Pre-exposure prophylaxis

FACT SHEET

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Summary

Pre-exposure prophylaxis, or PrEP, is a highly effective HIV prevention strategy that HIV-negative people can use to lower their chance of getting HIV. Use of PrEP involves taking antiretroviral (anti-HIV) drugs and having regular medical appointments for monitoring and support. When PrEP is taken as prescribed, the risk of HIV transmission is extremely low. PrEP is generally safe and well tolerated and is available by prescription. In Canada, PrEP is currently only available in pill form (also known as oral PrEP) but other types of PrEP may become available in the future.

What is PrEP?

PrEP is an HIV prevention method that uses antiretroviral (anti-HIV) drugs to help prevent HIV when taken by HIV-negative people. PrEP is available as a prescription pill containing two antiretroviral drugs. These same pills are also used together with other medications in people living with HIV for HIV treatment. An HIV-negative person can lower their chance of getting HIV by taking PrEP regularly, as prescribed. Most people take PrEP every day but gay, bisexual and other men who have sex with men (gbMSM) can also choose to take PrEP on-demand. On-demand (or intermittent) PrEP means taking pills only on days before and after having sex (see *What is on-demand PrEP and who does it work for?* for more information).

In general, PrEP involves taking antiretroviral drugs on an ongoing basis, both before and after potential exposure to HIV. PrEP is not the same as post-exposure prophylaxis (PEP), which involves taking antiretroviral drugs to help prevent getting HIV ***after*** a potential exposure has happened.

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Differences between PrEP and PEP	
PrEP	**PEP**
Taken both **before and after** potential exposure to HIV	Taken **as soon as possible** (up to a maximum of 72 hours) **after** a potential exposure to HIV
Usually taken **every day on an ongoing basis** (though some gbMSM take on-demand PrEP)	Taken **every day for 28 days**
A combination of **two** HIV medications	Usually a combination of **three** HIV medications
Intended for regular use as an **ongoing HIV prevention method**	Intended to be used to prevent HIV transmission from **a single** exposure

What types of PrEP are available?

Two PrEP pills are approved by Health Canada. Both pills contain emtricitabine (also called FTC) plus one other drug – either tenofovir disoproxil fumarate (also called TDF) or tenofovir alafenamide (also called TAF). TDF + FTC (brand name Truvada) was the original form of PrEP and it is available in generic drug formulations. The other combination, TAF + FTC, is only available as the brand name drug, called Descovy.

TDF + FTC has been approved for daily use, to reduce the risk of sexual HIV transmission in people at high risk for HIV infection; TAF + FTC is only approved for daily use by gbMSM. However, PrEP can be prescribed in other ways that have not been approved, called "off-label" prescribing. For example, healthcare providers can prescribe PrEP (TDF + FTC) for on-demand use by gbMSM, or for daily use by people who inject drugs to reduce the risk of HIV transmission via shared drug use equipment.

How does PrEP work to help prevent HIV?

PrEP interferes with the pathways that HIV uses to cause a permanent infection. For HIV to cause infection the virus must enter the body, infect certain immune cells, make copies of itself (replicate) within these immune cells, then spread throughout the body.

When PrEP is taken consistently and correctly, antiretroviral drugs get into the bloodstream and genital and rectal tissues. The drugs work to help prevent HIV from replicating within the body's immune cells, which helps to prevent a permanent infection.

For PrEP to help stop HIV replication from happening, drug levels in the body must remain high. If pills are not taken consistently as prescribed there may not be enough medication in the body to reduce the risk of HIV infection.

How well does daily PrEP work?

PrEP using TDF + FTC

A large body of evidence shows that daily PrEP (using TDF + FTC) is highly effective at reducing the risk of HIV acquisition when it is used consistently and correctly. Daily PrEP was initially proven effective on the basis of evidence from randomized controlled trials (RCTs) conducted in gbMSM, in transgender women and in heterosexual men and women. In addition, limited evidence from one RCT found that daily PrEP (with TDF alone), is effective at reducing the risk of HIV transmission among people who inject drugs when it is used consistently and correctly.

In all the RCTs, PrEP was provided as part of a comprehensive prevention package that included regular medical appointments for HIV testing, testing and treatment for sexually transmitted infections (STIs), risk reduction counselling and adherence counselling.

The overall reduction in HIV risk provided by PrEP in the RCTs ranged from zero to 86%, but these analyses did not consider whether people were taking the study drug as prescribed. Adherence (taking medications exactly as prescribed) is crucial

for PrEP to work. The evidence shows that higher adherence is associated with greater protection. To demonstrate the importance of adherence, some of these studies conducted adherence analyses that compared the risk of HIV infection among participants who had PrEP drugs detected in their blood with the risk among those who did not. These analyses found that the use of PrEP (determined by detectable drug in the blood) reduced the risk of sexual HIV transmission by between 85% and 92% among gbMSM and heterosexual men and women.

