



Undetectable Meant Zero HIV Transmissions After 89,000 Condomless Sex Acts

The newly released PARTNER2 study documented 77,000 condomless anal sex acts between mixed-HIV-status men; Opposites Attract had 12,000.

July 24, 2018 By [Benjamin Ryan](#)

An enormous trove of evidence has just been released that supports the increasingly solid global consensus that having an undetectable viral load thanks to antiretroviral (ARV) treatment is associated with effectively zero chance of transmission.

The long-awaited results from the PARTNER2 study of mixed-HIV-status gay male couples are finally in. Presented today at the International AIDS Conference in Amsterdam (AIDS 2018), the prospective observational study saw zero transmissions between study partners when the HIV-positive partner had a fully suppressed viral load, even after nearly 77,000 condomless anal sex acts. Together with the 12,000 condomless sex acts documented between such partners in the Opposites Attract study, researchers now have data on 89,000 such acts between male partners.

In recent years, three major studies have followed mixed-HIV-status couples over time in an effort to assess the power of ARV treatment to prevent transmission. None have seen the HIV-positive participants transmit the virus to their study partners when they had an undetectable viral load. The [HPTN 052](#) study included only heterosexual couples, while the [PARTNER](#) study included both male-female and male-male couples; the Opposites Attract study, which was [just published](#), focused exclusively on male-male couples.

Because the PARTNER study had less data on gay male partners compared with heterosexual partners, the study authors extended the study with a phase called PARTNER2 to gather more data pertaining to gay couples. The purpose of this extended and expanded study was to reach a refined level of mathematical certainty about the risk of transmission of HIV between men when one has an undetectable viral load and the other is HIV negative.

According to an agency press release, having reviewed the evidence from these studies, Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID), in an address he gave in a July 22 preconference meeting in Amsterdam, concluded “that the body of scientific evidence to date has established that there is effectively no risk of sexual transmission of HIV when the partner living with HIV has a durably undetectable viral load, validating the U=U [Undetectable = Untransmittable] message of HIV treatment as prevention.”

Anthony S. Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID) Benjamin Ryan

The PARTNER study was conducted in 14 European countries. The first phase, which ran from September 2010 to May 2014, recruited heterosexual and gay male mixed-HIV-status, or serodiscordant, couples. The second phase ran through April 2018 and continued following serodiscordant gay male couples already in the study while also recruiting new couples in this demographic.

The investigators collected sexual behavior information from participants upon their entry into the study and every six to 12 months thereafter. The HIV-negative partners also received testing for the virus while the HIV-positive partners received viral load tests at each study visit. If an initially HIV-negative partner contracted the virus, the study authors conducted genetic testing to determine whether his virus was genetically linked to his partner's, helping to determine whether the virus transmitted from one to the other.

As with Opposites Attract, the final analysis of the extended PARTNER study, known as PARTNER2, looked only at study follow-up time during which the HIV-positive partners had a viral load below 200, the HIV-negative partners were not on PrEP and the participants reported condomless anal sex within each couple.

Between September 2010 and July 2017, the study enrolled 972 serodiscordant gay male couples; 783 of these couples provided the study with 1,596 cumulative years of follow-up that qualified for

the final analysis. (Each year of follow-up for each couple counted as one year in this equation, not two.) Each couple was followed for a median of 1.6 years.

Upon entry into the study, the average age of the participants was 40 years old for the HIV-positive partners, with the 25th to 75th percentile range spanning 33 to 46 years old. The corresponding respective figures for the HIV-negative men were 38 years old and 31 to 45 years old. The HIV-positive men had been on treatment for the virus for a median 4.0 years at the study's outset. The couples reported condomless sex during a median of 1.0 years of follow-up.

Twenty-seven percent of the HIV-positive participants and 23 percent of the HIV-negative participants were diagnosed with a sexually transmitted infection (STI) during the study's follow-up period.

Thirty-seven percent of the HIV-negative men reported condomless sex with outside partners.

