

# HIV Treatment as Prevention: Including Undetectable = Untransmittable (updated January 2023)



# HIV Treatment as Prevention: Including Undetectable = Untransmittable

This educational packet is a curated compilation of resources on HIV treatment as prevention, including undetectable = untransmittable.

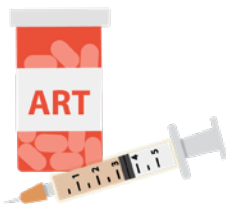
The contents of this packet are listed below:

- HIV Treatment Is HIV Prevention (CDC)
- HIV Treatment as Prevention (HIV.gov)
- Viral Suppression and an Undetectable Viral Load (HIV.gov)
- Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV (CDC)
- The Journey to Undetectable (CDC)
- Antiretroviral Therapy to Prevent Sexual Transmission of HIV (Treatment as Prevention) (HHS)

You may wish to customize this packet to meet the needs or interests of particular groups, such as event participants, providers, patients, clients, or the general public. So please feel free to distribute all or part of this document as either a printout or PDF.

# HIV TREATMENT IS HIV PREVENTION

## IF YOU HAVE HIV, YOU SHOULD START HIV TREATMENT AS SOON AS POSSIBLE TO



- Improve your health, and
- Prevent transmitting HIV to other people.

HIV treatment can reduce the amount of HIV in the blood (*viral load*). HIV treatment can make the viral load so low that a test can't detect it (*undetectable viral load*).

Having an undetectable viral load (or staying virally suppressed\*) is the best thing you can do to stay healthy. If your viral load stays undetectable, you will not transmit HIV to your sex partner.

## IF YOU WANT TO GET AND KEEP AN UNDETECTABLE VIRAL LOAD, YOU SHOULD



- **Take your HIV treatment as prescribed.** Most people can get the virus under control within 6 months of starting treatment. Missing doses of your treatment can increase your viral load and the risk of transmitting HIV. Talk to your health care provider about ways to follow your treatment plan.
- **See your provider regularly to check your viral load.** Not everyone taking HIV medicine has an undetectable viral load. The only way to know if you have an undetectable viral load is by getting tested regularly.

## GETTING AND KEEPING AN UNDETECTABLE VIRAL LOAD PREVENTS HIV TRANSMISSION DURING SEX. BUT THERE ARE SITUATIONS WHEN EITHER PARTNER MAY WANT TO USE ADDITIONAL PREVENTION OPTIONS.

Using condoms can prevent some other STDs. Using condoms or having your partner take PrEP (pre-exposure prophylaxis) can provide added peace of mind. Also consider using additional prevention options if you

- are unsure that you have an undetectable viral load;
- are having difficulty keeping an undetectable viral load; or
- missed some doses of HIV treatment since your last viral load test, stopped your treatment, or have trouble taking it regularly.



Get tested for other STDs. HIV treatment doesn't protect against other STDs like syphilis and gonorrhea, and other STDs can increase the chance of getting or transmitting HIV.



\* Being virally suppressed means having a very low viral load (less than 200 copies of HIV per milliliter of blood). The benefits of having an undetectable viral load also apply to people who stay virally suppressed.

[Scan to learn more!](#)

For more information, please visit [www.cdc.gov/hiv](http://www.cdc.gov/hiv).



# EL TRATAMIENTO DEL VIH ES PREVENCIÓN DEL VIH

## SI USTED TIENE EL VIH, DEBE COMENZAR EL TRATAMIENTO LO ANTES POSIBLE PARA LO SIGUIENTE



- Mejorar su salud, y
- Prevenir la transmisión del VIH a otras personas.

El tratamiento para el VIH puede reducir la cantidad de VIH en la sangre (carga viral). El tratamiento para el VIH puede reducir la carga viral a niveles tan bajos que las pruebas no la pueden detectar (carga viral indetectable).

Tener una carga viral indetectable (o mantener la supresión viral\*) es lo mejor que puede hacer para mantenerse sano. Si su carga viral se mantiene indetectable, usted no transmitirá el VIH a su pareja sexual.