When taken consistently, PrEP appears to prevent nearly 100% of sexual HIV transmission. Among all the studies and several million people now using PrEP globally (including all genders and sexual orientations), there have been very few documented cases of sexual HIV transmission in people who are adherent to PrEP.

For people who inject drugs, one RCT has evaluated the use of PrEP (with TDF alone). This study found a 49% overall risk reduction in people who inject drugs; however, HIV risk was reduced by 84% among people who used TDF consistently compared with those who did not. It should be noted that TDF alone is not recommended as PrEP for any population. Only daily PrEP with TDF and FTC is currently recommended in Canada for use by people who inject drugs. Besides this study, there is limited data available on PrEP use by people who inject drugs, but the Canadian PrEP guideline recommends that PrEP can be considered for use by people who inject drugs if they are at high risk for HIV.

PrEP using TAF + FTC

Data on the effectiveness and safety of TAF + FTC as PrEP come from one RCT with gbMSM and a small number of transgender women. Participants were randomly assigned to take either daily TAF + FTC or daily TDF + FTC. This trial found the newer version of PrEP (TAF + FTC) to be "non-inferior" to the original (TDF + FTC) – meaning it works just as well, in the population studied (gbMSM and transgender women). The efficacy and safety of the TAF + FTC PrEP formulation has not been studied for preventing HIV among people who have vaginal (or frontal) sex or among people who inject drugs.

What is on-demand PrEP and who does it work for?

On-demand (or intermittent) PrEP means taking pills only on days before and after having sex. It is sometimes referred to as 2-1-1 dosing. This involves taking:

- **2** pills between 2 and 24 hours *before* sex
- **1** pill 24 hours *after* the first dose
- **1** pill another 24 hours later

If a person continues to have sex, they should continue to take a pill every 24 hours until two days after the last time they have sex.

On-demand PrEP has only been studied using TDF + FTC. Evidence from several studies shows that it reduces the risk of sexual HIV transmission among gbMSM who take it consistently and correctly. No studies have been conducted to evaluate the effectiveness of this particular on-demand regimen in other populations.

An RCT called IPERGAY evaluated the 2-1-1 on-demand method and found an 86% reduced risk of HIV infection among gbMSM in the on-demand PrEP group compared with those in a placebo group (two participants in the PrEP group got HIV but neither had PrEP drugs detected in their blood, demonstrating that they were not actually taking the study drug). Men in the RCT took four pills a week on average, implying that they were having sex about once a week. When the RCT was completed, IPERGAY continued as an open-label extension with all participants offered on-demand PrEP. Results from the open-label phase showed that one more HIV transmission occurred among 362 participants, over 515 person-years of follow-up (equivalent to following 515 people for one year). None of the three participants who got HIV over the entire course of the study had PrEP drugs detected in their blood, which means they were not adherent.

Since IPERGAY, several demonstration projects in Europe have offered participants the option of choosing on-demand or daily PrEP. These studies have found no HIV infections among gbMSM and transgender women taking on-demand PrEP consistently and correctly.

The Canadian PrEP guideline states that on-demand PrEP using TDF + FTC can be considered as an alternative form of PrEP for gbMSM only. This could be a good option for men who know in advance when they will have sex. There is no evidence to support the use of on-demand PrEP by other populations. For people who have vaginal (or frontal) sex and people who use drugs, it is important to take PrEP every day and not miss any pills.

How well does PrEP work for different types of sex?

Evidence from RCTs suggests that daily PrEP is extremely effective for vaginal (or frontal) and anal sex when it is used consistently and correctly, but that adherence may be more important for people having vaginal sex.

For PrEP to work optimally, drug levels in the body need to be high enough to prevent HIV infection. There is some evidence showing that the drugs in PrEP take longer to reach maximum levels in vaginal tissues compared with rectal tissues and that drug levels are lower in vaginal tissues. This suggests that daily dosing of PrEP may be more important for cisgender women or transgender men potentially exposed to HIV through vaginal or frontal sex to maintain sufficient drug levels to help prevent HIV infection.

What else is involved with taking PrEP?

PrEP is part of a comprehensive HIV prevention strategy that involves routine medical appointments and should include access to other supports and services such as free condoms and safer injecting supplies and referrals to other services (e.g., mental health services, opioid substitution therapy).

The first step is to make sure a person is HIV negative before they start PrEP. They should also be tested for STIs and hepatitis A, B and C, and they should have their kidney function checked.

A person using PrEP needs to take it as prescribed by their healthcare provider. They must also attend regular medical appointments, typically once after the first 30 days on PrEP and then every three months thereafter. These regular visits are necessary so that the person can be tested for HIV and other STIs, monitored for drug side effects and receive ongoing adherence and risk-reduction counselling.

