



## HIV COMMUNITY LINK

### **Position Statement: Pre-Exposure Prophylaxis for HIV Prevention (PrEP)**

November 2014

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#### **Introduction**

Pre-exposure prophylaxis (PrEP) is an HIV prevention approach where an HIV-negative person uses anti-HIV medications to reduce the risk of HIV infection. Although PrEP is not approved for use in Canada, it is accessible as an off-label prescription. One type of PrEP, involving daily use of a common anti-HIV medication called Truvada, was approved for prevention in the United States in 2012 and continues to undergo rigorous international research and evaluation. PrEP is not a cure for HIV and is not intended to replace existing evidence-based HIV prevention strategies. Conversations and education about the use of PrEP in Canada are important and timely public health issues.

#### **HIV Community Link's position on Pre-Exposure Prophylaxis (PrEP)**

With careful consideration, HIV Community Link supports efforts to enhance medically supervised access to Pre-Exposure Prophylaxis in Canada. At HIV Community Link, we believe all individuals and communities have the right to make informed decisions and access evidence-based, proven technologies to improve individual and public health outcomes. We also believe that health officials, policy makers and those working in related service organizations have a responsibility to educate themselves and their communities about emerging issues and strategies to reduce the harms associated with HIV.

As a new tool in the HIV prevention toolkit, we recognize PrEP as a complementary approach to be used alongside existing scientifically sound HIV prevention strategies including: enhanced access to low barrier HIV testing; low barrier access to risk reduction tools such as condoms and safer injecting supplies; treatment as prevention; post-exposure prophylaxis; diagnosis and treatment of other sexually transmitted infections; and a suite of behavioural, psychosocial and structural interventions including education, outreach, support services, counseling and advocacy.

Over 30 years into our work addressing HIV in the communities we serve, HIV Community Link understands that a one-size-fits-all approach to HIV prevention does not exist. We look forward to continuing to assist our communities in identifying and accessing the right prevention tool at the right time, including Pre-Exposure Prophylaxis.

#### **What is the evidence?**

Over several years a large body of research has been established indicating that PrEP provides an up to 99% level of protection against HIV infection when used as prescribed. Cornerstone projects include iPrEx, Partners PrEP, and TDF2. Clinical trials have involved thousands of participants across multiple continents including Africa, North America, South America, and Asia. PrEP efficacy has been

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demonstrated among key populations affected by HIV including men who have sex with men (MSM), heterosexual men and women, people who inject drugs, and transgender women <sup>(1-6)</sup>.

As noted, using PrEP *as prescribed* is paramount to its ability to reduce the risk of HIV infection. Regular and daily use as directed, often referred to as adherence, is understood as the primary factor in the effectiveness of PrEP. Considering the iPrEx study as an example, individuals who used Truvada seven times per week had an estimated 99% level of protection, while those who only used Truvada two times per week had an estimated 76% level of protection <sup>(1)</sup>. Similar results are seen in other trials where low adherence meant lower levels of protection. In some cases, research has been halted due to evidence of very low adherence among participants <sup>(7,8)</sup>.

Recognizing the cumulative and emergent body of scientific evidence, the World Health 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” <sup>(9)</sup>.

### **Is PrEP safe?**

Truvada has been used as a highly effective treatment for People Living with HIV for more than 10 years. As with other anti-HIV medications, Truvada causes side effects. Truvada is selected for PrEP because it has a lower side-effect profile and is generally better tolerated than other anti-HIV drugs. Research indicates that side effects from Truvada as PrEP are generally mild and infrequent.

Common symptoms in the first few weeks of starting PrEP may include nausea, vomiting, dizziness and fatigue. In most cases these symptoms subside over time. A more concerning side effect noted in the research involves the potential for impaired kidney function. For this reason, regular monitoring of kidney function is a recommended part of routine medical supervision for people using PrEP. Reduced bone density has also been observed, though the changes were minimal, non-progressive and resolved upon stopping Truvada.

There is a possibility that drug resistance can develop if: 1) a person is HIV positive and undiagnosed when starting PrEP or 2) a person is not using PrEP regularly as prescribed and subsequently becomes HIV positive. If resistance develops, the drugs used in PrEP may not work to treat HIV infection. For this reason, regular HIV testing is a recommended part of routine medical supervision for people using PrEP.

### **Could PrEP increase risk behaviours?**

A common concern around PrEP is that people may increase risk activities as a result of a new “sense of security”. Examples include condomless sex, multiple partners, or decreased uptake of harm reduction interventions such as safer injecting practices.

