

# HIV treatment and an undetectable viral load to prevent HIV transmission

## FACT SHEET

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### Summary

The use of HIV treatment not only improves the health of people living with HIV but also is a highly effective strategy to prevent HIV transmission. This is because HIV treatment can reduce the amount of virus (known as the viral load) in the blood and other bodily fluids (such as semen and vaginal and rectal fluids) to undetectable levels. To achieve and maintain an undetectable viral load, people living with HIV need to take their HIV treatment as prescribed. In addition to taking HIV medications, regular medical visits are important to monitor viral load to make sure it stays undetectable and to receive other medical support.

Evidence shows that people living with HIV who are on treatment, engaged in care and have an ongoing undetectable viral load:

- do not transmit HIV to their sexual partners;
- do not transmit HIV to their baby during pregnancy and delivery (if they maintain an undetectable viral load throughout pregnancy and childbirth);
- have a greatly reduced chance of transmitting HIV through breastfeeding (also known as chestfeeding); however, breastfeeding is not recommended in Canada (exclusive formula feeding is recommended); and

- are likely to have a reduced chance of transmitting HIV to people with whom they share injection drug use equipment; however, there is not enough evidence to conclude that there is no risk. It is recommended that people use new needles and all other equipment every time they use drugs, regardless of their HIV status or viral load, to prevent HIV as well as other harms.

### **How does HIV treatment and an undetectable viral load work to prevent HIV transmission?**

HIV treatment, also called antiretroviral therapy (ART), works by controlling the replication of HIV in the body — that is, it reduces HIV's ability to make copies of itself. When HIV replication is controlled, the amount of virus (also known as the viral load) in the blood and other bodily fluids decreases. Research tells us that as the amount of virus in the body decreases, so does the risk of HIV transmission. When successful treatment lowers the viral load to undetectable levels, this can reduce or even eliminate the risk of HIV transmission.

HIV treatment usually consists of a combination of three antiretroviral drugs taken daily. Newer HIV treatments are safer, simpler and more effective than when treatment was first introduced. The power of treatment today is so profound that many people who start effective treatment soon after becoming HIV positive will have a normal lifespan.

For most people the virus becomes so well controlled that within three to six months of starting treatment the amount of virus in their blood becomes undetectable by routinely used tests. Most viral load tests used in Canada cannot detect HIV in the blood if there are fewer than 40 to 50 copies/ml of the virus but some newer tests can detect as few as 20 copies/ml. The virus is still present in very low amounts in the body when the viral load is undetectable.

### **What is involved in the consistent and correct use of HIV treatment to maintain an undetectable viral load for HIV prevention?**

The consistent and correct use of HIV treatment to maintain an undetectable viral load includes:

- high adherence to medications, to achieve and maintain an undetectable viral load
- regular medical appointments to monitor viral load and receive adherence support, if needed

Regular testing and treatment for sexually transmitted infections (STIs) is also important because HIV treatment does not protect against STIs.

A person on HIV treatment needs to work with their doctor to determine an appropriate schedule for medical checkups and viral load monitoring.

### **What is important for this approach to work?**

For HIV treatment to provide protection against HIV transmission, a person's viral load needs to become and remain undetectable after they start treatment.

When a person begins treatment, it usually takes three to six months for their viral load to become undetectable. Most people will eventually have an undetectable viral load if they are using HIV treatment that is effective against their strain of HIV and take it as prescribed by their doctor.

It is recommended that a person maintains a sustained undetectable viral load for at least six months before they start to rely on this approach as their main HIV prevention strategy. They must continue to have high adherence to treatment to maintain an undetectable viral load over time. The only way for someone to know if their viral load remains undetectable over the long term is to have regular viral load tests.

However, not everyone's viral load becomes and remains undetectable on treatment. The most common reason why a person's viral load stays detectable is low adherence to their medications, but drug resistance can also occur. When treatment fails, a person won't know that their viral load is

detectable until they get another viral load test. Depending on the reason the treatment failed, a person may require a change in treatment, or they may benefit from adherence counselling, to bring their viral load back down to undetectable levels. The best options for moving forward should be discussed with a doctor.