Who should take PrEP?

PrEP can be used by people who are HIV negative and at high risk for HIV infection. Canadian guidelines define this as:

- men or transgender women who report condomless sex with men and have any of the following:
  - infectious syphilis or rectal bacterial STI in the last year
  - use of post-exposure prophylaxis (PEP) more than once
  - a high score on a valid HIV risk assessment tool
- any person who has condomless anal or vaginal sex with a partner with HIV who is not on treatment and virally suppressed
- people who share injection drug use equipment

The above list includes people who are likely to be at the highest risk of getting HIV. These criteria can be used to identify PrEP candidates but should not be used to deny someone access to PrEP. Some people may not feel comfortable disclosing their sexual or drug use behaviours to a healthcare provider, but are in fact good candidates for PrEP.

How can people at high risk of getting HIV access PrEP?

An HIV-negative person who wants to take PrEP needs to get a prescription from a healthcare provider who is willing to provide the necessary medical follow-up. PrEP does not need to be prescribed by an HIV specialist. A person may be able to access PrEP from a sexual health clinic, a specialized HIV clinic, or from their family doctor.

The cost of TDF + FTC as PrEP is covered by most public and some private health insurance plans in Canada. Since TDF + FTC is available in generic

drug formulations, this has brought down the cost to as low as about $250 a month, without insurance coverage. However, TAF + FTC is currently not covered by most public health insurance plans in Canada. Since TAF + FTC is only available as the brand name drug (Descovy), it is much more expensive, around $1,000 to $1,200 a month.

What are some of the safety concerns associated with taking PrEP?

Side effects

Although the drugs used in PrEP are generally well tolerated, they are still capable of causing side effects. In clinical trials these side effects were generally mild and temporary, and they affected only between 1% and 10% of participants. Some of the possible side effects include nausea, vomiting, diarrhea, headache and dizziness. Side effects caused by PrEP may negatively affect a person's quality of life and ability to adhere to their medication schedule.

The use of PrEP has been associated with more concerning toxicities in a small number of people, such as small decreases in kidney, bone and, rarely, liver health. Promisingly, these changes were reversible after stopping PrEP. The TAF + FTC formulation (Descovy) is generally not associated with the kidney and bone risks of TDF + FTC.

Drug resistance

A person can develop resistance to the drugs in PrEP if they are HIV positive (and unaware of their positive status) when they start PrEP. Drug resistance can limit a person's future treatment options, so it is important to ensure that they are HIV negative before starting PrEP.

A person can also develop drug resistance if they become HIV positive while taking PrEP. In clinical trials, the risk of developing drug resistance was low for people who were HIV negative when they started taking PrEP.

This is why regular HIV testing is necessary while taking PrEP. If a person using PrEP gets HIV, PrEP must be discontinued as soon as possible, to reduce the risk of developing drug resistance. If a person's HIV becomes resistant to the drugs in PrEP, those same drugs may not work to treat HIV.

Can PrEP be stopped and restarted safely?

PrEP can be safely stopped and started again based on a person's risk for HIV. If a person wants to stop taking PrEP, or restart after a period of not taking PrEP, they should talk to their healthcare provider about how to stop and/or restart PrEP safely.

Generally, when stopping daily PrEP, it is recommended that the medication be continued for some time after the last possible exposure to HIV. It is recommended that gbMSM, whose risk for HIV is via anal sex, can stop taking daily PrEP two days after their last sexual encounter. For everyone else (transgender men and women and cisgender heterosexual men and women), the ideal number of days to take PrEP after their last exposure to HIV is unknown; it could be up to 28 days.

GbMSM who use on-demand PrEP should follow the on-demand schedule and continue taking PrEP for two days after the last time they have sex. PrEP can then be stopped safely.

If a person who has stopped taking PrEP wants to restart, they should be tested for HIV before starting again if there has been any possible HIV exposure since they last took PrEP. PrEP is only for HIV-negative people; if a person has HIV, they need HIV treatment. People starting daily PrEP should wait seven days after their first dose before having anal, vaginal or frontal sex.

GbMSM also have the option of restarting PrEP using an on-demand strategy, but they may need to be tested for HIV first. This could be a good option for men who know in advance when they will have sex or who find they are having sex less often.

How can service providers improve the uptake and correct use of PrEP?

Education and counselling activities related to HIV prevention should include information on the HIV prevention benefits of PrEP, along with information on other highly effective ways to help prevent HIV. These include the use of HIV

treatment to maintain an undetectable viral load, post-exposure prophylaxis (PEP), condoms for sex and new equipment for using drugs. Encourage clients to choose the combination of strategies that will work most effectively for them as there are multiple ways to prevent HIV that can be combined in different ways. PrEP only helps to prevent HIV; it does not prevent other STIs (such as chlamydia, gonorrhoea or syphilis) or blood-borne infections such as hepatitis C. Discuss how PrEP fits into a comprehensive plan for health, such as regular STI testing, using condoms and using new drug use equipment.

