

Pre-exposure prophylaxis (PrEP)

Summary

Pre-exposure prophylaxis, or PrEP, may be a way for an HIV-negative person who is at risk of HIV infection to reduce their risk of becoming infected. It involves taking anti-HIV medications on a regular basis. PrEP provides only partial protection from HIV infection and is not intended to replace consistent condom use. PrEP has not been approved by Health Canada and is not widely available.

What is PrEP?

PrEP is a promising new HIV prevention method. It involves an HIV-negative individual taking anti-HIV drugs in an effort to reduce their risk of becoming infected with HIV. A person at risk of infection would need to take PrEP drugs on a regular basis—starting before being exposed to HIV and continuing afterwards. A person using PrEP needs to take the drugs exactly as directed. They also need to commit to regular doctor’s appointments, so that any side effects can be monitored and they can be tested for HIV and other sexually transmitted infections.

There are several types of PrEP being investigated. PrEP drugs may be available in a variety of formats, including pills, a vaginal/rectal gel or injections. The drugs may need to be taken every day, or before and after sex, or intermittently (once or twice a week).

Does PrEP work?

Several PrEP research studies have been completed and some are still underway.

Each study is looking at the safety and effectiveness of a particular type of PrEP (such as pills and gels) in a specific population (such as gay and bisexual men, injection drug users, or heterosexual men and women). Some types of PrEP look promising for specific populations. Research shows that PrEP is much less effective if not taken consistently.

Pills

In some research studies, HIV-negative people are asked to take an anti-HIV pill every day to see if it will provide some protection against HIV infection. This type of PrEP is similar to the birth control pills women take daily to prevent pregnancy or the medications people travelling to certain tropical countries take daily to prevent malaria. These studies suggest that PrEP can reduce the sexual transmission of HIV for HIV-negative men and women, including gay and bisexual men, and heterosexual men and women.

In one study, HIV-negative gay and bisexual men who took an anti-HIV pill (containing tenofovir and emtricitabine) every day reduced

their risk of HIV infection by 44%. Men who took the pill more consistently reduced their risk by as much as 73%. In other studies, the same PrEP strategy provided similar levels of protection for heterosexual men and women. An anti-HIV pill containing tenofovir alone was also found to be effective for heterosexual men and women. Surprisingly, one study found that an anti-HIV pill (containing tenofovir and emtricitabine) taken every day *did not* work for women. Women in this study may not have been taking PrEP consistently.

Additional studies are needed to determine if the pill can also protect people who are at risk of HIV infection from injection drug use.

Vaginal gels

Other research studies are looking at gels that contain anti-HIV drugs. One study found that HIV-negative women who applied an anti-HIV gel (containing tenofovir) into the vagina before and after sex reduced their risk of infection by 39%. Women who applied the gel more consistently reduced their risk of infection by as much as 54%. More studies are needed to confirm these findings and to determine whether the gel would provide more protection if used every day and whether it would work if used rectally.

Is PrEP intended to replace condoms and other ways of preventing HIV?

No. People who use PrEP may be *partially* protected from HIV infection but not *fully* protected. Also, PrEP is not expected to protect against other sexually transmitted infections, such as gonorrhea, chlamydia or syphilis. This means that it will still be possible for a person using PrEP to become infected with HIV and other sexually transmitted infections.

People who use PrEP will also need to use other prevention methods, such as condoms, to make sure that they do not become infected

with HIV or other sexually transmitted infections. If people using PrEP stop using condoms or clean needles, their risk for HIV infection may actually increase because PrEP is less effective than other prevention methods.

Is PrEP a “morning-after” pill for people accidentally exposed to HIV?

No. For people who may have been exposed to HIV (at work or through unprotected sex, for example), there is another prevention method called *post-exposure* prophylaxis (PEP). With PEP, an HIV-negative person needs to start taking a combination of anti-HIV drugs as soon as possible (within 72 hours) *after* a potential exposure to HIV and must continue taking the drugs every day for four full weeks.

It is easy to confuse PEP and PrEP because they both involve the use of anti-HIV drugs by HIV-negative people to prevent HIV infection. With PrEP, a person will need to recognize that they are at risk of infection and begin taking anti-HIV drugs on a regular basis *before* an exposure occurs.

