

CATIE STATEMENT

on the use of antiretroviral treatment (ART) to maintain an undetectable viral load as a highly effective strategy to prevent the sexual transmission of HIV

The consistent and correct use of antiretroviral treatment (ART) by people living with HIV to maintain an undetectable viral load is a highly effective strategy to prevent the sexual transmission of HIV. When this strategy is used consistently and correctly the risk for HIV transmission is negligible.

Negligible = so small or unimportant as to be not worth considering; insignificant.

JULY 2019



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Over the past several years the HIV prevention toolbox has expanded significantly. This is due to a rapid growth in our knowledge of effective approaches that help prevent the transmission of HIV. However, to maximize the impact of these approaches on the HIV epidemic, we must effectively increase awareness, uptake and proper use of them.

The CATIE statements summarize the best available evidence on the effectiveness of three approaches to help prevent the sexual transmission of HIV. These statements were developed to help service providers in Canada adapt their programs and incorporate this evidence into their messaging.

There are three highly effective strategies to help prevent the risk of the sexual transmission of HIV:

- The consistent and correct use of antiretroviral treatment (ART) by people living with HIV to maintain an undetectable viral load
- The consistent and correct use of oral pre-exposure prophylaxis (PrEP)
- The consistent and correct use of condoms

When any highly effective strategy is used consistently and correctly, the risk for sexual HIV transmission ranges from zero to very low.

The following statement focuses on the use of antiretroviral treatment (ART) by people living with HIV to maintain an undetectable viral load. It begins with a simple key message, followed by recommendations for service providers and a list of available tools and resources. It also provides a review of the evidence that service providers can use for more specific discussions with clients. Please consult the companion statements for more information on the other two highly effective strategies.

KEY MESSAGE

The consistent and correct use of antiretroviral treatment (ART) by people living with HIV to maintain an undetectable viral load is a highly effective strategy to prevent the sexual transmission of HIV. When this strategy is used consistently and correctly there is no risk of sexual HIV transmission.

For more information, please see the evidence review at the end of this statement.

RECOMMENDATIONS FOR SERVICE PROVIDERS

In addition to improving the health of people living with HIV, ART has important HIV prevention benefits when it is used to maintain an undetectable viral load. People working with communities at risk for or living with HIV have an important role to play in promoting this approach as a highly effective prevention strategy.

Below are recommendations on how you might better integrate the use of ART for prevention into your programming.

1. Improve awareness of the use of ART to maintain an undetectable viral load as a highly effective HIV prevention strategy, including the factors important for maximizing its effectiveness. Any educational and counselling activities provided for HIV-positive and HIV-negative clients should include information on the prevention benefits of ART and an undetectable viral load and how to use it consistently and correctly.

Education and counselling activities should also include discussion of other prevention strategies such as, but not limited to, condoms and pre-exposure prophylaxis (PrEP). Encourage clients to choose the combination of strategies that will work most effectively for them.

It is important that clients – whether people living with HIV or those at risk for HIV – be given information and offered counselling about the use of ART to maintain an undetectable viral load as a highly effective strategy to prevent the sexual transmission of HIV. When talking to clients, you can explain to them that a body of evidence shows that people on ART who maintain an undetectable viral load and are engaged in care do not transmit HIV through sex. Discussions should include the factors necessary for maximizing the effectiveness of this strategy. Emphasize that:

- Adherence to ART is essential for the achievement and maintenance of an undetectable viral load (usually defined in Canada as less than 40 or 50 copies of the virus per millilitre of blood).
- It usually takes three to six months to achieve an undetectable viral load. A viral load test is the only way to know if the viral load has reached undetectable levels.
- Maintenance of a sustained undetectable viral load for at least six months is necessary for this approach to be effective. Regular viral load testing is the only way to monitor for a sustained undetectable viral load.
- Regular medical visits are required for ongoing care, including viral load monitoring.

When discussing with a client the use of ART to maintain an undetectable viral load, it is important to recognize that each client has the right to decide whether or not to take ART based on their own assessment of what is best for their health and well-being.

You can also lead or support efforts to improve awareness of the use of ART to maintain an undetectable viral load as a prevention approach among a range of service providers in your area including doctors, nurses, pharmacists and non-clinical staff at community-based organizations.

