



HIV COMMUNITY LINK

Pre Exposure Prophylaxis (PrEP): What You Need to Know

What is PrEP?

PrEP is the use of antiretroviral medication to prevent HIV infection (*prophylaxis*) before possible contact with the virus (*pre exposure*). PrEP is a new prevention technology to reduce a person's risk of becoming HIV positive. One type of PrEP, daily oral Truvada, has been estimated to provide an up to 99% level of protection when used as prescribed ⁽¹⁾.

Are there Different Types of PrEP?

Over the last several years, different types of PrEP have been studied:

- **Microbicides:** A common form of PrEP in recent research is the use of microbicides. Microbicides are topical gels or creams containing antiretroviral medication which are applied to the vagina or rectum before, during and/or after sexual activity to reduce the risk of acquiring HIV. The CAPRISA 004 Study has shown the most promising results from microbicide use: vaginal microbicides reduced the risk of HIV infection by 39% among sexually active HIV negative women ⁽²⁾.
- **Oral PrEP:** Another type of PrEP involves the use of antiretroviral medication orally in the form of pills. Oral PrEP has shown the highest rates of effectiveness when used as prescribed. Recent research into oral PrEP has focussed on the use of a specific antiretroviral medication called Truvada. Truvada is an effective and preferred medication that has been used to treat People Living with HIV for over 10 years.
- **Intermittent PrEP:** Intermittent PrEP refers to using oral PrEP for a short period of time before and after a possible exposure to HIV. For example, the IPERGAY study looks at PrEP use over a 72 hour period, with 2 pills taken before sexual activity and another 2 pills after ⁽³⁾. Research into intermittent PrEP use is ongoing.
- **Daily PrEP:** The most extensive research into oral PrEP involves ongoing, daily use of Truvada. International, multiyear trials involving thousands of participants have demonstrated high effectiveness of daily oral PrEP and clinical guidelines have been created for this indication.

Unless otherwise noted, the information below will describe PrEP in the context of ongoing and daily use of oral Truvada.

(prevention + support + advocacy)

Who is PrEP for?

PrEP can benefit anyone at increased risk of HIV infection. This can include people in serodiscordant relationships (where one partner is HIV positive and the other is HIV negative), partners of People Living with HIV who are trying to conceive, or people who do not consistently and effectively practice other risk reduction strategies such as sex with condoms. In May 2014, the United States Public Health Service and Centers for Disease Control and Prevention released a set of Clinical Practice Guidelines which recommend PrEP be considered for⁽⁴⁾:

- Anyone who is in an ongoing relationship with an HIV positive partner
- Anyone who is not in a mutually monogamous relationship with a partner who recently tested HIV negative, and 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
 - A 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 (i.e. people who inject drugs or have bisexual male partners)
- People who inject drugs, including those who have injected in the past 6 months and who have shared injection equipment or been in treatment for injection drug use in the past 6 months
- HIV discordant heterosexual couples during conception and pregnancy

In July 2014, the World Health Organization identified 5 key populations most at risk of HIV infection yet least likely to have adequate access to HIV prevention, testing and treatment services: men who have sex with men, people in prison, people who inject drugs, sex workers and transgender people⁽⁵⁾. On an international level, these 5 populations are the focus of enhanced access to PrEP.

What is the Evidence for PrEP?

Over several years, an extensive body of research and clinical trials have investigated PrEP. Clinical trials have involved thousands of participants across multiple continents including Africa, North America, South America, Europe and Asia. PrEP efficacy has been demonstrated among key populations affected by HIV including men who have sex with men, heterosexual men and women, people who inject drugs, and transgender women.

What is most clear from the research is that taking PrEP as prescribed and not skipping doses (also known as adherence) is *the most important factor in how well PrEP can protect against HIV infection*. In some cases, research has been halted due to evidence of very low adherence among participants^(6,7). Below is a brief overview of the foundational projects.