### **How well does the use of HIV treatment to maintain an undetectable viral load prevent the sexual transmission of HIV?**

Research conducted in serodiscordant couples (where one partner is HIV positive and the other is HIV negative) shows that consistent and correct use of HIV treatment to maintain an undetectable viral load is a highly effective strategy to prevent sexual HIV transmission for both heterosexual and same-sex male couples. Evidence from this research shows that when people are on successful treatment and engaged in care there is no risk of transmitting HIV through sex.

The first study to show that HIV treatment and an undetectable viral load provide a major prevention benefit in serodiscordant heterosexual couples was the randomized controlled trial known as HPTN 052. In the final analysis, which included 1,763 serodiscordant heterosexual 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 treatment 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 treatment; however, in all eight cases the HIV-positive partner's viral load was detectable, even though they were on treatment. 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, 26 people acquired HIV from a sex partner outside of the primary relationship, showing that in a serodiscordant couple in which the HIV-positive partner is on treatment with an undetectable viral

load, the risk of sexual HIV transmission comes from outside the relationship.

Results from a large two-phase observational study known as PARTNER/PARTNER2 showed that treatment and an undetectable viral load (defined as <200 copies/ml in this study) prevents sexual HIV transmission in both heterosexual and same-sex male couples in the absence of other forms of HIV prevention (condoms, pre-exposure prophylaxis [PrEP] or post-exposure prophylaxis [PEP]). 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 many unprotected sex acts (no condoms, PrEP or PEP) when the HIV-positive partner's 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 treatment and had an undetectable viral load. However, 16 new HIV infections (in 15 gay men and one heterosexual person) 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 HIV-positive partner was on treatment and maintained an undetectable viral load (<200 copies/ml in this study) 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.

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 20 to 50 copies/ml). There were no transmissions in the two studies when the viral load was less than 200 copies/ml (however, 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 the accuracy of the viral load results and to enable comparisons to be made 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. However, for optimal treatment outcomes, the goal 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.

In both the PARTNER/PARTNER2 and Opposites Attract studies, many participants (roughly 25%) contracted STIs. In the 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. This indicates that STIs do not increase the risk of HIV transmission from people who are on treatment and have an undetectable viral load.

All participants in these studies were engaged in regular healthcare appointments to check their viral load, test for STIs and receive adherence and prevention counselling. They were also treated for STIs when needed. These comprehensive supports are an important part of regular follow-up care while on HIV treatment.

The results of these (and earlier) studies provide a strong body of evidence showing that people living with HIV who adhere to their treatment and engage in regular healthcare, with a sustained undetectable viral load, do not transmit HIV sexually. The PARTNER/PARTNER2 and Opposites Attract studies show that this is true even when condoms are not used, and in the presence of other STIs.

### **How can service providers improve the uptake and correct use of HIV treatment and an undetectable viral load to prevent the sexual transmission of HIV?**

Educational and counselling activities for people — whether they have HIV or are at risk for HIV — should include information on the HIV prevention benefits of treatment and an undetectable viral

load, along with information on the other highly effective ways to help prevent HIV. These include PrEP, 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 approaches to HIV and STI prevention that can be combined in different ways. Discuss how the use of HIV treatment to maintain an undetectable viral load fits into a comprehensive plan for sexual health including regular STI testing and safer sex practices.

Education and counselling on the use of this HIV prevention strategy should include a discussion about the large body of evidence showing that people on HIV treatment who maintain an undetectable viral load do not transmit HIV through sex. Education should also include the factors necessary for maximizing the effectiveness of this strategy. Emphasize the following:

- Adherence to ART is essential for the achievement and maintenance of an undetectable viral load.
- It usually takes three to six months on treatment to achieve an undetectable viral load.
- Maintenance of a sustained undetectable viral load for at least six months is recommended before relying on this approach for HIV prevention.
- Regular medical visits are required for ongoing care and viral load monitoring. Regular viral load testing is the only way to know that an undetectable viral load is reached and sustained.

You can also lead or support efforts to improve awareness of the use of HIV treatment 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.

