

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.

The consistent and correct use of ART to maintain an undetectable viral load is a highly effective strategy to prevent perinatal transmission of HIV. When ART is used consistently and correctly before conception and throughout pregnancy, there is no risk of transmission during labour and delivery. When ART is used consistently and correctly after conception for the remainder of the pregnancy, there is a low risk of HIV transmission.*

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 among serodiscordant couples when they are trying to conceive. When ART is used consistently and correctly there is no risk of sexual HIV transmission.

Canadian guidelines recommend that infants be exclusively formula fed, as evidence suggests there is still a low risk of HIV transmission during breastfeeding (also called chestfeeding) when the lactating parent is on ART and maintains an undetectable viral load.

* Perinatal transmission is defined as HIV being passed from a parent to their baby during pregnancy or labour, or through breastfeeding (chestfeeding).

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Our knowledge of effective strategies for preventing perinatal transmission of HIV has improved significantly since the beginning of the epidemic. To maximize impact, we must effectively raise awareness and encourage uptake and proper use of these prevention tools.

This CATIE statement summarizes the best available evidence on the effectiveness of ART to maintain an undetectable viral load to prevent perinatal transmission of HIV.

This statement was developed to help service providers in Canada adapt their programs and incorporate this evidence into their messaging to clients. This statement begins with simple key messages, 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.

KEY MESSAGES

The consistent and correct use of ART to maintain an undetectable viral load is a highly effective strategy to prevent perinatal transmission of HIV. When ART is used consistently and correctly before conception and throughout pregnancy, there is no risk of transmission during labour and delivery. When ART is used consistently and correctly after conception for the remainder of the pregnancy, there is a low risk of HIV transmission.

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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 the important benefit of helping to prevent HIV transmission through multiple routes including sexual and perinatal transmission. People working with communities living with HIV have an important role to play in promoting the use of ART and an undetectable viral load to prevent transmission.

Below are recommendations on how you might better integrate the prevention of perinatal transmission of HIV into your messaging.

1. Facilitate and support the uptake of ART.

Treatment guidelines 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 not already in HIV care, you should help link them to care. The client's decision to start ART should be well informed. ART requires a lifelong commitment to taking medication and regular visits with a healthcare provider, including doctors, nurses, nurse practitioners and/or pharmacists. Facilitating informed decision-making for clients may require provision of services that support the healthcare provider–patient relationship.

2. Improve awareness that condomless sex is recommended as the primary method for conception among people in serodiscordant relationships when the HIV-positive partner is on ART and has maintained an undetectable viral load.

This prevents HIV transmission to the HIV-negative sex partner while allowing for conception.

Canadian pregnancy planning guidelines recommend condomless sex as the primary method for conception for people in a serodiscordant relationship when the HIV-positive partner is on ART and has a sustained undetectable viral load. People who are on ART and maintain an undetectable viral load do not pass HIV to their sex partner.

Any person who is in a serodiscordant relationship and wishes to conceive should be educated about the HIV prevention benefits of ART and an undetectable viral load when they are having condomless sex to conceive. Education and counselling should include how to use ART consistently and correctly.

Emphasize these points:

- 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; some newer tests can detect as few as 20 copies/ml).
- Canadian guidelines recommend that the HIV-positive partner should maintain an undetectable viral load for at least three months, ideally six months, before engaging in condomless sex for conception.

- Maintenance of a sustained undetectable viral load 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.
- People with HIV who are trying to conceive should speak to their doctor to ensure that the HIV medications they are taking are appropriate for pregnancy.
- Timing sex around ovulation increases the chance of conception.
- Upon successful conception, all pregnant people should be referred to prenatal care.

If conception through condomless sex is unsuccessful, the services of a fertility clinic may be needed. Adoption is also an option for people with HIV in Canada.

3. Improve awareness that the use of ART to maintain an undetectable viral load is a highly effective strategy to prevent the perinatal transmission of HIV during pregnancy and delivery.

Any person with HIV who is pregnant, who is considering pregnancy or who could become pregnant in the future should be educated about the benefit of ART and an undetectable viral load for preventing the perinatal transmission of HIV. Their partners should also receive this education. Education and counselling should include how to use ART consistently and correctly.

People who are on treatment and maintain an undetectable viral load *before* conception and for the duration of their pregnancy do not transmit HIV to their infants during pregnancy or delivery. However, for people who do not start treatment and achieve an undetectable viral load until after conception, there is still a low chance of HIV transmission during pregnancy or delivery. The sooner an HIV-positive pregnant person starts treatment and reaches an undetectable viral load the lower the risk of perinatal transmission. No matter what stage of pregnancy your clients are at, you can help to facilitate and support them to start treatment and use it consistently and correctly.