(prevention + support + advocacy)

- **IprEX** ⁽¹⁾: Among gay and bisexual men and transgender women, PrEP was estimated to provide an up to 99% level of protection when taken 7 days per week. As adherence decreases, effectiveness also decreased.
- **Partners PrEP** ⁽⁸⁾: Among heterosexual serodiscordant couples, PrEP reduced incidence of HIV transmission by up to 75% compared to placebo. Among those with detectable levels of Truvada in their blood, PrEP reduced the risk of HIV infection by up to 90%.
- **TDF2** ⁽⁹⁾: Among heterosexual men and women, PrEP reduced the risk of HIV infection by up to 78%. Low adherence was linked to lower effectiveness and HIV infection.
- **Bangkok Tenofovir Study** ⁽¹⁰⁾: Among injecting drug users, risk of HIV infection was reduced by 49% overall and up to 74% for participants who had detectable levels of Tenofovir in blood tests. This study did not use Truvada, but a single drug component of Truvada called Tenofovir.
- **IPEGAY** ⁽¹¹⁾: IPEGAY is an ongoing study of gay and men who have sex with men using PrEP on an intermittent basis (before and after sex, as opposed to daily). In October 2014, researchers announced that due to high effectiveness, the placebo arm of this study will be closed and PrEP will be offered to all participants. Full study details are expected in early 2015.

Who Has Endorsed PrEP?

As mentioned, Truvada is a common and well-tolerated antiretroviral medication that has been used in the treatment of People Living with HIV for over 10 years. In 2012, the United States approved the use of Truvada as PrEP for HIV negative people and has since created Clinical Practice Guidelines to assist physicians in prescribing Truvada for the prevention indication ⁽⁴⁾.

In 2012, the World Health Organization (WHO) also released a document providing guidance and recommendations for demonstration projects investigating PrEP for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV. In July of 2014, the WHO deepened their commitment to PrEP and published a statement announcing the organization “strongly recommends men who have sex with men consider taking antiretroviral medicines as an additional method of preventing HIV infection alongside the use of condoms” ⁽⁵⁾. According to WHO estimates, access to PrEP for MSM alone will avert more than 1 million new infections over the course of ten years.

In Canada, PrEP has not been approved by federal health authorities and few AIDS Service Organizations have directly expressed support for PrEP use in Canada. After more than 2 years of careful consideration, in November 2014 HIV Community Link released a position statement calling for enhanced access to PrEP in Alberta.

(prevention + support + advocacy)

Can I Access PrEP in Alberta?

Because PrEP has not been approved in Canada, a physician who prescribes Truvada for PrEP must do so as an “off-label” use. According to health officials, “off-label prescribing and use of drugs is common and has often been associated with innovative new uses for existing approved medicines” ⁽¹²⁾. However, because of a lack of information and clinical guidelines, many Canadian doctors are hesitant to prescribe Truvada off-label for prevention purposes ^(13,14). To date, we are only aware of a handful of Albertans who have successfully received prescriptions for Truvada as PrEP in Alberta. In most cases, an individual interested in accessing PrEP will need to self-advocate and educate their doctor about the relevant issues.

If someone is interested in discussing PrEP with their doctor, HIV Community Link recommends the following:

- Thoroughly educate yourself about PrEP before meeting with your doctor – it is not unlikely that this will be the first time they have heard about PrEP
- Provide your doctor with information resources such as this document, other fact sheets or research summaries, and the CDC Clinical Practice Guidelines ⁽⁴⁾.
- Be prepared if your doctor is not quick to consider prescribing PrEP – it may take several in depth and candid conversations for your doctor to understand the potential benefits of PrEP
- Be open with your doctor about why you feel you would benefit from PrEP – it can be difficult to have candid conversations but it may help your doctor make an informed decision
- Contact HIV Community Link for more information and resources
- Encourage your doctor to contact HIV Community Link for additional information and resources

A prescription for PrEP will not be covered by the Alberta Health Care Insurance Program. There is at least one private insurance provider who is currently covering the majority of costs for an individual PrEP prescription. Whether or not other individuals interested in accessing PrEP will successfully receive private coverage remains to be seen. In Alberta the cost of Truvada for PrEP is approximately \$1100 per month.

