New Proof That Passing On HIV While Undetectable Is Very Unlikely

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A major study examining how antiretrovirals (ARVs) reduce the risk of HIV transmission among heterosexuals has found that no participant with a fully suppressed viral load infected his or her long-term HIV-negative partner. These final results from the HPTN 052 study of 1,763 mixed-HIV-status heterosexual couples were presented at the Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in Vancouver, British Columbia.

“The study now makes crystal clear that when an HIV-infected person takes antiretroviral therapy that keeps the virus suppressed, the treatment is highly effective at preventing sexual transmission of HIV to an uninfected heterosexual partner,” Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases, said in a press release. “For heterosexuals who can achieve and maintain viral suppression, the risk to their partners is exceedingly low.”

In 2011, interim results from HPTN 052 revolutionized the global approach to HIV prevention by showing that starting ARV treatment reduced by 96 percent the risk than an individual with HIV would transmit the virus to an HIV-negative primary partner (at least among heterosexuals). The notion of “treatment as prevention” (TasP) went mainstream. With the U.S. approval of Truvada (tenofovir/emtricitabine) as pre-exposure prophylaxis (PrEP) in 2012, biomedical prevention efforts extended to at-risk HIV-negative individuals as well: giving them the opportunity to take ARVs to reduce their risk of acquiring the virus.

Then, in 2014, an interim analysis of the still-ongoing PARTNER trial, focusing on 767 heterosexual and gay mixed-HIV status couples in which the HIV-positive partner was taking ARVs, found that there were no transmissions of the virus within the couples. (The trial is set to complete in 2017.) When presenting the findings at a major conference, Jens Lundgren, MD, chief physician and director of the Copenhagen HIV Programme, estimated that the chance of transmitting HIV when the virus is fully suppressed by ARVs is close to zero, and might even be zero.

The final results of HPTN 052 add support to Lundgren’s assessment.

HPTN 052 included couples in Malawi, Zimbabwe, South Africa, Botswana, Kenya, Thailand, India, Brazil, and the United States. Enrollment began in April 2005 and the trial concluded in May 2015. The HIV-positive partners had CD4 counts between 350 and 500 upon entering the study and were randomly divided into two groups: Members of one group, called the early arm, received HIV

treatment immediately; those in the other group, the delayed arm, received ARVs once their CD4s hit 250 or below, or they developed AIDS-defining illnesses.

After the 2011 analysis showed how well ARVs prevented transmission, all participants were offered treatment.

By the end of the trial, 1,171 (66 percent) of the original couples remained in the study, including 603 of 886 (68 percent) in the early arm and 568 of 877 (65 percent) in the delayed arm. All told, the participants contributed 9,822 person-years of follow-up.

Before the investigators offered HIV treatment to all, there was one HIV transmission within a couple in the immediate arm. The investigators proved that this was what they call a "linked infection" by conducting genetic testing on all HIV-positive partners' viruses as well as anyone who contracted the virus during the study, and then comparing genetic similarity. There were also 35 linked infections in the delayed arm.

During the entire decade-long study, there were 46 linked infections, 3 in the immeidate arm and 43 in the delayed arm. Eight of these cases were transmissions from an HIV-positive partner taking ARVs. Four of those eight infections were diagnosed not long after the HIV-positive partner started treatment, suggesting that the partner may not have had an undetectable viral load yet, or that the transmission occured just before he or she started treatment. The remaining four transmissions were diagnosed when the HIV-positive partner experienced failure of their ARV regimen (perhaps because they were not taking their medications as prescribed or had a strain of the virus resistant to one or more ARV in their regimen) and developed a detectable viral load.

"These findings demonstrate that HIV transmission is very unlikely when viral replication is suppressed," the study authors conclude.

The new analysis estimates that starting ARVs earlier rather than waiting reduces the risk of HIV transmission by 93 percent.

The study results highlight that failing an HIV regimen can open the door for transmission of the virus. (A separate analysis found that taking longer to suppress the virus in the first place raises the likelihood of eventual treatment failure, and that those who start treatment with a higher viral load tend to take longer to suppress the virus on treatment.) So, in the context of treatment as prevention, simply being on ARVs is not necessarily a safeguard against passing on the virus; the most central factor is actually succeeding on therapy and having an undetectable viral load.

ARVs, the authors write, "combined with counseling and provision of condoms provides durable, highly effective protection from HIV transmission in serodiscordant couples."

To read the press release, click here.

To read a Q&A about the trial, click here.

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