## SI USTED QUIERE LOGRAR Y MANTENER UNA CARGA VIRAL INDETECTABLE, DEBERÁ HACER LO SIGUIENTE



- **Tomar el tratamiento para el VIH según las indicaciones.** La mayoría de las personas logra tener el virus bajo control dentro de los 6 meses de haber empezado el tratamiento. Saltarse dosis de su tratamiento puede aumentar su carga viral y el riesgo de transmitir el VIH. Hable con su proveedor de atención médica sobre las maneras de seguir con el plan de tratamiento.
- **Ver al proveedor de atención médica con regularidad para que revise su carga viral.** No todas las personas que toman los medicamentos para el VIH logran una carga viral indetectable. La única manera de saber si usted tiene una carga viral indetectable es hacerse las pruebas regularmente.

## LOGRAR Y MANTENER UNA CARGA VIRAL INDETECTABLE PREVIENE LA TRANSMISIÓN DEL VIH DURANTE LAS RELACIONES SEXUALES. PERO HAY SITUACIONES EN LAS QUE UN MIEMBRO DE LA PAREJA POSIBLEMENTE QUIERA USAR OPCIONES DE PREVENCIÓN ADICIONALES.

El uso de condones puede prevenir algunas de las otras ETS. Si usan condones o su pareja toma la PrEP (profilaxis preexposición), esto les puede dar más tranquilidad. También considere usar opciones de prevención adicionales si usted:

- no está seguro de tener una carga viral indetectable;
- tiene dificultad para mantener una carga viral indetectable; o
- se saltó algunas dosis del tratamiento para el VIH desde que se hizo la última prueba de carga viral, dejó el tratamiento o tiene dificultad para seguirlo regularmente.



Hágase las pruebas de detección de otras ETS. El tratamiento del VIH no protege contra otras ETS como la sífilis y la gonorrea, y tener otras ETS puede aumentar la probabilidad de contraer o transmitir el VIH.



\* Tener supresión viral significa tener una carga viral muy baja (menos de 200 copias del VIH por mililitro de sangre). Los beneficios de tener una carga viral indetectable también los tienen las personas que mantienen la supresión.

¡Escanea para obtener más información!

Para obtener más información, visite la página [www.cdc.gov/hiv/spanish](http://www.cdc.gov/hiv/spanish).



# HIV Treatment as Prevention

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 [hiv.gov/tasp](https://hiv.gov/tasp)

## What Is Treatment as Prevention?

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**Treatment as Prevention** (TasP) refers to taking HIV medicine to prevent the sexual transmission of HIV. It is one of the most highly effective options for preventing HIV transmission.

People with HIV who take HIV medicine (called antiretroviral therapy or ART) as prescribed and get and keep an undetectable viral load—a very low level of HIV in the blood—can **live long and healthy lives** and **will not transmit HIV to their HIV-negative partners through sex**. This is sometimes called undetectable = untransmittable (U=U).

TasP works when a person with HIV takes HIV medicine exactly as prescribed and has regular follow-up care, including routine viral load tests to ensure their viral load stays undetectable.

## Taking HIV Medicine to Stay Healthy and Prevent Transmission

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HIV treatment involves taking highly effective medicine that reduces the amount of HIV in your body. HIV medicine is recommended for everyone with HIV, and people with HIV should start HIV medicine as soon as possible after diagnosis, even on that same day.

People on HIV treatment take a combination of HIV medicines (called an HIV treatment regimen). A person's initial HIV treatment regimen generally includes three HIV medicines from at least two different HIV drug classes that must be taken every day. Many people with HIV take two or more different HIV medicines combined in one pill. Long-acting injections of HIV medicine, given every two months, are also available if your health care provider determines that you meet certain requirements.

If taken as prescribed, HIV medicine reduces the amount of HIV in your blood (also called your viral load) to a very low level, which keeps your immune system working and prevents illness. This is called **viral suppression, defined as 200 copies of HIV per milliliter of blood**.

HIV medicine can also make your viral load so low that a standard lab test can't detect it. This is called having an **undetectable viral load**. Almost everyone who takes HIV medicine as prescribed can achieve an undetectable viral load, usually within 6 months after starting treatment. Many will bring their viral load to an undetectable level very quickly, but it could take more time for a small portion of people just starting HIV medicine.

There are important **health benefits** to getting the viral load as low as possible. People with HIV who know their status, take HIV medicine as prescribed, and get and keep an undetectable viral load can live long and healthy lives.

