

PROVIDING HIV PrEP

Steps to Patient Engagement



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This guide is designed for health care providers interested in prescribing HIV pre-exposure prophylaxis or PrEP. It provides background on what PrEP is and outlines the process of providing PrEP including how and why patients might be interested in PrEP, how to engage patients in conversation about PrEP, assessments needed before prescribing PrEP, and ongoing care. It also provides links to other resources that can be useful for you and your patients to learn more about PrEP.

WHAT IS PrEP? WHY IS IT NEEDED?

PrEP involves the use of antiretroviral medications by an HIV-negative person to reduce their risk of contracting HIV when exposed to the virus. As of March 2017, daily use of the medication Truvada is the only approved option for PrEP in Canada. Effective PrEP delivery goes beyond just taking medication and involves regular testing for HIV and other sexually transmitted infections (STIs), monitoring for side effects, and adherence and sexual health counselling.

PrEP has been shown to be highly effective when taken properly. While there has been a wide range of overall efficacy in clinical trials and real-world implementation projects on Truvada as PrEP, analyses of people using the medication on a daily basis have found roughly a 90% reduction in the probability of HIV infection. This same body of research has shown that poor adherence to PrEP is the primary reason for it to be ineffective at preventing HIV. While alternative dosing strategies for PrEP have been tested in clinical trials, only the daily use of Truvada is currently supported in the product monograph and clinical guidelines.

There are a variety of highly effective options for HIV prevention including external and internal condoms, HIV post-exposure prophylaxis, and if a person's partner is HIV positive but has an undetectable HIV viral load. While these prevention tools have slowed the pace of HIV in Canada, the persistence of HIV is evidence that other strategies are needed to reduce new infections. PrEP has proven highly effective as a prevention tool for people at substantial risk from HIV—in clinical trials, demonstration projects, and real-world settings—even in the absence of consistent condom use and the elevated prevalence of other sexually transmitted infections.

For more information on what PrEP is, how it works and how effective it is, visit www.catie.ca/en/prep

Truvada

Truvada is an oral fixed-dose combination tablet containing two HIV antiretroviral agents, emtricitabine and tenofovir disoproxil fumarate. Truvada was first approved by Health Canada in 2006 for the treatment of HIV-1 infection in adults. It must be used in combination with a third antiretroviral drug to be an effective treatment for someone living with HIV. In February 2016, Health Canada approved Truvada for use as HIV pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infections in HIV-negative adults.

ASSESSING PATIENTS FOR PrEP

There are three general steps to prescribing PrEP: determining factors that might expose your patient to HIV, informing your patient about PrEP and discussing whether they feel PrEP is something they would want for themselves, and testing for possible contraindications or drug interactions. Conversations about PrEP may be initiated by a patient who is interested in starting PrEP, but they may also be initiated with a patient if you feel they might benefit from PrEP.

Many patients will have had limited experience with healthcare providers willing to talk about sexual health or may have had negative experiences talking to other providers about their sexual health needs. It is important to emphasize that your conversations are confidential and non-judgmental, and that you're discussing their sex life to determine what the best option is for their sexual health. While the immediate goal of these conversations is to assess whether PrEP is appropriate for your patient, they are also valuable sexual health education opportunities regardless of whether a patient ends up using PrEP.

EXPLORING YOUR PATIENT'S SEXUAL HEALTH NEEDS

There is not one clearly defined profile of patients who can benefit from PrEP. PrEP is available to anyone who is interested, and can have benefits for a wide range of people. While clinical guidelines often focus on identifying people who are "high risk", in practice PrEP has been made available to people based on mutual decisions between themselves and their doctor. Discussing a patient's sexual behavior and sexual health practices provides you with context about where they might have exposure to HIV and how PrEP might benefit them. These discussions will also help you communicate to your patient whether PrEP may fill a role as a primary HIV prevention strategy, whether it could supplement other sexual health tools they use, or whether it might not be necessary for them. Here are some key areas to talk to your patients about:

Current HIV Prevention Strategies:

Condoms are the primary HIV prevention tool for most people, but they are often used inconsistently. When talking to a patient about their condom use, it's important to explore how condom use fits into their sex life, when and why they might not be using condoms, and whether they are using other HIV prevention strategies when they aren't using condoms. Patients may expect a judgmental response when talking about not using condoms; it can be useful to normalize slip ups and to acknowledge that inconsistent condom use is not an individual problem.

What types of sex do you use condoms for? Are there partners who you choose not to use condoms with, and why? Are there times when you intend to use condoms and don't?