2. Facilitate and support the use of ART to maintain an undetectable viral load as a prevention strategy.

Treatment guidelines now recommend the offer of ART to all people living with HIV, regardless of their CD4 count. This recommendation is based on the health benefits of starting ART early for people living with HIV, although an important secondary benefit is HIV prevention. If your client is HIV positive, you should help link them to HIV care if they are not already in care. The client's decision to start ART should be well-informed. ART requires a life-long commitment to daily pill-taking and regular visits with a healthcare provider. Facilitating informed decision-making for clients may require provision of services that support the doctor–patient relationship.

Support clients who are using ART with education about its consistent and correct use to maintain an undetectable viral load as a prevention strategy. You may have to deliver, or link clients to, interventions to support medication adherence and continued engagement in medical care. Encourage clients to have regular viral load testing if they want to use ART to maintain an undetectable viral load for prevention, in addition to the benefit to their own health. They should also discuss their viral load test results with their partner(s) on an ongoing basis (if possible).

Encourage and support clients to communicate openly with their sex partner(s). Clients may need support to disclose their HIV status to a sex partner. If a client is in a serodiscordant relationship, important discussion topics for the couple may also include whether there are sexual partners outside the relationship, and the results of viral load monitoring and sexually transmitted infection (STI) tests. Educating HIV-negative clients about HIV viral load and what it means to be undetectable may give them a better understanding of the concept of treatment as prevention.

3. Encourage a comprehensive plan for sexual health. Discuss how the use of ART to maintain an undetectable viral load fits into a comprehensive plan for sexual health including regular STI testing and safer sex practices.

There are circumstances in which HIV transmission can occur when a person living with HIV is on ART. There is a risk of HIV transmission just after starting ART before the viral load becomes undetectable. There is also a risk of HIV transmission if treatment fails to maintain the positive partner's viral load at undetectable levels. This usually happens due to low treatment adherence but can also happen because of drug resistance. If this occurs, the person should discuss options with their doctor. However, studies show that the main risk of transmission to an HIV-negative partner comes from sexual partners outside a serodiscordant relationship, where highly effective prevention strategies may not be used.

It is important that clients understand these risks and the options available to them so they can make an informed decision about using ART as part of a comprehensive sexual health plan to further minimize the risk for HIV transmission over the long term. A comprehensive sexual health plan also helps to protect against STIs because ART does not provide any protection against STIs.

4. Address underlying risk of HIV transmission.

HIV prevention counselling offers an opportunity to engage individuals in additional services. You can help your clients address the underlying factors that may increase their HIV risk, such as depression or alcohol and other substance use; reinforce safer sex strategies; and facilitate the increased use of all appropriate prevention strategies. You may find that counselling alone is not enough. You may need to provide – or link clients to – appropriate and relevant support services.

5. Offer comprehensive couples-based counselling.

For couples, you may want to offer to counsel both partners in the relationship at the same time (couples-based counselling) as this may be more effective than counselling partners individually. Couples-based counselling can create a supportive space where clients can come to a consensual agreement on how to reduce their risk of HIV transmission, develop ways to support each other in using HIV prevention strategies consistently and correctly, and discuss potentially sensitive issues relevant to HIV prevention. Be prepared to discuss issues such as what a couple wants from sex and the type of sex they enjoy most; the desire for pleasure, intimacy, conception, and monogamy or non-monogamy; and disclosure of sex outside the relationship. This counselling can also support non-monogamous clients to develop strategies or agreements

to help prevent HIV or STIs from outside partners, such as the consistent and correct use of condoms for sex outside the relationship.

6. Incorporate information about the use of ART to maintain an undetectable viral load into all prevention programming to increase its impact.

In-person counselling is one way to convey information about ART as a highly effective prevention strategy. However, this information can be integrated into a variety of other communication channels, such as print publications, websites and campaigns to increase its reach and impact.

7. Be prepared to discuss the legal issues around HIV disclosure. Canadian law requires that people tell their sex partners that they have HIV in certain circumstances. However, the law and its application are evolving. For the most up-to-date information on when people with HIV have a legal duty to disclose their HIV status, contact the Canadian HIV/AIDS Legal Network.