On the contrary, available evidence illustrates that risk behaviours do not increase among PrEP users, nor do key populations anticipate access to PrEP would affect decision making about risk activities <sup>(10-13)</sup>. In addition to no evidence of sexual risk compensation, studies also confirmed indicators of *decreased* risk behaviours, such as lower syphilis incidence, fewer sexual partners and lower rates of condomless sex, in both participants receiving PrEP and those receiving placebo <sup>(10, 12, 13)</sup>. These findings are consistent with additional research considering risk compensation in the context of other prevention technologies such as post exposure-prophylaxis (PEP), voluntary male circumcision and vaccines <sup>(14)</sup>.

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## What about condoms?

It is important to stress that PrEP is not intended to undermine or replace availability and promotion of other HIV prevention strategies, particularly the use of condoms and safer injecting supplies. PrEP is a new tool in a suite of evidence based HIV prevention approaches. Clinical guidelines for PrEP include regular patient counseling about additional risk reduction strategies including condom use.

Human behaviour is complex and influenced by a number of intersecting personal, social and structural factors, particularly in the case of risk related to sexual activity and substance use. There are many reasons why people engage in condomless sex. Examples include: lack of access to condoms; stigma associated with condom use; power imbalances which create an inability to negotiate condom use; the effect of mental health or substance use on decision making; assumptions about personal risk and HIV status, myths and misunderstanding about HIV transmission; personal preferences; and informed decision making about other risk reduction strategies including regular testing, PrEP, treatment as prevention, strategic positioning, or sero-sorting.

## What does PrEP cost?

In Alberta, PrEP will cost approximately \$1200 dollars per month for the indicated daily usage. In low-resource countries, global access programs provide daily PrEP at a cost of under \$50 per month. PrEP is not covered through provincial health insurance in Alberta. To date, private insurance coverage is rare and limited, requiring out-of pocket co-payments.

More research is needed to determine the cost-benefit ratio of enhanced access to PrEP. However, considering that the cost of care for a Person Living with HIV in Alberta is steadily increasing and the lifetime cost of each HIV infection in Canada is estimated at 1.3 million dollars, it is reasonable to expect access to PrEP could be cost effective for public health spending <sup>(15,16)</sup>. A recent analysis in New York City, where the state Governor has committed to providing access to PrEP for high risk populations, concluded that cost effectiveness is viable. For cost savings to occur in high income settings, PrEP use “needs to be restricted to those most in need, adherence needs to be maintained and drug costs need to fall” <sup>(17-20)</sup>.

To further illustrate the potential impact of PrEP to prevent new HIV infection and thereby reduce both economic and human costs, the World Health Organization estimates access to PrEP for MSM alone will avert more than 1 million new infections over the course of ten years <sup>(9)</sup>.

## What are additional barriers to PrEP?

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 federal health officials, “Off-label prescribing and use of drugs is common and has often been associated with innovative new uses for existing approved medicines” and “off-label use is not in itself prohibited, but rather considered a “practice of medicine”” <sup>(21)</sup>.

However, due to the lack of approval and clinical guidelines in Canada, research shows physicians are hesitant to prescribe *despite* expressing support for the use of PrEP as a new HIV prevention technology. In two recent surveys, a clear majority of participating Canadian physicians affirmed support for PrEP but identified a lack of clinical guidelines and prohibitive costs to the patient as primary barriers <sup>(22,23)</sup>.

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Other potentially significant barriers to PrEP are accessibility and acceptability for some of the hardest to reach and most at risk populations for HIV. Many people experiencing high risk will not be able to access PrEP through private insurance or out of pocket payments. People, who already lack access to appropriate basic services due to remote location, stigma and discrimination, or intersecting health issues such as mental health and addictions, may experience especially limited access.

Furthermore, in order to achieve the necessary levels of adherence and maximize both individual and public health outcomes, key populations must understand personal risk and view PrEP as acceptable and useful. Stigmatization and negative attitudes from both peers and service providers have been identified as barriers to PrEP uptake and adherence <sup>(24-28)</sup>.

As such, how to best implement and deliver access to PrEP will require careful coordination and roll-out across multiple policy and service levels.

### **HIV Community Link's Recommendations**

In collaboration with the community, partner organizations, policy makers and other stakeholders, we are eager to move forward with the following recommendations to enhance access to PrEP in Alberta:

- Education, information and consultation with key populations affected by HIV
- Professional development and continuing medical education for health professionals
- Dialogue and consultation with regulatory bodies including the Alberta Medical Association and the Royal College of Physicians and Surgeons
- Consideration of provincial and/or federal guidelines to inform clinical use of PrEP
- Timely and coordinated provincial responses to proven HIV prevention technologies

*Note: The preceding is provided as information and not medical advice. Decisions about medical care and treatments should be made in consultation with a physician.*

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