There is also a **major prevention benefit**. People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load will not transmit HIV to their HIV-negative partners through sex.

## Keep Your Viral Load Undetectable

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HIV treatment is not a cure and HIV is still in your body, even when your viral load is undetectable, so you need to keep taking your HIV medicine as prescribed. If you skip doses of your HIV medicine, even now and then, you give HIV the chance to multiply rapidly. This could weaken your immune system, and you could become sick.

If you have stopped taking your HIV medicine or are having trouble taking all the doses as prescribed, talk to your health care provider as soon as possible. Your provider can help you get back on track and discuss the best strategies to prevent transmitting HIV to your sexual partners until your viral load is confirmed to be undetectable again.

[Get tips on taking HIV medicine as prescribed.](#)

## How Do We Know Treatment as Prevention Works?

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Large research studies with newer HIV medicines have shown that treatment *is* prevention. Over several years, these studies monitored thousands of male-female and male-male couples in which one partner has HIV and the other does not. No HIV transmissions were observed when the HIV-positive partner was virally suppressed. This means that if you keep your viral load undetectable, you will not transmit HIV to someone you have vaginal, anal, or oral sex with.

In addition to preventing sexual transmission of HIV, studies have shown that there are other prevention benefits of taking HIV medicine to get and keep an undetectable viral load:

- **It reduces the risk of HIV transmission to the child during pregnancy, labor, and delivery.** If a pregnant person takes HIV medicine daily as prescribed throughout pregnancy, labor, and delivery and gives HIV medicine to the infant for 4-6 weeks after giving birth, the risk of transmitting HIV to the baby can be 1% or less.
- **It substantially reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding.** The current recommendation in the United States is that mothers with HIV should not breastfeed their infants.

- **It may reduce HIV transmission risk for people who inject drugs.** Scientists do not have enough data to know whether having a suppressed or undetectable viral load prevents HIV transmission through sharing needles, syringes, or other injection drug equipment (for example, cookers). It very likely reduces risk, but it's unknown by how much. Even if you are taking HIV medicine and have an undetectable viral load, use new equipment each time you inject and do not share needles and syringes with other people.

[Read about the scientific evidence of having an undetectable viral load and preventing sexual HIV transmission.](#)

## **Talk with Your Health Care Provider about Getting to Undetectable**

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Talk with your health care provider about the benefits of HIV treatment and which HIV medicine is right for you. Discuss how frequently you should get your viral load tested to make sure you get and keep an undetectable viral load. If your lab results show that the virus is detectable or if you are having trouble taking every dose of your medicine, you can still protect your HIV-negative partner by using other methods of preventing sexual transmission of HIV such as condoms, safer sex practices, and/or pre-exposure prophylaxis (PrEP) for an HIV-negative partner until your viral load is undetectable again. Talk to your partner about post-exposure prophylaxis (PEP) if you think they may have had a possible exposure to HIV (for example, if the condom breaks during sex and you don't have an undetectable viral load).

Taking HIV medicine to maintain an undetectable viral load does not protect you or your partner from getting other sexually transmitted infections (STIs), so talk to your provider about ways to prevent other STIs.

## **Talk to Your Partner**

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TasP can be used alone or in conjunction with other prevention strategies. Talk about your HIV status with your sexual partners and decide together which prevention methods to use. Some states have laws that require you to tell your sexual partner that you have HIV in certain circumstances.

# Viral Suppression and an Undetectable Viral Load

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 [hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/viral-suppression](https://hiv.gov/hiv-basics/staying-in-hiv-care/hiv-treatment/viral-suppression)

## Viral Suppression and Undetectable Viral Load: What Do They Mean?

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If taken as prescribed, HIV medicine reduces the amount of HIV in your blood (also called your viral load) to a very low level. This is called **viral suppression**. Viral suppression is defined as having less than 200 copies of HIV per milliliter of blood. Viral suppression helps to keep you healthy and prevents transmission.

HIV medicine can make your viral load so low that it doesn't show up in a standard lab test. This is called having an **undetectable viral load**.

Reaching and maintaining HIV viral suppression (or an undetectable viral load) is a primary goal of HIV treatment. Treatment with HIV medicine is recommended for all people with HIV, regardless of how long they've had the virus or how healthy they are.