When talking to your clients, you can explain to them that a body of evidence shows that being on ART and maintaining an undetectable viral load is a highly effective approach to prevent perinatal transmission. Emphasize the following:

- 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; some newer tests can detect as few as 20 copies/ml).
- It usually takes three months or less to achieve an undetectable viral load, but it can take as long as six months. 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 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 during pregnancy, including viral load monitoring (every four to eight weeks).
- In addition to ART, Canadian guidelines recommend that people with HIV receive intravenous HIV medication during labour and delivery to further reduce the risk of passing HIV to their baby.
- Canadian guidelines recommend that if a person has an undetectable viral load they can have a vaginal delivery, unless there is another medical reason why they should not deliver vaginally.
- Canadian guidelines recommend that newborn babies be prescribed a six-week course of HIV medication to further reduce the chance of perinatal transmission. However, some physicians prescribe a four-week course based on recent evidence.
- Babies born to an HIV-positive parent will receive an HIV test immediately after birth. If the result of this test is negative, the child will receive testing three more times (at one month of age, three to four months of age and 18 months of age) to confirm they are HIV negative.

You can also lead or support efforts to improve awareness that using ART to maintain an undetectable viral load is an approach to prevent perinatal transmission among a range of service providers in your area, including doctors, nurses, reproductive health specialists, pharmacists and non-clinical staff at community-based organizations.

4. Improve awareness that guidelines recommend exclusive formula feeding of infants.

Educate clients about the Canadian recommendation that people with HIV exclusively formula feed their babies. Explain that while taking ART and maintaining an undetectable viral load does dramatically reduce the chance of passing HIV to a baby through breastfeeding, the evidence suggests there is still a low risk of transmission.

Assure clients that formula gives babies the nutrients they need for healthy development. Explain that Canadian guidelines are different from guidelines in low-income countries because most people in Canada are able to access clean water to mix formula with and therefore formula feeding is safe in Canada. Refer clients to free formula programs if they are available in your community.

Let clients know that if they do not breastfeed they may experience breast pain for several days after the birth. Advise clients not to pump their milk because doing so would cause their body to produce more milk. You can provide suggestions for managing pain such as using a cold compress or taking over-the-counter pain medication. Advise clients to see a healthcare provider if they are having difficulty managing the pain.

Talk to clients about their feelings about infant feeding. Some clients may have a strong desire to breastfeed for personal reasons or because of social or cultural pressures. It is important to listen to clients' concerns without judgment. Clients who choose to formula feed may need support to address their concerns, such as how to bond with their baby without breastfeeding, and how to deal with social and cultural pressures to breastfeed.

Clients who decide to breastfeed should be encouraged to get support from an HIV doctor. An HIV doctor can help a person to breastfeed as safely as possible. This will include educating the client about factors that might increase the risk of transmission. The doctor will make a plan for ongoing monitoring of the health of the lactating parent and baby and may prescribe HIV medication for the baby while the baby is breastfeeding to further reduce the risk of transmission.

5. Address underlying health and social issues that clients may be experiencing.

When a client is planning to have a baby, is pregnant or has a new baby, you should be prepared to refer them to any needed services, such as:

- income support programs

- housing
- food security programs
- drug and alcohol programs
- mental health programs
- health care
- programs that address intimate partner violence

Recognizing that these issues are very important and affect a person's well-being and potentially their adherence to ART, you should make yourself aware of services available in your local community. You can then refer your clients and their partners to these services when necessary.

TOOLS AND RESOURCES

Client resources

Growing your Family: An introduction to pregnancy planning, surrogacy and adoption for people living with HIV

Is Formula Good for My Baby?

Service provider resources

A step by step process on how we can support mothers living with HIV – *CATIE Blog*

Pregnancy and infant feeding: Can we say U=U about the risk of passing HIV to an infant? – *Prevention in Focus*

Views from the front lines: Pregnancy and infant feeding – *Prevention in Focus*

HIV treatment and an undetectable viral load to prevent HIV transmission – *Fact sheet*

Guidelines, position papers and consensus statements

Canadian HIV Pregnancy Planning Guidelines

Prevention of vertical HIV transmission and management of HIV-exposed infant in Canada in 2014

Guidelines for the Care of Pregnant Women Living With HIV and Interventions to Reduce Perinatal Transmission

EVIDENCE

In the studies related to labour, delivery and infant feeding, we refer to women and mothers, consistent with the language used in these studies, which did not indicate any inclusion of trans people. Results may be relevant to people who have babies who do not identify as women.

