# Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV

HIV treatment has dramatically improved the health, quality of life, and life expectancy of people with HIV.<sup>1,2,3,4</sup> HIV treatment has also transformed the HIV prevention landscape. Over the last decade, research has shown the profound impact of HIV treatment in preventing the sexual transmission of HIV, sometimes called "Treatment as Prevention" (TasP).<sup>1,5,6,7,8,9,10</sup> This fact sheet summarizes the evidence, reviews key factors needed to maximize the effectiveness of TasP, and provides an overview of what CDC is doing to increase awareness of this prevention strategy.



People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load (or stay virally suppressed) have effectively no risk of transmitting HIV to their HIV-negative sexual partners.

# The Evidence

In 2011, the interim results of the HPTN052 clinical trial¹ demonstrated a 96% reduction in HIV transmission risk among heterosexual mixed-status (also referred to as HIV-discordant) couples where the partner with HIV started antiretroviral therapy (ART) immediately versus those delaying ART initiation. The final results published in 2016 reported that there had been no HIV transmissions within these couples when the partner with HIV had a suppressed viral load (defined as having a viral load of less than 400 copies of HIV RNA per milliliter). Genetically linked HIV infections were observed between sexual partners in 8 couples; however, all of these transmissions occurred while the partner with HIV was not virally suppressed. In other words, linked HIV transmissions occurred only when:

- The partner with HIV had started ART but *before* the partner with HIV had achieved and maintained viral suppression, or
- The partner with HIV had achieved viral suppression but the ART regimen later failed or the partner with HIV had stopped taking their medication.

Three recent studies, PARTNER, Opposites Attract, and PARTNER2 (an extension of PARTNER focusing on HIV-discordant MSM couples), report similar results. None of these studies observed any genetically linked infections while the partner with HIV was virally suppressed and the couples were engaging in sex without a condom and not using pre-exposure prophylaxis (PrEP).<sup>8,9,10</sup> In these studies, viral suppression was defined as less than 200 copies of HIV RNA per milliliter of blood; most participants with HIV in the PARTNER study had less than 50 copies of HIV RNA per milliliter of blood.<sup>8</sup> The three studies included over 500 HIV-discordant heterosexual couples, with about half having a male partner with HIV (PARTNER), and more than 1,100 HIV-discordant MSM couples (PARTNER2; Opposites Attract) from 14 European countries, Australia, Brazil, and Thailand. Combined, these couples engaged in over 125,000 sex acts without a condom or PrEP over more than 2,600 couple-years of observation.

The studies reported transmission risk estimates and their corresponding 95% confidence intervals as:

- PARTNER study:8
- For any sex among heterosexual and male-male couples: 0.00 (0.00 0.30) per 100 couple-years
- For anal sex among male-male couples: 0.00 (0.00 0.89) per 100 couple-years
- Opposites Attract study:9
  - For anal sex among male-male couples: 0.00 (0.00 1.59) per 100 couple-years
- PARTNER2 study (which includes data from PARTNER):10
- For anal sex among male-male couples: 0.00 (0.00 0.24) per 100 couple-years

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Together, the data from the PARTNER2 and Opposites Attract studies produce a combined transmission risk estimate for anal sex without a condom and PrEP among MSM couples of 0.00 (0.00-0.21) per 100 coupleyears, with the upper bound equal to a 0.21% annual risk (unpublished data). Pooling data from all three studies produces a combined transmission risk estimate for sex without a condom among heterosexual or MSM couples of 0.00 (0.00-0.14) per 100 couple-years, with the upper bound indicating a 0.14% annual risk (unpublished data). These data provide conclusive evidence of the power of viral suppression in preventing HIV transmission. Although statistically a non-zero risk estimate can never be completely ruled out in a mathematical sense, despite the number of observations, the data tell us that the best estimate for the transmission risk is zero and that future HIV transmissions are not expected when people with HIV remain virally suppressed.

# Maximizing the Effectiveness of the Prevention Strategy in Practice

The success of the TasP strategy depends on achieving and maintaining an undetectable viral load. While many people with HIV taking ART are virally suppressed, some people with HIV are currently not virally suppressed or do not maintain viral suppression over time. CDC's national surveillance data estimate that 65% of all people with diagnosed HIV in 41 states and the District of Columbia in 2018 were virally suppressed, defined as less than 200 copies of HIV RNA per mL of blood at most recent test.<sup>11</sup> Among people in HIV clinical care (defined as either receiving HIV medical care or having a CD4 or viral load test within the past year), about 85% were virally suppressed at their last test.<sup>11</sup> In a cross-sectional analysis of people with diagnosed HIV, most of whom were in care in the last 12 months (95%), about two-thirds (62%) achieved and maintained viral suppression over 12 months, which means around one-third (or 1 in 3) did not maintain viral suppression over that time period.<sup>12</sup>

About 85% of people in HIV care were virally suppressed at their last test.