For people living with HIV, it's important to facilitate and support the use of HIV treatment to maintain an undetectable viral load as a prevention strategy. This can include supporting people to start treatment. Treatment guidelines recommend that HIV treatment be offered to all people

living with HIV as soon as they test positive. This recommendation is based on the health benefits of starting treatment early for people living with HIV, although an important secondary benefit is HIV prevention. A person's decision to start treatment should be well-informed. HIV treatment requires a lifelong commitment to taking medication and regular visits with a healthcare provider. Each person has the right to decide whether to take treatment based on their own assessment of what is best for their health and well-being. Help link HIV-positive clients to HIV care if they are not already in care. Facilitating informed decision-making may require providing services that support a client's relationship with their doctor.

While starting HIV treatment is a choice, it is important to recognize that broader social, economic and structural factors (such as racism, homelessness and poverty) create health inequities by affecting people's ability to access and engage with treatment, care and support services. Service providers can help to address these barriers. People who are on HIV treatment may need to be provided with or linked to supports that can help address other health and social issues they are dealing with, such as depression, substance use disorders or housing instability. They may also benefit from other supports to overcome barriers and successfully adopt this strategy — such as medication adherence support, health navigation and/or outreach services.

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. Consider couples-based counselling for people in relationships (whether monogamous or not). If a client is in a serodiscordant relationship, important discussion topics for the couple may include whether there are sexual partners outside the relationship, and the results of viral load monitoring and 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.

Finally, 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 [HIV Legal Network](#).

### **How well does the use of HIV treatment to maintain an undetectable viral load prevent HIV transmission to a baby during pregnancy and birth?**

Without treatment, there is a 15% to 30% chance that a baby born to a person living with HIV will get HIV during pregnancy or delivery. Taking HIV treatment is the most effective way to reduce transmission to the baby. In fact, research has shown that if a pregnant person starts HIV treatment before conception and maintains an undetectable viral load throughout pregnancy and delivery, they do not transmit HIV to their baby. A short course of HIV medications is also given to the infant to prevent HIV transmission.

For the last three decades, a growing body of evidence has shown that babies are much less likely to be born with HIV if the pregnant parent is on treatment. A study of the French Perinatal Cohort, conducted between 2000 and 2017, is the largest study to show the impact of treatment on preventing HIV transmission to a newborn. This study found that no HIV transmissions occurred among 5,482 infants born to cisgender women who were on treatment before they conceived and throughout their pregnancy, who had an undetectable viral load (defined as less than 50 copies/ml) at delivery and who did not breastfeed.

The French study also showed that starting HIV treatment as soon as possible in pregnancy dramatically lowers the chance of transmission. In the study, there was a 0.52% chance of passing HIV to a baby if treatment was started in the first trimester, a 0.75% chance if treatment was started in the second trimester and a 1.67% chance if treatment was started in the third trimester. Viral load was not taken into account in this analysis.

It is important that people who are pregnant or considering becoming pregnant get tested for HIV. People who test positive should begin HIV treatment

as soon as possible to reduce or eliminate the risk of passing HIV to their babies. Likewise, people living with HIV who wish to become pregnant should consult with an HIV specialist as soon as possible, preferably before conception, to determine a suitable treatment regimen for pregnancy.

### **How well does the use of HIV treatment to maintain an undetectable viral load prevent HIV transmission to a baby during breastfeeding?**

Without HIV treatment, the risk for HIV transmission through breastfeeding is estimated to be roughly 15%. The rates of HIV transmission through breastfeeding for people who are taking HIV treatment are much lower. A systematic review of HIV transmission in breastfed infants of cisgender women on treatment found that the risk of transmission after birth was 1% after six months of breastfeeding, rising to almost 3% after one year. However, in these studies, the women were on treatment for varying amounts of time and did not continue treatment beyond six months after giving birth. The systematic review did not account for adherence or for viral load, which means that even though the women were taking HIV treatment we do not know how many of them had a detectable viral load at the time of transmission.

Only a few studies have measured the risk of transmission through breastfeeding when the mother was on treatment and had an undetectable viral load. The largest study to do so is called PROMISE and was done in several African countries and India. Among the 1,220 infants whose mother was taking treatment, seven acquired HIV through breastfeeding, an infection rate of 0.57%. In five out of the seven cases, the mother had a detectable viral load at their most recent viral load test before the baby tested positive. In the other two cases, the mother had an undetectable viral load at their most recent viral load test. This means that some infants acquired HIV despite the mother being on treatment and having an undetectable viral load near the time of transmission.