Are there times when you feel unable to ask partners to use condoms? Has a partner ever ignored or denied your request to use condoms?

Past Post-Exposure Prophylaxis Use:

Post-exposure prophylaxis or PEP involves the use of antiretroviral medications by an HIV-negative person. If your patient has used PEP previously, this may be an indication of regular exposure to HIV without other preventive tools. Explore the situation(s) that have led your patient to use PEP and their likelihood of recurring.

Have you ever used PEP? If so, what led you to use PEP? How likely is it that you might be in a similar scenario in the future?

Partners:

Talking to your patients about who their sexual partners are is critical, as many people make assumptions about what prevention tools to use based on their knowledge and assumptions about their sexual partners' health. Exploring what conversations your patient has had with their partners about sexual health can help establish whether they have an accurate understanding of their possible exposure to HIV. If your patient has partners who are HIV positive, explore what they know about those partners' HIV treatment. There is a negligible likelihood of HIV transmission when a person is adherent to their HIV medications and has had a sustained undetectable viral load for six months or more; having regular partners who are living with HIV but are undetectable may mean that PrEP is not necessary.

Who are your regular sex partner(s)? How often do you have sex with casual or unknown partners? What sort of conversations do you have with partners about HIV status and sexual health? If you have a partner living with HIV, what do you know about their treatment? Have you discussed your partner's viral load?

Previous STIs:

A recent history of sexually transmitted infections can be an indicator of increased probability of acquiring HIV. STIs contribute both to increased potential to acquire HIV or, in people living with HIV, increased potential to transmit HIV. While testing for STIs is part of the standard diagnostic procedures for prescribing PrEP, discussing past infections is valuable as it helps to establish your patient's sexual health needs.

Have you ever been diagnosed with other STIs? Were you provided with treatment for these infections?

Substance Use:

Substance use can be either a direct cause of HIV (via injection drug use) or an associated factor. Not all substance use is problematic, so it's important to listen to how patients describe their substance use fitting into their life and whether it has any negative impacts. For patients who use injection drugs, it's important to explore their use and whether they are already reducing their possible exposure to HIV by avoiding sharing needles and using a new needle every time they inject. When discussing other drug use, explore how drugs might be implicated in a person's sexual health decision making and ability to negotiate sexual health strategies with their partners.

Do you use injection drugs? If you use injection drugs, are there ever times when you share needles with others? Do you use drugs when you're meeting sexual partners? Does your drug use ever interfere with your ability to use sexual health tools? Does your substance use ever lead you to have sex you don't want?

Are you feeling unsure about prescribing Truvada?

Some doctors and medical care providers who are unfamiliar with HIV prevention and treatment are nervous about providing PrEP, particularly when it comes to prescribing medication. However, PrEP administration is relatively straightforward. Truvada has a good safety profile and the potential side effects are well-known and easy to monitor. If you need extra support before providing this medication, you can review the CDC guidelines on providing PrEP or connect with a pharmacist or local infectious disease specialist.

PROVIDING KEY INFORMATION ABOUT PrEP

Along with exploring why PrEP might be needed, it's important to explain to your patient what PrEP involves so that they can make an informed decision about whether PrEP is right for them. Many patients who might seem like a good candidate for PrEP will ultimately decide it is not a great fit for them.

PrEP is highly effective at preventing HIV

Clinical trials of PrEP have shown that it is greater than 90% effective when taken daily as prescribed. CATIE, Canada's leading source for information on HIV, has equated PrEP with condoms and an undetectable viral load as "highly effective strategies to reduce the risk of the sexual transmission of HIV." PrEP's effectiveness drastically decreases when it is not taken regularly.

PrEP is not effective at preventing other STIs. Other prevention options like using condoms, talking to partners about STIs, getting tested for HIV and STIs regularly, and getting vaccinated for HPV, Hepatitis A and Hepatitis B are still useful for someone taking PrEP. As part of ongoing PrEP related health care, a patient will be regularly screened for other STIs and receive treatment for any infections they might have.

PrEP is more than just a daily pill

Using PrEP requires regular appointments with a doctor. A patient will need regular checkups every three months to monitor their HIV status and check for toxicity or side effects from the medication. This can be a barrier if a patient doesn't have health insurance or if it is difficult for them to schedule and maintain regular appointments.

When does it become effective?

PrEP takes time to build up effective levels in the body to prevent infection. The drug also disperses at different rates to different types of tissue in the body. PrEP reaches effective levels in the body after:

- 7 days for receptive anal sex and insertive penile sex
- 21 days for receptive vaginal or frontal sex, and injection drug use

What happens if a dose is missed?