## How Do You Get Your Viral Load to Undetectable and Keep It There?

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People with HIV can get and keep an undetectable viral load by taking HIV medicine (called antiretroviral therapy or ART) exactly as prescribed. Almost everyone who takes HIV medicine as prescribed can reach an undetectable viral load, usually within six months after starting treatment. But treatment is not a cure. HIV is still in your body when your viral load is suppressed, even when it is undetectable. If you skip doses of your HIV medicine, even now and then, your viral load will quickly go back up. If you have stopped taking your HIV medicine or are having trouble with taking your doses as prescribed, talk to your health care provider as soon as possible about strategies to get your viral load suppressed.

[Get tips on taking HIV medicine as prescribed.](#)

If the HIV medicines you are taking don't suppress your viral load, you and your health care provider can talk about whether another combination of HIV medicines might work better for you. There are many different [treatment options](#) available.

## Benefits of Having an Undetectable Viral Load

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**There are important health benefits** to having a suppressed or undetectable viral load. People with HIV who know their status, take HIV medicine as prescribed, and get and keep an undetectable viral load can **live long and healthy lives**.



**There is also a major prevention benefit.** People with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load **will not transmit HIV to their HIV-negative partners through sex.** This is sometimes called treatment as prevention or undetectable = untransmittable (U=U).

In addition to preventing sexual transmission of HIV, studies have shown that there are other prevention benefits of taking HIV medicine to get and keep an undetectable viral load:

- **It reduces the risk of HIV transmission to the child during pregnancy, labor, and delivery.** If a pregnant person takes HIV medicine daily as prescribed throughout pregnancy, labor, and delivery and gives HIV medicine to the baby for four to six weeks after delivery, the risk of HIV transmission to the baby can be 1% or less.
- **It substantially reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding.** The current recommendation in the United States is that mothers with HIV should not breastfeed their infants.
- **It may reduce HIV transmission risk for people who inject drugs.** Scientists do not have enough data to know whether having a suppressed or undetectable viral load prevents HIV transmission through sharing needles, syringes, or other injection drug equipment (for example, cookers). It very likely reduces risk, but it's unknown by how much. Even if you are taking HIV medicine and have an undetectable viral load, use new equipment each time you inject and do not share needles and syringes with other people.

[Read about the scientific evidence of an undetectable viral load in preventing the sexual transmission of HIV.](#)

## **Talk with Your Health Care Provider**

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Talk with your health care provider about these benefits of HIV treatment and discuss which HIV medicine is right for you. Stay in medical care and discuss how frequently you should get your viral load tested to make sure you get and keep an undetectable viral load.

If your lab results show that the virus is detectable or if you are having trouble taking every dose of your medicine, you can still protect your HIV-negative partner by using other methods of preventing sexual transmission of HIV such as pre-exposure prophylaxis (PrEP) for an HIV-negative partner until your viral load is undetectable again. PrEP is medicine that people at risk for HIV take to prevent getting HIV from sex or injection drug use. Also talk to your partner about post-exposure prophylaxis (PEP) if you think they may have had a possible exposure to HIV (for example, if a condom breaks during sex and you don't have an undetectable viral load).

Also talk to your provider about ways to prevent *other* sexually transmitted infections (STIs), such as gonorrhea, chlamydia, or syphilis. Having an undetectable viral load only prevents transmission of HIV, not other STIs.

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

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 [cdc.gov/hiv/risk/art/evidence-of-hiv-treatment.html](https://www.cdc.gov/hiv/risk/art/evidence-of-hiv-treatment.html)

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.

## The Evidence

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In 2011, the interim results of the HPTN052 clinical trial<sup>1</sup> 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).<sup>7</sup> 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:<sup>8</sup>
  - 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:<sup>9</sup>
  - For anal sex among male-male couples: 0.00 (0.00 – 1.59) per 100 couple-years
- PARTNER2 study (*which includes data from PARTNER*):<sup>10</sup>
  - For anal sex among male-male couples: 0.00 (0.00 – 0.24) per 100 couple-years

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 couple-years, 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

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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>

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.<sup>13</sup> 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

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CDC is working with prevention partners across the nation to prioritize efforts 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 in the U.S.* 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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# THE JOURNEY TO UNDETECTABLE



HIV medicine can reduce the amount of HIV in your blood (called viral load) to a level so low that a test can't detect it. This is known as an "**undetectable viral load**," or "**undetectable**."