Three smaller studies have also looked at HIV transmission through breastfeeding in the context

of treatment and an undetectable viral load. Two of those studies found no transmissions when the mother was taking treatment and had an undetectable viral load throughout the time they were breastfeeding. In the third study, two infants acquired HIV although their mothers had an undetectable viral load at their last test. Taken together, these studies suggest that the risk of transmission when the parent is on treatment and has an undetectable viral load is very low but not zero.

Canadian guidelines continue to recommend that HIV-positive parents exclusively feed their babies formula to eliminate the possibility of transmission. However, guidelines also recommend supporting people with HIV who wish to breastfeed and helping them do so as safely as possible. This includes offering unbiased information on the risk of HIV transmission through breastfeeding, providing increased viral load monitoring and adherence support, and providing prophylactic treatment for infants born to people living with HIV. Several case studies have documented women with HIV in North America who were supported to breastfeed by their medical team. None of the babies from these case reports have contracted HIV.

### **How can service providers improve the uptake and correct use of HIV treatment and an undetectable viral load to help prevent perinatal HIV transmission?**

Please see the [CATIE Statement on the use of antiretroviral treatment \(ART\) to maintain an undetectable viral load as a highly effective strategy to prevent perinatal transmission of HIV](#).

### **How well does the use of HIV treatment to maintain an undetectable viral load prevent HIV transmission through injection drug use?**

The limited available research suggests that being on HIV treatment and maintaining an undetectable viral load is effective at helping to prevent HIV transmission among people who inject drugs; however, people who use drugs can get

HIV through sex and through sharing drug use equipment. While we know that maintaining an undetectable viral load will prevent HIV transmission through sex, we don't know how much it reduces the chance of passing HIV through shared drug use equipment. The best way to prevent passing HIV through drug use is to use new needles and other equipment every time. People who use drugs need access to enough new equipment to be able to do this consistently and to avoid having to share with others.

The three major studies looking at sexual HIV transmission (HPTN 052, PARTNER and Opposites Attract) did not systematically recruit people who inject drugs, they did not ask whether participants were sharing injection equipment and they did not provide any analysis related to participants who reported using drugs.

Two ecological studies from Vancouver and Baltimore reported on reductions in new HIV infections over time and found an association with a reduction in the community viral load of people who inject drugs. Although it is likely that increased uptake of HIV treatment is partly responsible for the observed decline in the number of new infections, it is difficult to know how much of this change can be attributed to an increase in harm reduction services that also occurred during this period. A cohort study in India among 14,481 people who inject drugs and 12,022 men who have sex with men found a clear correlation between estimated HIV incidence and both community-level treatment coverage and viral suppression. This study found significant correlations at the community level, but since it was not designed to look at individual risk of transmission, no estimate of effectiveness was available.

## Resources

### CATIE resources

[The Power of Undetectable: How HIV Treatment Prevents Transmission – booklet](#)

[HIV Treatment to Prevent HIV - video](#)

[Can't Pass It On – awareness campaign](#)

[CATIE Statement on the use of antiretroviral treatment \(ART\) to maintain an undetectable viral load as a highly effective strategy to prevent perinatal transmission of HIV](#)

[Getting to undetectable: Population differences in Canada – \*Prevention in Focus\*](#)

[U=U: A guide for service providers](#)

### Guidelines, position papers and consensus statements

[Expert consensus statement on the science of HIV in the context of criminal law \(2018\) – \*Journal of the International AIDS Society\*](#)

[Expert Consensus: Viral Load and the Risk of HIV Transmission – Institut National de Santé Publique du Quebec \(INSPQ\)](#)

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

[Human immunodeficiency virus \(HIV\) Sexual Transmission Risk with Bacterial Sexually Transmitted Infection \(STI\) Co-infection – Public Health Ontario](#)

[Canadian HIV Pregnancy Planning Guidelines](#)

[Canadian Pediatric & Perinatal HIV/AIDS Research Group consensus recommendations for infant feeding in the HIV context](#)

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