TOOLS AND RESOURCES

CATIE resources

- HIV treatment and an undetectable viral load to prevent HIV transmission – fact sheet
- Undetectable viral load and HIV sexual transmission – client resource
- The power of undetectable – client resource
- Getting to undetectable: Population differences in Canada – *Prevention in Focus*
- Couples HIV testing and counselling – *Prevention in Focus*

Guidelines, position papers and consensus statements

- Risk of sexual transmission of HIV from a person with HIV who has an undetectable viral load: Messaging Primer & Consensus Statement – Prevention Access Campaign
- Community Consensus Statement on access to HIV treatment and its use for prevention – AVAC, EATG, MSMGF, GNP+, HIV i-Base, the International HIV/AIDS Alliance, ITPC, NAM/aidsmap
- Position ministérielle – L’effet du traitement des personnes vivant avec le VIH sur le risque de transmission sexuelle de l’infection — ministère de la Santé et des Services sociaux du Québec (in French only)

Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – World Health Organization (WHO)

HIV disclosure

- The Criminalization of HIV Non-Disclosure in Canada: Current status and the need for change (2019) – Canadian HIV/AIDS Legal Network
- Expert consensus statement on the science of HIV in the context of criminal law (2018) – *Journal of the International AIDS Society*
- Criminal Justice System’s Response to Non-Disclosure of HIV (2017) – Department of Justice, Government of Canada
- Sexual Offences against Adults (2017) – Ontario Crown Prosecution Manual
- Sexual Transmission, or Realistic Possibility of Transmission, of HIV (2019) – British Columbia Prosecution Service Crown Counsel Policy Manual
- HIV disclosure to sexual partners: Question and answers for newcomers (2015) – Canadian HIV/AIDS Legal Network

EVIDENCE

In people living with HIV, successful ART can reduce the amount of virus (viral load) in the blood and other bodily fluids to undetectable levels, usually within three to six months of starting treatment.¹ In Canada, an undetectable viral load is usually defined as fewer than 40 or 50 copies of the virus per millilitre of blood.

We know that the amount of HIV in the fluid of someone living with HIV is an important predictor of HIV transmission to an HIV-negative person after a sexual exposure. Research shows that a lower blood viral load is associated with a reduced risk of sexual HIV transmission.² This is because when the viral load in the blood decreases, it also decreases in the sexual fluids (semen, vaginal fluid and rectal fluid) that are commonly involved in the sexual transmission of HIV.³

The first study to conclusively show that ART and an undetectable viral load prevents the sexual transmission of HIV in serodiscordant heterosexual couples was the randomized controlled trial known as HPTN 052.^{4,5} In the final analysis, which included 1,763 heterosexual serodiscordant couples (half of whom were followed for over five and a half years), no HIV transmissions occurred between couples in the study when the HIV-positive partner was on ART and had an undetectable viral load (defined as <400 copies/ml in this study). In total,

eight transmissions occurred between couples while the HIV-positive partner was on ART; however, in all eight cases the viral load was detectable, despite being on ART. Four transmissions occurred in the first three months after the HIV-positive partner started treatment, before the viral load was undetectable. The other four happened when treatment failed to maintain the viral load at undetectable levels. In addition to these eight transmissions, there were 26 people who acquired HIV infection from a sex partner outside of the primary relationship, showing that in a serodiscordant couple in which the HIV-positive partner is on ART with an undetectable viral load, the main risk of HIV transmission comes from outside the relationship. The results of HPTN 052⁵ support the findings from three earlier observational studies among heterosexual serodiscordant couples that ART is a highly effective HIV prevention strategy.⁶⁻⁸

Results from a large two-phase observational study known as PARTNER/PARTNER2 showed that ART and an undetectable viral load (defined as <200 copies/ml in this study) prevents the sexual transmission of HIV in both heterosexual and same-sex male couples in the absence of other forms of HIV prevention (condoms, PrEP or PEP).^{9,10} The first phase of the study included heterosexual and same-sex male couples, and the second phase continued with only same-sex male couples. In this study there were a large number of unprotected sex acts (no condoms, PrEP or PEP) when the viral load was undetectable – approximately 36,000 among heterosexual couples and 76,000 among same-sex male couples enrolled in the study. By the end of the study, there were no HIV transmissions between couples in the study when the HIV-positive partner was on ART and had an undetectable viral load. However, there were sixteen new HIV infections (15 gay men and one heterosexual person) that were transmitted from a sex partner outside of the relationship.