If you get an undetectable viral load and keep it, you have **effectively no risk** of transmitting HIV to an HIV-negative partner through sex.



If you have HIV, you should take medicine to treat HIV as soon as possible to:



**Improve your overall health**



**Prevent transmitting HIV to other people**

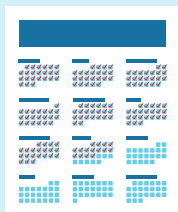


Once you start taking HIV medicine, you are on your journey to being undetectable.

By taking medicine daily, as prescribed, most people can get an undetectable viral load within **6 months**.



The longer you are undetectable, the more likely you will stay undetectable.



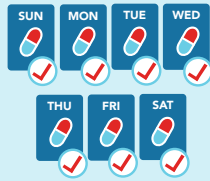
Not everyone taking HIV medicine is undetectable.





The only way to **know** if you are undetectable is by visiting your provider regularly.

Best ways to **keep** an undetectable viral load and stay healthy:

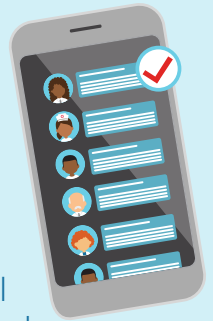


**Take your medicine daily, as prescribed**



**Visit your provider regularly**

To help you stay on your journey, it's important that you find a provider who makes you feel comfortable and supported. This extends to the other health care professionals involved in your treatment.



Getting and keeping an undetectable viral load prevents HIV transmission during sex, but there are reasons why you and your partner may consider adding other prevention options like condoms and PrEP.



**Difficulty keeping an undetectable viral load**



**Missed doses of medicine since last viral load test**



**Protection from other STDs, like syphilis and gonorrhea**



**You or your partner want added peace of mind**

**YOU CAN DO THIS!**



Wherever you are on the journey to undetectable, staying in treatment will improve your health no matter what challenges you may face along the way. Reach out to family and friends who support you on your journey.

[www.cdc.gov/StopHIVTogether](http://www.cdc.gov/StopHIVTogether)  
**#JourneyToUndetectable**  
**#TalkUndetectable**

 /ActAgainstAids  /CDCHIV  /CDC\_HIVAIDS



# Antiretroviral Therapy to Prevent Sexual Transmission of HIV (Treatment as Prevention)

 [clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/antiretroviral-therapy-prevent-sexual](https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/antiretroviral-therapy-prevent-sexual)

Updated

Dec. 18, 2019

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## Panel's Recommendations

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- All persons with HIV should be informed that maintaining a plasma HIV RNA (viral load) of <200 copies/mL, including any measurable value below this threshold value, with antiretroviral therapy (ART) prevents sexual transmission of HIV to their partners. Patients may recognize this concept as Undetectable = Untransmittable or U=U **(AII)**.
- Persons with HIV who are starting ART should use another form of prevention with sexual partners (e.g., condoms, pre-exposure prophylaxis [PrEP] for the HIV-negative sexual partner, sexual abstinence) for at least the first 6 months of treatment and until a viral load of <200 copies/mL has been documented **(AII)**. Many experts would recommend confirming sustained suppression before assuming that there is no further risk of sexual HIV transmission **(AIII)**.
- When the viral load is  $\geq 200$  copies/mL, additional methods are needed to prevent transmission of HIV to sexual partners until resuppression to <200 copies/mL has been confirmed **(AIII)**.
- Persons with HIV who intend to rely upon ART for prevention need to maintain high levels of ART adherence **(AIII)**. They should be informed that transmission is possible during periods of poor adherence or treatment interruption **(AIII)**.
- At each visit for HIV care, clinicians should assess adherence to ART and counsel patients regarding the importance of ART to their own health as well as its role in preventing sexual HIV transmission **(AIII)**.
- Providers should inform patients that maintaining a viral load of <200 copies/mL does not prevent acquisition or transmission of other sexually transmitted infections (STIs) **(AII)**.
- Providers should also routinely screen all sexually active persons with HIV for STIs, both for their own health and to prevent transmission of STIs to others **(AIII)**.