There is some leeway with PrEP if a person occasionally misses a dose, but PrEP can lose its effectiveness if a person is regularly missing doses or misses multiple doses in the span of several days. Similar to differences in when PrEP becomes effective, there is less adherence forgiveness for receptive vaginal or frontal sex and injection drug use than for receptive anal sex and insertive penile sex.

If a patient forgets to take their pill they should not double dose the following day. However, if a person forgets to take their pill until later in the day (e.g. they regularly take the pill in the morning but forget until the afternoon), it is OK to take that day's dose then and continue with their regularly scheduled doses the following day.

Open, honest communication

Taking PrEP requires that both a patient and their medical provider be comfortable and open in talking about the patient's sexuality, their interest in PrEP, and reasons why it may or may not be a good fit for them. A patient also needs to be able to talk honestly about their ability to take the medication and times they might miss doses so that they receive proper adherence support.

What is the purpose of all this testing?

While PrEP is generally very safe, some people may be negatively impacted by the medication. Long-term Truvada use has been shown to have some negative impact on kidney function and bone loss, and people with pre-existing medical conditions, such as prior kidney or bone disease, may be told that Truvada isn't a good option for them. Regular screening for HIV is also important because Truvada on its own cannot treat an HIV infection and an existing or acute infection could develop resistance to this medication. Testing regularly for other STIs is also important as STIs may reduce PrEP's effectiveness.

What are the side effects?

Side effects are typically mild but can include nausea, stomach cramps, vomiting, headaches, dizziness and fatigue. A patient is most likely to experience side effects in the first few weeks after starting on PrEP. A patient experiencing side effects that are disruptive or persistent should receive advice on reducing their impact and possibly be screened for complications.

Birth control and pregnancy

PrEP does not impact the effectiveness of hormonal contraceptive pills, injectable birth control or insertable birth control devices.

PrEP can be an option for mixed HIV status couples who are trying to conceive. Research on the use of PrEP during pregnancy and breastfeeding is limited, but research on the use of Truvada for treatment of HIV has not shown any increase in birth defects among children born to a parent using Truvada and there have been no signs of negative side effects for babies breastfeeding from a parent using Truvada. It's important to talk to patients who are pregnant or who may want to become pregnant about whether they would like to continue or halt using PrEP.

Transgender and gender non-binary people and PrEP

Transgender and gender non-binary people have been underrepresented in research on PrEP. However, we know from existing research on the use of Truvada as HIV treatment that hormone therapy does not negatively impact the effectiveness of Truvada.

Given the difference in how Truvada is distributed in various tissues in the body, it is important that transgender and gender non-binary people be provided with accurate information about the length of time before Truvada is effective for the types of sex they're having. If you would like to learn more about providing care to transgender and gender non-binary people, visit <http://sherbourne.on.ca/lgbt-health/guidelines-protocols-for-trans-care/>.

For more FAQs patients may have about PrEP visit the AIDS Committee of Toronto's PrEP page (actoronto.org/prep) or the US-based prepfacts.org.

Discussing Coverage/Access Issues

Talking to a patient about PrEP necessitates conversations about how to access this medication. As of March 2017, only two of Canada's 18 public drug plans (Quebec's Public Prescription Drug Insurance Plan and Non-Insured Health Benefits for First Nations and Inuit people) include Truvada for HIV PrEP. These and other public drug plans are in the process of deciding whether to include, or continue to include, Truvada for PrEP. Few people can afford the approximately \$1000 monthly retail cost of Truvada for PrEP in Canada. Many people at high risk of HIV infection will not be able to access Truvada for PrEP unless it is listed on public drug plans. Private insurance is uneven, coverage is restricted by standard policy terms that exclude preventative therapies, and deductibles and monetary claim limits set out in policies all restrict access to PrEP.

It's important to have a conversation with your patients about how they plan to access PrEP well in advance of prescribing the medication. Cost and the challenge of obtaining coverage may cause some patients to decide PrEP is impractical for them. Those who are interested will want time to explore what options exist for them. You as a service provider can help by referring patients to an identified drug coverage expert in your community. This professional may work as part of your interprofessional healthcare team or be a community service provider. They will assist patients in exploring all available coverage options.