More Information

For more information about PrEP, please do not hesitate to contact HIV Community Link at (403) 508-2500 or email info@hivcl.org. At HIV Community Link we are committed to regularly monitoring emerging information and connecting the community with the most up-to-date PrEP facts and resources. For a more detailed analysis of the benefits and concerns related to PrEP, please see our November 2014 [Position Statement on Enhanced Access to PrEP](#).

(prevention + support + advocacy)

References

1. Grant, R.M., Lama, J.R., & Glidden, D.V. (2010). Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *New England Journal of Medicine*, 363(27), 2587-2599. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3079639/>
2. Abdool Karim Q, Abdool Karim SS, Frohlich JA, et al. (2010). Effectiveness and safety of tenofovir gel, an antiretroviral microbicide, for the prevention of HIV infection in women. *Science*, 329(5996):1168-1174.
3. Fonsart, J., et al. (presenter Molina, J-M). (2014). High adherence rate to intermittent oral PrEP with TDF/FTC among high risk MSM (ANRS Ipergay). 20th International AIDS Conference, Melbourne, abstract TUAC0103.
4. US Public Health Service. (2014). Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014 clinical practice guideline. Retrieved from <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>
5. World Health Organization. (2014). *WHO: People most at risk of HIV are not getting the health services they need*. Retrieved from <http://www.who.int/mediacentre/news/releases/2014/key-populations-to-hiv/en/>
6. Van Damme, L., Corneli, A., Ahmed, K., Agot, K., & Lombaard, J. (2012). Preexposure prophylaxis for HIV infection among African women. *New England Journal of Medicine*, 367, 411-422. Retrieved from <http://www.nejm.org/doi/full/10.1056/NEJMoa1202614#t=abstract>
7. Marrazzo, J., Ramjee, G., Nair, G., et al. (2013). Pre-exposure prophylaxis for HIV in women: daily oral tenofovir, oral tenofovir/emtricitabine, or vaginal tenofovir gel in the VOICE Study. *20th Conference on Retroviruses and Opportunistic Infections*. Atlanta.
8. Baeten, J., Donnell, D., Ndase, P. et. al. (2012). Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *New England Journal of Medicine*, 367:399-410. DOI: 10.1056/NEJMoa1108524
9. Thigpen, M.C., Kebaabetswe, P.M., Smith, D.K., Segolodi, T.M., Soud, F.A., Chillag, K., ... Paxton, L.A. (2011). Daily oral antiretroviral use for the prevention of HIV infection in heterosexually active young adults in Botswana: results from the TDF2 study [Abstract]. *Sixth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. Rome.
10. Choopanya, K., Martin, M., Suntharasamai, P., Sangkum, U., Mock, P.A., Leethochawalit, M., ... Vanichseni, S. (2013). 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*, 381(9883), 2083 - 2090.
11. Cairns, G. (2014). Second European PrEP study closes placebo arm early due to high effectiveness. AIDS Map. Oct 29, 2014. Retrieved from <http://www.aidsmap.com/page/2917367/>
12. Government of Canada, Standing Senate Committee on Social Affairs, Science and Technology. (2014). Prescription pharmaceuticals in Canada: Off label use. Retrieved from <http://www.parl.gc.ca/Content/SEN/Committee/412/soci/rep/rep05jan14-e.pdf>
13. Karris M.Y., Beekmann, S.E., Mehta, S.R., Anderson, C.M. & Polgreen, P.M. (2013). Are we prepped for PrEP? Provider opinions on the real-world use of PrEP in the U.S. and Canada. *Clinical Infectious Diseases: Oxford Journals*. 58(5):704–12
14. Sharma, M., Wilton, J., & Senn, H. (2014). Preparing for PrEP: perceptions and readiness of Canadian physicians for the implementation of HIV pre-exposure prophylaxis. *PLoS Med*. Retrieved from <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0105283>

(prevention + support + advocacy)