

Undetectable Viral Load Reduces the Risk of Sexual Transmission of HIV to Negligible levels

A growing body of evidence demonstrates that people living with HIV who have a sustained undetectable viral load for six months or more have a negligible – meaning so insignificant, small, or unimportant as to not worth being considered – chance of passing on the virus during sex, regardless of whether condoms are used. This applies to all genders and methods of sexual transmission, including vaginal, front hole, anal and oral.

Given this breakthrough, ACT is confident in the use of effective HIV treatment as a reliable form of HIV prevention.

ACT's position rests upon evidence from two scientifically and statistically sound, largescale research studies. Together, these studies have demonstrated the effectiveness of HIV treatment and undetectable viral loads at preventing HIV transmission. With a combined but approximate 58,000 sex acts reported, there was no linked HIV transmission between couples.

The Studies:

The HPTN 052 study first reported interim results in 2011 and final results in 2015.¹ HPTN 052 compared the rates of HIV transmission between serodiscordant (mixed HIV status) couples. In one group, the HIV-positive partner waited to start HIV treatment after being diagnosed. In the other group, the HIV-positive partner began HIV treatment upon learning of their diagnosis.

Takeaways from HPTN 052:



- beginning HIV treatment upon learning of a diagnosis reduced the risk of onwards transmission by 96% compared to people who were HIV-positive but not on treatment
- the study was interested in the effects of antiretroviral treatment more broadly on HIV transmission risk, not just people who attained and sustained an undetectable HIV viral load
- the study looked only at heterosexual transmission risk
- HPTN 052 did not investigate HIV transmission risk through anal sex among serodiscordant (mixed HIV status) MSM couples (men who have sex with men)
- the results demonstrate that effective HIV treatment is an effective form of HIV prevention among heterosexual serodiscordant couples

<u>The PARTNER study</u> reported interim results in 2014 and published final results in 2016.² PARTNER looked at the risk of HIV transmission when a person's viral load had been rendered undetectable. The criteria used to qualify as undetectable was a viral load below 200 copies/ml of blood.³ Participants included serodiscordant heterosexual and MSM couples having condomless anal and vaginal sex, both receptive and penetrative.

Takeaways from PARTNER:

 effective HIV treatment lowers the viral load in many people living with HIV to undetectable levels, and an undetectable viral load renders the risk of transmitting HIV to effectively zero



- some participants were removed from the study because their viral load ceased to be undetectable and did not return to being undetectable, rendering them outside of the eligibility criteria for the study and outside of the research question being considered
- the study observed that some participants' viral load briefly rose but then returned to undetectable levels. In these cases, the participants were kept in the study. Notably, these people did not transmit HIV despite a temporary rise in their viral load⁴
- the presence of an STI did not impact the risk of transmission for a person living with HIV when accompanied by an undetectable viral load⁵

What These Results Mean

The results of these studies attest to the truth and power of HIV treatment as HIV prevention. A Canadian-born strategy, "treatment as prevention," or TasP, improves the health of people living with HIV, reduces the stigma surrounding HIV, and dramatically reduces the risk of HIV transmission.⁶

This new research should be embraced and celebrated by people living with HIV, their care providers, community partners, and the public. It should also serve as further motivation to ensure all people living with HIV in Canada and around the world have low-barrier access to HIV treatment, as well as the supports to remain adherent and address any underlying mental health challenges that can impact treatment adherence.



While the results of these studies are definitive, that does not mean there are not considerations. The authors of the PARTNER study report a 95% confidence limit to its data and explain that "with eligible couple-years accrued so far, appreciable levels of risk cannot be excluded, particularly for anal sex and when considered from the perspective of a cumulative risk over several years."⁷ If concerned about STIs or pregnancy, an undetectable HIV viral load is not applicable and other safer sex methods should be used. The PARTNER study results had an upper 95% confidence limit of 0.3% risk per year. The study includes the following interpretation: "Compared with risks of daily life, this maximum estimate of risk is considered relatively low (no study can confirm 100% safety). However, deciding whether health risks are considered high or low is a personal decision. Deciphering whether benefits outweigh risks is up to the individual."

ACT recognizes that for some people living with HIV, attaining and maintaining an undetectable viral load may not be possible. Reasons for this are complex and relate to treatment access, treatment effectiveness, and other personal health challenges. As a result, we understand the benefits of an undetectable viral load to be absolute but recognize that further work is required to extend the benefits to as many people living with HIV in Canada as possible. While HIV treatment will not always yield an undetectable viral load, it can consistently lower viral loads and generate a host of benefits to the overall health and well-being of people living with HIV.

ACT is dedicated to strengthening the health and well-being of the communities it works with, and recognizes its role in communicating the benefits and limitations of emerging



HIV treatment and prevention technologies. We will continue our tradition of challenging HIV-related stigma and commit to achieving our vision of a Toronto with zero AIDS-related deaths and zero new HIV infections. HIV treatment as HIV prevention and undetectable viral loads are crucial to securing this optimistic future.



Endnotes:

¹ Safren SA, Mayer KH, Ou SS, McCauley M, Grinsztejn B, Hosseinipour MC, Kumarasamy N, Gamble T, Hoffman I, Celentano D, Chen YQ, Cohen MS; HPTN 052 Study Team, Adherence to Early Antiretroviral Therapy: Results From HPTN 052, a Phase III, Multinational Randomized Trial of ART to Prevent HIV-1, <u>Journal of Acquired</u> <u>Immune Deficiency Syndrome.</u> 2015 Jun 1;69(2):234-40.

² Rodger AJ, Cambiano V, Bruun T, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy. *JAMA*. 2016;316(2):171-181.

³ This is a significantly higher threshold than in Canada, which defined undetectable as a viral load below 40 copies/ml of blood.

⁴ Rodger, Cambiano, Bruun et al, "Sexual Activity Without Condoms," 177.

⁵ Rodger, Cambiano, Bruun et al, "Sexual Activity Without Condoms," 179.

⁶ Montaner JS, Hogg R, Wood E, Kerr T, Tyndall M, Levy AR, Harrigan PR. The case for expanding access to highly active antiretroviral therapy to curb the growth of the HIV epidemic. Lancet. 2006 Aug 5; 368(9534):531-6.

⁷ Rodger, Cambiano, Bruun et al, "Sexual Activity Without Condoms," 179.