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**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

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Panel's Recommendations Regarding Using Antiretroviral Therapy to Prevent Sexual Transmission of HIV

Antiretroviral therapy (ART) not only reduces morbidity and mortality for persons with HIV but has now been definitively shown to prevent sexual transmission of the virus when the plasma HIV RNA (viral load) is consistently suppressed to <200 copies/mL, which includes any measurable viral load that is lower than this threshold value. Providers who manage patients with HIV need to be aware of the data supporting treatment as prevention (TasP, which persons with HIV may recognize as Undetectable = Untransmittable or U=U), its implications, and how to operationalize this prevention strategy in clinical practice. For persons with HIV who intend to rely on TasP for HIV prevention, providers should make an individualized assessment of the person's risk tolerance, personal health, history of maintaining viral suppression on treatment, and access to health care services and ART, as well as other factors that may affect their ability to maintain a high level of adherence to ART.

## **Evidence that Viral Load Suppression Prevents Sexual HIV Transmission**

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Suppressing the HIV viral load to <200 copies/mL with ART prevents sexual transmission of HIV. Observational data collected in the early 1990s from heterosexual couples demonstrated that sexual transmission from untreated persons with HIV was rare at viral loads of <1,000 copies/mL to 1,500 copies/mL and that the risk of transmission increased in dose-response fashion with increasing viral load.<sup>1,2</sup> Additional reports<sup>3-7</sup> and a meta-analysis<sup>8</sup> supported the observation that sexual HIV transmission risk in heterosexual persons was correlated with plasma viral load, and transmission was infrequent below the lowest limits of quantification for the viral load assays used at the time.

The first prospective clinical trial designed specifically to address this question was HPTN 052, which randomized people with HIV who were in mixed HIV status couples (previously referred to as serodiscordant couples) to initiate ART early or to delay initiation. Initial results from this study were reported in 2011,<sup>9</sup> with final results reported in 2016.<sup>10</sup> The 2016 analysis reported that no phylogenetically linked sexual transmissions of HIV occurred among 1,763 couples who were followed a median of 5.5 years while the person with HIV was on ART and had a viral load <400 copies/mL for at least 6 months. Notably, four phylogenetically linked infections occurred within the 90 days after the partner with HIV had started ART and was presumably not yet virally suppressed, and four others occurred after the partner with HIV had experienced virologic failure. There were also a number of transmission events that were not phylogenetically linked, indicating acquisition from someone other than the enrolled study index partner.<sup>11</sup> HPTN 052 was conducted almost exclusively among heterosexual couples that lived in Africa and Asia and did not track the number or type of sexual exposures. In addition, ART was used as an adjunct to a comprehensive prevention package that provided condoms and encouraged condom use, as well as frequent testing for HIV and other sexually transmitted infections (STIs).

Three prospective observational studies—PARTNER 1,<sup>12</sup> PARTNER 2,<sup>13</sup> and Opposites Attract<sup>14</sup>—provided data from more diverse populations of mixed HIV status couples in which condomless sex was common. Clinical follow-up in these studies closely mimicked that of routine clinical care. Conducted in 14 European countries (PARTNER 1 and PARTNER 2) as well as Australia, Thailand, and Brazil (Opposites Attract), the investigators followed 548 heterosexual and 1,481 male-male mixed HIV status couples that engaged in 144,631 episodes of condomless vaginal or anal sex while the partner with HIV had a suppressed viral load on ART, defined as <200 copies/mL. In these studies, no phylogenetically linked transmissions were observed; however, as in HPTN 052, there were numerous non-phylogenetically linked transmissions attributed to partners outside the enrolled study couple relationship.

## Integrating the Principles of Treatment as Prevention into Clinical Care

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The Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) recommends that providers inform all persons with HIV that maintaining an HIV viral load <200 copies/mL with ART prevents sexual transmission of HIV **(AII)**. This information may help motivate patients and help relieve stigma that can be a barrier to getting tested and entering into care, starting and remaining adherent to ART, and ultimately achieving and maintaining a viral load <200 copies/mL.<sup>15</sup> Although PARTNER 1, PARTNER 2, and Opposites Attract were designed to follow patients in the study as they would be typically be followed in clinical care for HIV, the participants reported high levels of ART adherence at study entry and many reported at least 1 year of condomless sex with an established sexual partner without transmission. As the principles of TasP are integrated into the clinical management of people with HIV who are on ART, implementation research will be critical to maximize the effectiveness of TasP in practice.