What are the advantages of PrEP?

PrEP could provide an additional prevention method that could be used in combination with other prevention strategies, to help protect a person from HIV infection.

Although PrEP is not intended to replace other methods for HIV prevention, in certain situations, it may provide an alternative form of prevention for those who do not use condoms or new needles regularly. For example, PrEP may provide another method of protection for those who are unable to negotiate condom use with their partner, people in serodiscordant relationships (where one partner is HIV-negative and the other is HIV-positive) who wish to conceive a child, or people who inject drugs but are not able to use new needles.

What are some of the safety concerns associated with PrEP?

Drug resistance

A person could develop drug resistance if they are HIV-positive (and don't know it) when starting PrEP or they become HIV-positive while taking PrEP. Once a person's HIV becomes resistant to the PrEP drugs, those same anti-HIV drugs may not work for treating their HIV.

A person who uses PrEP needs to follow the medication schedule that their doctor recommends. If the schedule is not followed—if a person misses too many doses or experiments with another schedule—then the risk of becoming infected and developing drug resistance can increase.

Side effects

Anti-HIV drugs cause side effects, which may negatively affect a person's quality of life and ability to adhere to their medication schedule. Although the drugs selected for PrEP studies are generally better tolerated than other drugs used to treat HIV, they are still capable of causing mild to severe side effects. Some of the more common side effects include nausea, vomiting, diarrhea, headache and dizziness.

A false sense of security

Another concern is that people may feel a false sense of security when using PrEP and decide to engage in more risky activities. If people using PrEP decide to have sex with more partners, use condoms less often or share needles more frequently, then their overall risk for HIV infection (and other sexually transmitted infections) may increase because PrEP does not provide complete protection.

Now that studies have found that PrEP can reduce the risk of HIV infection, *where* will people be able to get it?

The anti-HIV drugs used for PrEP must be prescribed by a doctor, who can provide them in a safe and informed way. Obtaining anti-HIV drugs from other sources—from a friend, people at parties, or over the internet—may be dangerous. Anti-HIV drugs obtained from these sources may be fake, of poor quality or contain a different medication than expected.

Not all anti-HIV drugs may be appropriate for PrEP. Researchers are currently looking at only two anti-HIV drugs (there are more than 25 available) and are asking study participants to follow a specific medication schedule. Obtaining PrEP from a doctor will help ensure that a person is prescribed the right medications at a safe dose and provided with accurate information on how to use them safely and effectively.

Incorrect use of anti-HIV drugs can cause serious, even life-threatening, reactions in some people. These drugs can also interact with other prescription drugs, recreational drugs and other substances. These interactions can be harmful, even when there are no symptoms. In rare cases, when not taken correctly, anti-HIV drugs have caused fatal overdoses.

Regular testing and medical check-ups will help ensure that a person remains healthy while using PrEP. To avoid drug resistance, regular HIV testing will be needed to ensure that a person is HIV-negative before starting PrEP and that they remain HIV-negative while using it. If a person becomes HIV-positive, they will need to stop using PrEP.

Now that studies have found that PrEP can reduce the risk of HIV infection, *when* will people be able to get it?

It is difficult to predict if and when PrEP will be widely available from healthcare providers. Although some studies have found that PrEP

works, additional research studies may need to be completed to confirm the findings, in the same populations and in other populations.

If repeated trials show that PrEP is effective, an extensive regulatory and approval process, involving the government and pharmaceutical companies, will be required before PrEP becomes widely available. There is an ongoing debate about how much protection PrEP would need to provide in order for it to be approved.

Although anti-HIV drugs have not been approved for the prevention of HIV (as PrEP), they have been approved for the *treatment* of HIV. Once a drug has been approved, it can be prescribed by doctors for other conditions. This practice is called “off-label” use of prescription drugs. Some forms of PrEP can be prescribed by doctors in this way.

Because of the high cost of anti-HIV drugs, advocacy may be needed to get PrEP covered by provincial and territorial drug programs and ensure that people who need PrEP can access it.

Credits

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