DIAGNOSTIC TESTING

Once a patient has been identified as having both a need for and interest in starting PrEP, they will need to undergo physical assessment. Candidates for PrEP should be screened for the following:

HIV infection:

It is critical to confirm a patient seeking PrEP is not already living with HIV. Truvada is not a standalone treatment for HIV; using Truvada by itself could cause a person to develop drug resistant HIV infection. Patients should be tested with a 4th generation HIV test that can detect both HIV antibodies and the HIV protein P24 antigen. If a patient's sexual history and presenting symptoms indicate possible acute HIV infection, it is recommended that they are screened with HIV RNA NAAT testing or repeat a 4th generation test 7 to 21 days after their initial test.

Other Sexually Transmitted and Blood Borne Infections:

STIs can increase the risk of HIV infection and are not protected against by PrEP. Screening for Chlamydia, Gonorrhea, Syphilis, Hepatitis A, B and C are all recommended to allow for treatment.

- › Blood screening for Syphilis and Hepatitis A, B and C
- › Urine test, rectal and oral swabs for Chlamydia and Gonorrhea. These are site specific infections; urine testing alone will miss many infections.

Kidney Screening:

Tenofovir Disoproxil Fumarate, one of the components in Truvada, is associated with possible decreases in kidney function. A baseline screening of serum creatinine (with eGFR >60 mL/min) is recommended. Patients with eGFR below this level should not initiate PrEP

Monitoring patients with Hepatitis B Infection:

Although not typically prescribed to treat chronic Hepatitis B infection, Truvada is active against Hepatitis B. Patients who use Truvada as PrEP and later discontinue the medication can experience flare ups in HBV. Patients living with Hepatitis B should have their HBV monitored in collaboration with a provider experienced in Hepatitis B treatment.

Monitoring patients with Hepatitis C Infection:

Screening for Hepatitis C should be provided to all patients. Patients without a history of Hepatitis C can be screened using antibody testing; patients who have previously cleared Hepatitis C infection require RNA viral testing. If a patient is diagnosed with Hepatitis C, they can be referred to a specialist for treatment.

BEGINNING PrEP

Once a patient has been assessed for PrEP and has figured out how they plan to cover it, you can provide a prescription for the medication. All patients receiving Truvada as PrEP receive the same prescription- one pill taken daily containing 200 mg of tenofovir disoproxil fumarate and 300 mg of emtricitabine. It is recommended that you provide your patients with a four month prescription without refills- a lack of refills encourages patients to return for their three month follow-up appointments, while the extra month of prescription ensures patients don't go without medication if they miss an appointment and need to reschedule.

Once a patient has filled their prescription, they can begin taking PrEP. The length of time for PrEP to become effective varies based on how the medication disperses in the body. PrEP reaches effective levels in the body after:

- 7 days for receptive anal sex and penile sex
- 21 days for receptive vaginal or frontal sex, and injection drug use

Truvada is typically well-tolerated but can have side effects, particularly in the first month after a patient begins taking medication. Patients should be encouraged to contact you if they are having difficulties with side effects. Patients should not skip doses as a means of reducing side effects. Although not common, some patients may choose to stop using PrEP altogether if side effects are persistent.

Side Effect Management

PrEP may have side effects in some patients, particularly in the first month after initiating treatment. Here is a list of common side effects that patients may experience and options to reduce their impact:

- **Nausea, stomach cramps and vomiting:** Stomach issues can occur when starting this medication. Patients should avoid taking this medication on an empty stomach and try to schedule doses around a regular meal. Avoiding foods that are overly spicy, rich or acidic can also help with short-term stomach issues. Rarely, prolonged experience of these symptoms and headaches may be a sign of lactic acidosis. Patients can be screened for lactic acidosis through blood tests for lactic acid, or a blood test or ultrasound of the liver.
- **Fatigue:** While fatigue related to PrEP often subsides quickly, some people find it useful to take PrEP before they go to bed.
- **Dizziness:** Similar to fatigue, dizziness symptoms typically only occur when initiating PrEP and some people find it useful to take PrEP before they go to bed to lessen the impact of these symptoms.
- **Headaches:** Headaches can occur when starting a new medication. Patients experiencing headaches can benefit from over the counter pain relievers. If headaches are persistent, check for possible drug interactions and screen for lactic acidosis and other conditions.

FOLLOW-UP CARE

A one-month check-in appointment with patients is recommended. This provides an opportunity to talk to your patient about their experience with the medication and to address any side effects they may be having. Patients should be tested for HIV using a 4th generation test to ensure they do not have acute HIV infection and complete another serum creatinine test to screen for any complications since starting the medication.