About 2/3 of people with diagnosed HIV maintained viral suppression over a year.

To help all individuals with HIV and their partners get maximal benefit from this prevention strategy, it is important to give providers, people with HIV, and their partners clear information regarding the benefits as well as the challenges with achieving and maintaining viral suppression. The challenges include the following:

**Time to viral suppression:** Most people will achieve an undetectable viral load within 6 months of starting ART. Many will become undetectable very quickly, but it could take more time for a small portion of people just starting ART.

Adherence to daily treatment: Taking HIV medicine as prescribed is the best way to achieve and maintain an undetectable viral load. Poor adherence, such as missing multiple doses in a month, could increase a person's viral load and their risk for transmitting HIV. People who are having trouble taking their HIV medicine as prescribed can work with health care providers to improve their adherence. If an individual is experiencing adherence challenges, other prevention strategies could provide additional protection until the individual's viral load is confirmed to be undetectable.

**Knowledge of viral load:** Regular viral load testing is critical to confirm that an individual has achieved and is maintaining an undetectable viral load. It is not known if viral load testing should be conducted more frequently than currently recommended for treatment if someone is relying on treatment and viral suppression as a prevention strategy. Data show a discordance between some people's self-report of their viral load status and laboratory measurements, suggesting that people may not know or be able to accurately report their viral load level. Just because someone was virally suppressed in the past does not guarantee they are still virally suppressed. However, the good news is the longer someone is virally suppressed, the more likely they will remain virally suppressed if they continue to take HIV medicine as prescribed.

**Stopping HIV medication:** If an individual stops taking their HIV medicine, their viral load will increase, in some cases within a few days, and eventually return to around the same level it was before starting their HIV medicine. People who have stopped taking their HIV medicine should talk to their health care provider as soon as possible about their own health and use other strategies to prevent sexual HIV transmission.

**Protection against other STDs:** Taking HIV medicine and achieving and maintaining an undetectable viral load does not protect either partner from getting other sexually transmitted diseases (STDs). Other prevention strategies, such as condoms, are needed to provide protection from STDs.

Lack of knowledge or awareness about the benefits of viral suppression: Knowledge of the prevention benefits of viral suppression may help motivate people with HIV and their partners to adopt this strategy. <sup>14</sup> Studies have shown that a significant proportion of people do not know or do not believe that viral suppression works for prevention. For example, a recent study of over 111,000 men who have sex with men found that about half the study population indicated that a message about the prevention benefits of having an undetectable viral load was accurate, including nearly 84% of people with HIV, followed by 54% of people without HIV and 39% of people with an unknown HIV status. <sup>15</sup> Though knowledge appears to be increasing over time, more work is needed to increase knowledge and awareness among people with HIV and their sexual partners, as well as people without HIV and those who don't know their HIV status. <sup>16</sup>

# What CDC Is Doing

CDC is working with prevention partners across the nation to prioritize efforts to maximize the impact of TasP. CDC joined other federal agencies in an effort led by the U.S. Department of Health and Human Services (HHS) to help ensure that each agency communicates about the effectiveness of TasP in a clear, concise, and accurate manner. The HHS workgroup agreed on the following core prevention message:

People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load (or stay virally suppressed) have effectively no risk of transmitting HIV to their HIV-negative sexual partners.

The term "effectively no risk" was selected to reflect that while it is not possible to statistically rule out a non-zero risk, all evidence to date suggests that it is not realistically possible to sexually transmit HIV while the person with HIV remains undetectable or virally suppressed. There is also strong evidence that TasP helps prevent transmission to others through injection drug use, and from mother-to-child during pregnancy, birth, and breastfeeding.

As CDC continues to maximize the impact of TasP, we will continue to strengthen longstanding programs and respond with new efforts funded through the *Ending the HIV Epidemic* initiative.<sup>17</sup> Programmatic efforts help expand HIV testing services to people not recently tested or not aware of their HIV status, diagnose people with HIV earlier, link or re-engage them to effective HIV care and treatment, and support adherence to HIV treatment to achieve viral suppression and ultimately reduce transmission.<sup>18,19,20</sup> Through education campaigns and online risk reduction tools and resources, CDC is committed to increasing awareness of the full range of available prevention strategies and their effectiveness.<sup>21,22</sup>

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