Preventing sexual transmission during conception

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. In Canada, an undetectable viral load is usually defined as fewer than 40 or 50 copies of the virus per millilitre of blood (though some newer tests can detect as few as 20 copies/ml).

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.¹ 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.²

Studies looking at the connection between viral load and sexual transmission have included heterosexual couples as well as same-sex male couples. Though studies with same-sex male couples do not relate directly to conception, we have included them in this review because these studies contribute to the body of evidence showing that maintaining an undetectable viral load prevents the sexual transmission of HIV.

The first study to conclusively show that ART and an undetectable viral load prevent the sexual transmission of HIV in serodiscordant heterosexual couples was the randomized controlled trial known as HPTN 052.^{3,4} 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 HIV-positive partner's viral load was detectable, even though they were on ART. Four transmissions occurred in the first three months after the HIV-positive partner started treatment, before their viral load was undetectable. The other four happened when treatment failed to maintain the HIV-positive partner's viral load at undetectable levels. In addition to these eight transmissions, 26 people 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 052⁴ support the findings from three earlier observational studies among heterosexual serodiscordant couples that ART is a highly effective HIV prevention strategy.⁵⁻⁷

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) prevent the sexual transmission of HIV 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]).^{8,9} 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 16 new HIV infections (in 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.¹⁰

Preventing transmission during pregnancy and delivery

In the absence of successful HIV treatment, HIV can be passed from a person living with HIV to a baby during pregnancy and delivery. The chance of passing HIV during pregnancy or delivery is estimated to be between 15% and 30% without any HIV treatment.¹¹

Without HIV treatment, the chance of passing HIV to a baby is highest during delivery or very close to the time of delivery. Studies done before highly effective HIV treatment became available found that roughly two-thirds of babies who were born with HIV contracted the virus during delivery or very late

in pregnancy, and the remaining one-third contracted HIV earlier in pregnancy.^{12,13}

For the last three decades, evidence has been mounting showing that babies are much less likely to be born with HIV if the mother is on treatment.^{12,14–19} A study of the French Perinatal Cohort is the largest study to show the impact of treatment on preventing HIV transmission to a newborn.¹⁶ This study was conducted between 2000 and 2011 and included 8,075 mother–infant pairs, where the mother was living with HIV. In 2,651 of these cases, the mother started HIV treatment before becoming pregnant, continued treatment throughout her pregnancy, had an undetectable viral load (defined as <50 copies/ml in this study) at the time of delivery and did not breastfeed. In these cases, none of the newborns contracted HIV.

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 0.4% chance of passing HIV to a baby if the mother started treatment in the first trimester, a 0.9% chance if she started it in the second trimester and a 2.2% chance if she started it in the third trimester. The mother's viral load was not taken into account for these calculations.

Preventing transmission through infant feeding

Before highly effective HIV treatment became available, the risk for HIV transmission through breastfeeding was estimated to be roughly 15%.^{20,21} With ART the rates of HIV transmission through breastfeeding are much lower. A systematic review found that among women on HIV treatment who breastfed, there was a 1% postnatal transmission rate after six months and a 3% postnatal transmission rate after one year.²² 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.

One Tanzanian study has found that treatment and an undetectable viral load dramatically lower the chance of transmission to the infant.²³ That study reported no HIV transmissions through breastfeeding among women who were engaged in care and had a suppressed viral load (defined as <100 copies/ml in this study). The study included 186 infants. Two infants contracted HIV, and in both cases the mother had a detectable viral load.

The PROMISE study, conducted in Africa and India, provided treatment to 2,431 breastfeeding women or their newborn infants. Among the 1,219 women receiving treatment, seven had infants who acquired HIV by 12 months (for an HIV transmission rate of 0.57%).²⁴ Only two of these cases were among women who had an undetectable viral load. Another study found two cases of HIV transmission among breastfeeding women who appeared to have an undetectable viral load close to the time of transmission (defined as <400 copies/ml in this study).²⁵

Large studies that examine breastfeeding have been done in low-income countries where the benefits of breastfeeding may outweigh the risks of transmitting HIV through breastfeeding. No large study has been done in a high-income country to show the risk of transmission when the mother has an undetectable viral load (at the 50 copies/ml threshold).²⁶ However, some researchers have suggested that the risk of transmission with an undetectable viral load is so low that women who want to breastfeed could reasonably decide that the health benefits of breastfeeding may be worth the risk.^{26,27} In Canada, three babies were supported to breastfeed when the mothers had undetectable viral loads and both the mothers and infants received ART. None of the babies contracted HIV.²⁸

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