## Frequency of Viral Load Assessment

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The Panel has issued recommendations for viral load monitoring to manage the health of persons with HIV (see [Plasma HIV-1 RNA \(Viral Load\) and CD4 Count Monitoring](#)). However, current data are insufficient to determine whether these recommendations represent the optimal monitoring schedule for the purpose of preventing sexual transmission of HIV. In the PARTNER studies and Opposites Attract, viral loads were generally assessed every 3 to 6 months during study follow-up, usually during the course of regular HIV care. Pending further data, the Panel recommends no change to the existing recommendations for monitoring viral load (see [Plasma HIV-1 RNA \(Viral Load\) and CD4 Count Monitoring](#)) **(BII)**.

## Time to Adequate Suppression after Starting Antiretroviral Therapy

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A subgroup analysis from the Partners PrEP Study provided data regarding the risk of HIV transmission during and after the first 6 months on ART for the partner with HIV.<sup>16</sup> This analysis included 1,573 heterosexual East African couples in which the partners without HIV were randomized to the placebo arm of the Partners PrEP Study and were tested monthly for HIV while the viral load of the partner with HIV was assessed every 6 months. Three phylogenetically linked infections were diagnosed in the 6 months prior to the first follow-up visit for the partners with HIV. The observed incidence rate of 1.79 per 100 person-years during this initial 6-month period after the partner with HIV started ART was slightly less than the 2.08 per person-years incidence rate observed in couples in which the person with HIV was not receiving ART. Viral suppression in this study was defined as <40 copies/mL, and the three infections were diagnosed at 0 days, 56 days, and 149 days after the partner with HIV started ART. After the partners with HIV had been taking ART for ≥6 months, no further transmissions were observed.

At this time, the Panel recommends that persons with HIV who are starting ART use another form of prevention with sexual partners for at least the first 6 months of treatment and until a viral load of <200 copies/mL has been documented **(AII)**. Many experts would recommend confirming sustained suppression before assuming that there is no further risk of sexual transmission of HIV **(AIII)**.

## **Adherence to Antiretroviral Therapy**

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Adherence to ART is paramount for persons who intend to prevent HIV transmission by achieving and maintaining a suppressed viral load. Viral rebound typically occurs within days to weeks after ART cessation and has been observed as early as 3 to 6 days after stopping treatment.<sup>17-29</sup> The minimum level of adherence that is required to prevent sexual transmission has not been determined and may vary depending on the ART regimen. In the key studies that defined the efficacy of TasP, adherence levels prior to study entry and during follow-up were very high. In clinical practice, most people who start ART will achieve a viral load <200 copies/mL within 6 months, but once this viral load is achieved, maintaining viral suppression can be a challenge, especially for those who have difficulty accessing ART and other HIV care. The Centers for Disease Control and Prevention (CDC) estimates that during 2015, 60% of persons with HIV and 78% of persons engaged in clinical care had viral loads <200 copies/mL at their most recent assessment.<sup>30</sup> Observational cohort data have demonstrated that within the first year of starting ART, up to 10% of persons with HIV can experience loss of viral suppression; however, the likelihood of maintaining a suppressed viral load generally improves over time. After a few years, 5% or fewer of persons on ART may experience loss of viral suppression.<sup>31,32</sup>

The Panel recommends that persons with HIV who intend to rely upon TasP be made aware of the need for high levels of ART adherence **(AIII)**. The Panel further recommends that adherence be assessed and counseling be provided at each visit for HIV care to reinforce the

importance of adherence for the individual's health as well as its role in preventing HIV transmission **(AIII)**. Patients should be informed that transmission is possible during periods of poor adherence or treatment interruption **(AIII)**.

Adherence can be especially challenging for certain groups of patients, such as adolescents and young adults, homeless persons, persons with active substance use disorder, and persons who are involved with the criminal justice system. Recommendations to help manage and maximize ART adherence can be found in Adherence to the Continuum of Care. Persons for whom there is concern about adherence also merit counseling on how to properly use other prevention methods, especially barrier methods that prevent STIs.

