use stimulant drugs such as methamphetamine and have unprotected sex;
- Have had more than one STD in the last year; or,
- Have taken HIV post-exposure prophylaxis more than twice in the last year.

It is important to weigh the pros and cons and have an open and honest conversation about PrEP with your medical provider before beginning PrEP. PrEP is always voluntary and only you can determine if PrEP is right for you.

6. I prefer sex without a condom so I don't always use them. Would PrEP still work to prevent HIV if I don't use condoms?

If a person takes the PrEP medication consistently, it provides a high level of protection against HIV. Condoms are a part of the six-point PrEP program in order to provide protection against STDs. People who are on the PrEP medication but are not using condoms may be exposed to an STD. It is important to be aware that having an STD can increase a person's chance of becoming infected with HIV if he or she is exposed to HIV. If you are not using condoms regularly, it would be especially important to have regular screening for STDs and to get treated as soon as possible if infected with an STD. Learning about the signs and symptoms of STDs can be helpful in identifying whether you or one of your partners has an STD. Condom use is recommended as part of PrEP but choosing to not use condoms routinely should not prevent you from being prescribed Truvada.

7. How would I pay for PrEP?

Medicaid and many private health insurance plans will cover the cost of PrEP, including the medication, medical appointments and lab tests associated with PrEP. If you have Medicaid, your medical provider must apply for prior approval to pay for the medication. Prior approval is granted for three months at a time and must be renewed in order for Medicaid to continue paying for the medication. If you have private health insurance, check with your plan to see if PrEP is covered and ask about the amount of any medication co-pay. For people without access to health coverage, a medication assistance program is available from the drug manufacturer. To find out if you are eligible for the Gilead medication assistance program, visit <http://www.truvada.com/truvada-patient-assistance> or call 1-855-330-5479. If you have health coverage but the amount of medication co-pay would present a financial challenge, you may be

eligible for a Co-pay Coupon Card from the drug manufacturer. Visit <http://www.gileadcopay.com/> or call 1-877-505-6986 for more information.

The NYSDOH *PrEP Assistance Program* (PrEP-AP) fills an important gap for people who are uninsured or underinsured by covering the cost of PrEP-associated health care and laboratory services provided through enrolled providers. PrEP-AP does not pay for the cost of medications but will give you information about how to apply to the drug manufacturer's patient assistance program, co-payment assistance program, or other resources that help cover the cost of medications. To find out more about PrEP-AP, call 1-800-542-2437.

Without health coverage or financial assistance from the drug manufacturer, the cost of the PrEP medication is between \$15,000 and \$18,000 per year.

8. Can I get the PrEP medication from my regular doctor or do I have to go to a special doctor?

It depends on your doctor. Any physician, nurse practitioner or physician assistant can prescribe PrEP but not all will be familiar with the six-point program. The New York State Department of Health is preparing a directory of medical providers that prescribe PrEP. That directory can be found at:

<http://www.health.ny.gov/diseases/aids/general/prep/>.

9. What are the side effects of the medicine?

The PrEP medication, Truvada, has been included in different HIV treatment regimens for ten years and it is recognized as a well-tolerated medication with few side effects. The main side effect felt by people in the PrEP clinical trials was mild nausea. Only a small number of people found the side effects serious enough to stop taking the medication. Lab tests to monitor kidney functions every six months are part of the medical protocol for PrEP. People who are on PrEP, or considering PrEP, should discuss possible side effects with the medical provider and weigh side effects against the potential benefits of PrEP in reducing the chance of HIV infection and the resulting life-long antiretroviral treatment.

10. My risk for HIV happens only periodically – like on certain weekends. Can I only take the medication when I am going to have unprotected sex?

You should not start and stop the PrEP medication based on when you think you will be exposed to HIV. Each individual is different and it is not specifically known how long before or after an exposure you have to take the medication to be fully protected (see question #9). Only people with a strong commitment to taking PrEP regularly should take the medication.

11. Would I have to take PrEP for the rest of my life? What if I want to stop?

PrEP is not intended to be a life-long program. Rather, it is a program where the medical care provider prescribes the medication for up to three months at a time, with as many renewals of the prescription as you and the provider agree to. For many people, over time life circumstances may change and the risk for HIV may be reduced or eliminated. You should discuss the issue of how long you want to take the PrEP medication with your medical provider. If for any reason you want to stop taking the PrEP medication, consult with the doctor who prescribed it for you or another doctor familiar with PrEP. Generally speaking, people should continue taking the PrEP medication for 28 days after any possible exposure to provide protection from that exposure.

12. I have sex partners who are living with HIV and have an undetectable viral load because they are on HIV treatment. Do I still need to take PrEP?

Having an undetectable viral load decreases the chances of passing the virus to others but it does not eliminate the chance. Consistent, correct use of condoms is an option that will provide protection against infection. Taking the PrEP medication will provide another level of protection against HIV, especially if condoms are not used consistently. PrEP is recommended for HIV negative people who engage in sex with partners who are living with HIV.

13. If I drink alcohol and/or use recreational drugs, is it safe to take Truvada for PrEP?

Alcohol and recreational drugs are not known to interact with Truvada for PrEP. It is safe to take PrEP after “partying.”

14. What happens if I do become infected with HIV? Will the PrEP medication treat my HIV infection?

Truvada, the PrEP medication, is not effective alone for treating HIV infection. If you become infected with HIV while taking Truvada you should stop taking it. The provider who conducted the HIV test should either provide HIV medical care or refer you to a medical provider who can provide HIV care. The HIV care provider will conduct lab tests and determine the most effective regimen to treat your HIV infection. There is no evidence that having taken PrEP will impact the effectiveness of your HIV treatment. People who were on PrEP and become infected can be successfully treated with HIV medications.

15. Since Truvada alone is not effective at treating HIV, is it possible that taking Truvada for PrEP could lead to my developing drug resistant HIV if I become infected? Could it lead to higher levels of drug resistant virus in the community?

HIV testing is a critical component in the six-point PrEP program. HIV testing is done before a

person begins PrEP to ensure that only HIV negative people are prescribed the PrEP medication. Periodic HIV testing for everyone taking PrEP ensures early identification of anyone who becomes infected so that the person can stop taking Truvada and avoid the development of drug resistance. If a person on PrEP develops HIV infection, drug resistance testing is done to determine an effective treatment regimen. Evidence shows that people who were on PrEP and become infected can be successfully treated. There is no evidence supporting the concern that PrEP can lead to higher rates of drug resistant virus in the community.