Ongoing follow-up visits are a critical part of PrEP care. They allow for ongoing sexual health counselling, adherence support and testing for HIV, other STIs and kidney health. Appointments should be scheduled every three months prior to your patient needing to refill their medication. These appointments can be brief; patients are followed up with about their experience with PrEP, whether they feel their sexual activity and/or drug use still warrants using PrEP, and if they are having any other issues that might be impacting adherence. From there, patients can be sent for lab screening for their regular lab work. For women and transmen who may become pregnant, it is also recommended that pregnancy screening is part of these regular check-ins.

Supporting Adherence

Building PrEP into a routine - Many people find that it is easier to remember to regularly take their medication if it can be done along with other activities. Ask patients if they can take their medication around a regular meal or when they take other medications. Having an alarm or reminder on a cell phone can also be beneficial.

Normalize missed doses while problem solving lapses - It's not uncommon to miss doses but it can be problematic if it occurs regularly. Talk to your patient about times they've missed doses and if there are other factors that get in the way. If a patient has other activities getting in the way or finds it difficult to take medication at a certain time because of lack of privacy, brainstorm ways to ensure they can take medication or discuss changing their medication schedule.

CYCLING OFF PrEP

While PrEP may make sense for someone to start at a point in their life when they identify periods of high risk, many will also identify a point when their risk profile no longer makes PrEP use necessary. Entering into a monogamous relationship, reduction in the number of sexual partners someone has, moving away from injection drug use or adopting other HIV prevention tools may all lead your patients to choose to stop using PrEP. Here are a few things to keep in mind when patients are stopping PrEP:

Inform your clients early on about what is involved in stopping PrEP:

Ideally all patients stopping PrEP would follow up with their doctor before doing so. However, we know some patients who choose to stop medication may drop out of care entirely. Talk to your patients during their initial consultation about what cycling off of PrEP looks like so that they're more informed should they choose to stop later on.

When to stop taking pills:

When a patient has decided to stop taking PrEP, it's important that they continue taking their medication for at least 48 hours since their last possible exposure to HIV.

HIV testing:

It's recommended that any patient who is concluding a course of PrEP also be screened again for HIV.

Continuing care:

A patient who decides they no longer need PrEP may still benefit from the suite of services associated with PrEP. Talk to your patients about regular HIV and STI testing, and what routine sexual health screening might look like off of PrEP.

Going back on PrEP:

It's also best to discuss with patients the possibility of starting PrEP again at a later date. In particular, patients should be informed that they should be screened for HIV, other STIs and kidney function in their initial assessment. Patients who still have medication that they have not taken should be warned against starting PrEP again without proper screening for HIV and other health conditions.

Special considerations for patients with HBV:

Truvada is an active agent against Hepatitis B. Patients with chronic HBV infection may experience flare ups when they stop using Truvada. Discuss with patients their options for using other HBV therapies. Patients should also be monitored for HBV related flare ups.

BUILDING A NETWORK OF CARE

Patients at high risk for HIV may also benefit from connection with other care providers like social workers, counsellors and therapists. Knowing where to provide referrals can ensure that patients who are taking PrEP get the holistic support that they need to stay healthy and adhere to their medication.

Connect with your local AIDS Service Organization:

ASOs specialize in providing health education and support to people living with or impacted by HIV. Many ASOs have support staff who can work directly with your patients if they need support. They can also provide connections to local counsellors and therapists who are skilled at working with people from communities impacted by HIV. If you are working in a clinic or community health centre that has an interdisciplinary care team, ASOs can work with your staff to provide capacity building training on HIV and issues impacting at risk communities. You can find your nearest ASO by searching HIV411.ca.

Link with local mental health providers and services for people who use drugs:

Having access to additional supports can be beneficial if a patient has ongoing mental health issues or struggles with problematic substance use. Establishing relationships with local providers and knowing what services they provide, what their approach is, and whether their services require user fees can be useful to establish before needing to make referrals. It can be particularly useful to know whether providers you're referring to follow a harm-reduction or abstinence only philosophy; patients who want to make their use more manageable will benefit from the former and a patient who would prefer to stop their use entirely will benefit from the latter.

Know your local community:

There may be a variety of other services in your area that can benefit your patients. Take some time to explore what resources are available. Agencies serving specific ethnic communities, aboriginal people, LGBTQ people, women, people who use drugs, and sex workers often have unique programs that may be beneficial for patients seeking PrEP. These community groups may not be familiar with PrEP, so starting a conversation can also be an opportunity to spread information and help create access to PrEP.