An observational study similar to PARTNER, called Opposites Attract, also found no HIV transmissions between serodiscordant same-sex male couples when the partner was on treatment and maintained an undetectable viral load (<200 copies/ml) despite approximately 16,800 condomless anal sex acts. In this study, three of the HIV-negative partners got HIV from a partner outside of the relationship.¹¹

The results of these (and earlier) studies provide a strong body of evidence showing that people living with HIV who are adherent to ART, engaged in healthcare, and have a sustained undetectable viral load do not transmit HIV sexually. The PARTNER/PARTNER2 and Opposites Attract studies show this is true even when condoms are not used.

In the PARTNER/PARTNER2 and Opposites Attract studies an undetectable viral load was defined as less than 200 copies/ml. This is higher than the level for undetectable viral load defined by tests commonly used in Canada (less than 40 or 50 copies/ml). There were no transmissions in the two studies when the viral load was less than 200 copies/ml (although the vast majority of participants did in fact have a viral load of less than 50 copies/ml). The studies used a higher cut off to ensure accuracy of the viral load results and to enable comparison between research studies. Also, a higher cut off can capture minor viral load “blips” (a temporary viral load increase above 50 copies/ml on one viral load test that returns to undetectable on the subsequent test). This is important as it helped to determine whether viral load blips create a risk for HIV transmission. The results of these studies show that if a person experiences a blip this does not increase their risk for HIV transmission.^{9,10,11} However, the goal for optimal treatment outcomes for an individual living with HIV in Canada is a viral load of less than 50 copies/ml, because when the viral load is low but stays above 50 copies/ml this creates a risk for drug resistance and viral rebound that can lead to treatment failure.

All study participants in the HPTN 052, PARTNER/PARTNER2 and Opposites Attract studies were engaged in ongoing healthcare services, including adherence counselling and regular medical care to monitor viral load. Partners in all three studies were also tested and treated for STIs on an ongoing basis.

While all of this evidence strongly supports the ability of ART to prevent HIV transmissions, this is contingent on the achievement and maintenance of an undetectable viral load. Achieving an undetectable viral load can take time – up to six months or more. HPTN 052 conducted an analysis to determine how long it takes to achieve an undetectable viral load. In HIV-positive participants on ART the cumulative percentage of participants who achieved an undetectable viral load by three, six, nine and 12 months were 76%, 87%, 90%, and 91%.¹

Maintenance of an undetectable viral load over time is also critical, and this requires high adherence to ART. Treatment can sometimes fail to maintain the viral load at undetectable levels due to low treatment adherence or drug resistance. If treatment fails, a person won't know their viral load is detectable until their next viral load test. This time period between viral load tests may provide an opportunity for the transmission of HIV. A change in therapy or adherence support may be required to suppress the viral load if treatment failure does occur. The best options for moving forward should be discussed with a doctor.

Several studies show that STIs can increase the risk of HIV transmission, but these studies did not measure the viral load of the HIV-positive partner.¹³ Results from the PARTNER/ PARTNER2 and Opposites Attract studies show that an undetectable viral load prevents HIV transmission even in the presence of other STIs.^{10,11} Between these two studies, no HIV transmissions occurred when the HIV-positive or HIV-negative partner had an STI. In PARTNER/PARTNER2 alone, there were 6,090 instances of condomless sex when an STI was present. However, regular STI testing and treatment should be part of any comprehensive sexual health plan.

Based on studies that looked at people who were on ART and had an undetectable viral load, we conclude that the consistent and correct use of ART to maintain an undetectable viral load, is a highly effective strategy to prevent the sexual transmission of HIV.

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DISCLAIMER

Decisions about particular medical treatments should always be made in consultation with a qualified medical practitioner knowledgeable about HIV- and hepatitis C-related illness and the treatments in question.

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Funding has been provided by the Public Health Agency of Canada.

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