## **Managing Transient Viremia, or “Blips”**

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Highly adherent patients may experience intermittent or transient viremia, commonly termed “viral blips.” Blips are defined in the context of effective treatment as a single, measurable HIV RNA level, typically <200 copies/mL, that is followed by a return to a viral load below the limit of detection or quantification. With contemporary ART regimens, about 10% of persons per year who are adherent to ART may experience a blip.<sup>33-35</sup> Most blips likely represent normal biological fluctuation (i.e., variation around a mean undetectable viral load) or laboratory artifact and not inadequate adherence.<sup>36-38</sup> Persistent viremia  $\geq 200$  copies/mL has been associated with increasing risk of virologic failure<sup>33,39</sup> that, in the context of TasP, can lead to increased risk of sexual transmission.<sup>10</sup> The PARTNER studies and Opposites Attract excluded observation time when the viral load of the participant with HIV was  $\geq 200$  copies/mL. The frequency of blips <200 copies/mL was not reported in Opposites Attract; however, in PARTNER 1 and PARTNER 2, transient elevations in viral loads above the limit of detection (50 copies/mL in these studies) but <200 copies/mL were observed for 6% and 4% of the total follow-up time, respectively, during which time no phylogenetically linked infections were observed.

One of the clinical challenges with blips is that they can only be defined retrospectively once the viral load has returned to a suppressed value. The Panel recommends that when the viral load is  $\geq 200$  copies/mL, persons with HIV and their sexual partners should use another form of prevention (e.g., condoms, pre-exposure prophylaxis for sexual partners without HIV, sexual abstinence) to protect against HIV transmission until a viral load <200 copies/mL is achieved **(AII)**. This recommendation applies both to persons who are starting ART (as noted earlier) and to those who have been taking ART and have achieved viral suppression but develop viral loads  $\geq 200$  copies/mL.

In cases where a patient achieves resuppression to <200 copies/mL after a detectable viral load  $\geq 200$  copies/mL, or when a patient with a viral load <200 copies/mL switches regimens (e.g., for regimen simplification or to avoid certain side effects), providers should check the viral load per recommendations in Plasma HIV-1 RNA (Viral Load) and CD4 Count Monitoring and Optimizing Antiretroviral Therapy in the Setting of Virologic Suppression, respectively **(AIII)**. There are presently no data to guide how long, if at all, a person might

need to continue to use another form of prevention in these two circumstances. Individualized assessment is recommended based on the length and quality of adherence and time with viral load <200 copies/mL preceding the viral load  $\geq$ 200 copies/mL.

## **Effect of Sexually Transmitted Infections on Treatment as Prevention**

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The presence of STIs in a person with HIV does not appear to meaningfully alter the risk of sexual transmission when the person's viral load is <200 copies/mL. The PARTNER studies and the Opposites Attract study regularly assessed participants for STIs, which were diagnosed in 6% of heterosexual participants and 13% to 27% of men who have sex with men. Although the authors of the studies noted that their findings could not rule out the possibility that STIs in participants with viral loads <200 copies/mL might affect the risk of HIV transmission, when viewed collectively, these data suggest that any effect is very small, since STIs were common and no linked infections were observed. The Panel recommends that patients using TasP be informed that maintaining a viral load of <200 copies/mL does not prevent acquisition or transmission of other STIs, and that it is not substitute for condoms or behavioral modifications **(AII)**. Providers should also routinely screen all sexually active persons with HIV for STIs, both for their own health and to prevent transmission of STIs to others **(AIII)**. Refer to CDC's [Sexually Transmitted Diseases Treatment Guidelines](#) for details.

## **Treatment as Prevention Applies Only to Sexual Transmission of HIV**

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Available clinical data only support the use of TasP to prevent sexual HIV transmission in patients with viral loads <200 copies/mL. The effectiveness of this strategy to prevent transmission from blood exposure (e.g., through nonsterile drug injection) has not been determined. In addition, while suppression of maternal viral load substantially reduces the risk of perinatal transmission and transmission through breastfeeding, it does not eliminate these risks, and transmission has occurred via breastfeeding despite continuous viral suppression (refer to the [Perinatal Guidelines](#) for details).