PrEP is not for everyone. You can support clients to decide whether PrEP is right for them. During discussions, help your clients consider their level of HIV risk and the possible side effects, as well as their ability to cover the cost (i.e., insurance coverage), access a knowledgeable healthcare provider, adhere to a pill-taking regimen and attend regular medical visits. Each person has the right to decide whether or not to use PrEP as a prevention approach, on the basis of their own assessment of what is best for their health and well-being.

For people who are interested in taking PrEP, provide education on how to use it correctly, to maximize safety and effectiveness. Emphasize the following:

- PrEP should only be used by people who are HIV negative.
- PrEP should only be accessed through a healthcare provider.
- PrEP requires that people be highly adherent to PrEP medications.
- People who want to start taking PrEP should first be tested for kidney function and screened for STIs and hepatitis A, B and C.
- People who are taking PrEP should have regular clinic visits with a healthcare provider, typically every three months. During these visits they should be tested for HIV and STIs, monitored for side effects and toxicity, and given adherence and risk-reduction counselling.

Whenever possible, be aware of — and develop partnerships with — local healthcare providers, clinics and health centres that are willing to prescribe PrEP. By establishing these connections, you can ensure that you will be able to link clients who want to use PrEP to a location where it is available. Clients may need support in talking to a healthcare provider about PrEP and determining how they will cover the cost of the medications (e.g., through private or public insurance). Clients who start PrEP should also be supported to use this strategy consistently and correctly. You may have to offer, or link clients to, interventions and services to support medication adherence and continued engagement in medical care.

Encourage and support clients to communicate openly with their sex partners. Consider couples-based counselling for people in relationships (whether monogamous or not). This may help to create a supportive space for couples to come to a consensual agreement on how to lower their chances of HIV transmission, find ways to support each other in using HIV prevention strategies consistently and correctly, and discuss potentially sensitive issues relevant to HIV prevention.

It is important to recognize that broader social, economic and structural factors (such as colonization, racism, homelessness and poverty) create health inequities by affecting people's ability to access and engage with health and social services. Service providers can help to address these barriers and help clients address other health and social issues that clients may be experiencing, such as mental health challenges or substance dependence. HIV prevention counselling offers an opportunity to engage individuals in additional services. Providing referrals and linkage to other appropriate and relevant support services can help set people up to successfully adopt HIV prevention strategies.

Are there other types of PrEP?

An injectable form of PrEP, using a drug called cabotegravir, has been tested in gbMSM, transgender women and cisgender women. This long-acting form of PrEP is injected into the gluteal muscle (buttocks) every two months. Two large

studies have found long-acting cabotegravir to be generally safe and effective at reducing the risk of getting HIV. Long-acting injectable PrEP is not currently approved for use as PrEP in Canada, but it has been approved in other countries including the United States and it may eventually be licenced in Canada.

Other types of PrEP, including vaginal or rectal gels, and implants, are currently in experimental stages. These forms of PrEP have not been approved for use by any regulatory agency in the world, and we do not expect them to be available for use in Canada in the near future. An intravaginal ring that can be used by cisgender women to prevent HIV has been approved for use in some African countries. It has not been approved in any high-income countries because the level of protection is much lower than oral PrEP.

Client resources

PrEP to prevent HIV: Your questions answered – *brochure*

8 Questions about PrEP for guys – *brochure*

Is PrEP right for me? – *pocket card*

Did you know there is a pill that can prevent HIV? – *poster*

How does PrEP prevent HIV? – *video*

Service provider resources

PrEP use among gbMSM: What does it mean for STI prevention? – *Prevention in Focus*

Worth a shot: Injectable PrEP for HIV prevention – *Prevention in Focus*

Canadian guideline on HIV pre-exposure prophylaxis and nonoccupational post-exposure prophylaxis – CATIE

La prophylaxie préexposition au virus de l'immunodéficience humaine : Guide pour les professionnels de la santé du Québec – Ministère de la Santé et des Services sociaux du Québec (French only)

Guidance for the use of Pre-Exposure Prophylaxis (PrEP) for the prevention of HIV acquisition in British Columbia – BC Centre for Excellence in HIV/AIDS

2021 Alberta HIV Pre-Exposure Prophylaxis (PrEP) Guidelines – Alberta Health Services

Pre-exposure prophylaxis: Guideline review for primary care practitioners in Saskatchewan – Saskatchewan HIV Collaborative

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Author(s): **Arkell C, Harrigan C.**

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