During the follow-up periods eligible for the final analysis, the couples in PARTNER2 reported 76,991 condomless sex acts with one another, or a median of 43 such sex acts per couple per year, with a 25th to 75th percentile range of 19 to 74 acts per couple per year.

Opposites Attract, meanwhile, had data on 12,447 reported acts of condomless anal intercourse between two men in which one was HIV positive and had a viral load below 200 and the other was HIV negative and not on PrEP.

So between PARTNER2 and Opposites Attract, researchers have now documented 89,438 condomless sex acts and zero HIV transmissions within mixed-HIV-status gay-male couples in which the HIV-positive partner had a fully suppressed viral load. When Opposites Attract's findings were first [presented](#) at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017) a year ago, this cumulative figure was far less than half that, at 35,000 such sex acts.

The first phase of PARTNER, meanwhile, had data on about 36,000 condomless sex acts between mixed-HIV-status heterosexual couples and zero transmissions of the virus between them.

In PARTNER2, 37 percent of the HIV-negative men reported condomless sex with partners other than their main partner.

Fifteen of the initially HIV-negative men in PARTNER 2 tested positive for the virus during follow-up, 11 of whom reported recent condomless sex with outside partners. None of these infections were genetically linked to these men's primary partners. Consequently, the study authors concluded that there were zero genetically linked HIV transmissions within the couples during the follow-up time that qualified for the final analysis.

When the PARTNER results were published in 2016, the study authors provided various estimate ranges within which the true risk of transmission lies for various sex acts when one partner has a

fully suppressed HIV viral load and the other is HIV negative. For heterosexuals engaging in anal or vaginal sex, the investigators estimated that the risk of transmission per 100 cumulative years of follow-up in this context was between zero and 0.97 transmissions when the male has and between zero and 0.88 when the female has HIV.

Because this initial phase of the study had less data on gay male couples, the estimate range on HIV transmission risk for this demographic was less precise than for heterosexuals. Breaking down these estimate ranges by sex acts, the PARTNER study estimated that per 100 cumulative years of follow-up among gay-male couples, the risk of transmission was as little as zero for all sex acts and as great as 0.84 transmissions for any kind of sex, 0.89 transmissions for anal sex in general, 1.0 transmission for insertive anal sex (being the top), 2.7 transmissions for receptive anal sex with ejaculation (bottoming with the top cumming inside) and 1.68 transmissions for receptive anal sex without ejaculation.

Thanks to the much greater level of follow-up data supporting the PARTNER2 findings, these upper limits of the risk of transmission were narrowed to a respective 0.23, 0.24, 0.27, 0.57 and 0.43 transmissions per cumulative 100 years for any kind of sex, anal sex in general, insertive anal sex, receptive anal sex with ejaculation and receptive anal sex without ejaculation. In addition, the study authors calculated that the upper limits of the risk of transmission for any type of sex while infected with an STI was 2.74 transmissions per cumulative 100 years.

Again, the low end of all these estimate ranges was zero, meaning that the true risk of HIV transmission for any kind of intercourse between men may indeed be zero, provided the partner living with the virus has a fully suppressed virus.

“Now we can have just as much confidence in the power of [HIV] treatment as prevention for gay-male couples as we have had for heterosexual couples,” said Linda-Gail Bekker, MD, PhD, president of the International AIDS Society and the international chair of AIDS 2018, in a call with reporters prior to the conference. Bekker is a professor of medicine and the deputy director of the Desmond Tutu HIV Centre at the University of Cape Town in South Africa.

Linda-Gail Bekker, MD, PhD Benjamin Ryan

In PARTNER2, the respective cumulative years of follow-up and number of reported condomless sex acts for any kind of sex was 1,596 years and 76,991 acts for any kind of sex, 1,546 years and 70,743 acts for anal sex in general, 1,345 years and 52,572 acts for insertive anal sex, 652 years and 20,770 acts for receptive anal sex with ejaculation, 867 years and 23,153 acts of receptive anal sex without ejaculation, and 135 years and 6,301 acts for any sex with an STI.

Editor's note: The figures in this article have been updated to reflect more up-to-date data from the researchers.

To read the NIAID press release, [click here](#).