U=U Frequently Asked Questions

In September 2017, the New York State Department of Health became the first state health department in the United States to sign on to the Prevention Access Campaign’s Undetectable equals Untransmittable (U=U) Consensus Statement. In doing so, the Health Department endorsed the following statement:

“People living with HIV on ART with an undetectable viral load in their blood have a negligible risk of sexual transmission of HIV. Depending on the drugs employed it may take as long as six months for the viral load to become undetectable. Continued and reliable HIV suppression requires selection of appropriate agents and excellent adherence to treatment. HIV viral suppression should be monitored to assure both personal health and public health benefits.”

The framework of U=U offers a unique opportunity to dismantle HIV stigma and discrimination, and reemphasizes the critical importance of antiretroviral therapy (ART), daily adherence, and continuous engagement in medical care for people living with HIV.

1. What does ‘undetectable’ mean?
The word ‘undetectable’ is the lowest limit of the laboratory tests (lab tests) used to measure HIV viral load. Some viral load tests are very sensitive and can find – or detect – HIV in a sample of blood when there are only 20 copies of the virus per milliliter (mL). Other viral load tests need up to 200 copies per mL of blood to detect any HIV. In the context of U=U, it does not matter which type of test your doctor uses to measure your viral load. As long as your viral load remains below 200 copies/mL, your risk of sexually transmitting HIV is negligible.

2. What does ‘untransmittable’ mean?
If your viral load is undetectable you will not sexually transmit HIV, making your HIV ‘untransmittable’. In other words, HIV will not be passed sexually to another person through saliva, pre-seminal fluids, semen, rectal fluids or vaginal fluids. (As the scientific evidence currently stands, U=U applies only to sexual transmission.)

3. What does negligible risk mean?
Negligible risk means so small or unimportant as to be not worth considering; insignificant, having effectively no risk of sexually transmitting the virus. For U=U, ‘risk’ is a projection – talking about chances of something happening in the future – and cannot be quantified, or given an exact number. What can be said for sure is that there have been zero transmissions in studies so far. And those studies included tens of thousands of unprotected sex acts. Undetectable individuals do not transmit HIV sexually, so the risk of transmission is negligible.

*Blue text are defined in Appendix A: Definitions for U=U FAQ
4. Are U=U and Treatment as Prevention (TasP) the same?
U=U and TasP are one and the same, just different ways of stating the same concept about people living with HIV (PLWH) who are on effective ART. TasP has been used widely in medical and public health literature for years and means what it sounds like: taking ART and staying virally suppressed stops people from transmitting HIV, meaning it also acts as a form of HIV prevention. Both TasP and U=U are based on the important goal of having everyone with HIV be aware of their status so they can take ART. ART not only improves the health of PLWH, but also reduces the virus in a person’s cells to the point of being ‘undetectable.’ Viral load measures the effectiveness of ART. When a person is undetectable, they do not transmit HIV sexually. U=U has been taken up by the broader HIV-affected community to spread awareness that if you are undetectable, you will not transmit HIV. U=U sends a hopeful, empowering message and addresses the stigma often associated with living with HIV and an HIV/AIDS diagnosis.

5. How does U=U address stigma?
Since the beginning of the HIV epidemic, PLWH have been seen by many as ‘infectious,’ feeding widespread discrimination and the unfortunate internalization of shame and stigma. HIV-negative people feared starting relationships with people living with HIV, and sex with a person living with HIV was seen as a possible health risk to the HIV-negative partner. U=U presents an opportunity to silence those damaging narratives by breaking the link between sex and HIV transmission.

6. Does U=U apply to all types of sex?
Yes. PLWH with an undetectable viral load do not transmit HIV through insertive or receptive anal sex, vaginal sex, or oral sex.

7. How do we know that U=U? What is the evidence?
The evidence for U=U comes from several groundbreaking research studies and clinical trials. A study called HPTN 052, a randomized control trial to find out if ART can stop transmission of HIV in sero-different couples, enrolled more than 1,700 sero-different heterosexual couples who were randomly assigned to have the HIV-positive partner either immediately start ART or delay the start of ART. Over time, results among study participants showed no linked transmissions when the index (HIV+) partner was suppressed.2

Another study, the PARTNER Study, which was carried out at 13 sites in Europe, had specific enrollment eligibility criteria that included undetectable sero-different couples (both heterosexual and men who have sex with men) who had condom-less sex. In what were a reported 58,213 sexual encounters during this study, there were no transmissions linked to the HIV-positive partners.3 In the summer of 2017, at the International AIDS Conference in Paris, the results of

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the Opposites Attract study were reported. It studied 358 gay male **sero-different couples** and found no linked HIV **transmissions** in nearly 17,000 condom-less sexual acts.4

The findings from these three key studies show that not only does being on effective antiretroviral treatment improve the health of each person with HIV, it also keeps them from transmitting HIV to sexual partners.

8. **Suppressed Viral Load and ‘Undetectable’—is there a distinction? Is there a difference in transmission risk with a viral load of 200 copies/mL vs. 20 copies/mL?**

When it comes to transmission risk, there is no difference between **suppressed viral load** and undetectable **viral load**. As long as your **viral load** is below 200 copies/mL, and has stayed that way for at least six months, your risk of sexually transmitting HIV remains negligible.

The word ‘undetectable’ comes from the **sensitivity** of the **laboratory viral load assay** used. Even if the **viral load** test could not detect virus in the blood sample, it does not mean HIV has disappeared from the body, but that **ART** has **suppressed** the virus so much that the usual lab tests cannot ‘detect’ or find it.

‘Undetectable’ is now commonly defined as having fewer than 20 copies/mL because a lot of lab tests can now ‘detect’ HIV at that level. And **viral load suppression** is usually defined as having fewer than 200 copies of HIV per **milliliter** of blood (copies/mL). However, in the context of **U=U**, the two terms can be used **interchangeably**: a person is considered undetectable (and therefore untransmittable) if they have reached **viral load** suppression of fewer than 200 copies/mL.

9. **How long do I need to be on ART and be ‘undetectable’ in order not to transmit HIV?**

First, being on **ART** and being undetectable are two different things. When you start on **ART**, it takes a while for the medication to do its job. Generally, if the **ART** is working, it should reduce the amount of virus in your blood to an undetectable level within a few months. Once you are undetectable (under 200 copies/mL), you then need to stay undetectable for at least six months before your HIV is considered ‘untransmittable.’ In other words, you need at least two **confirmatory tests** that your **viral load** is less than 200 copies/mL - at the beginning and the end of a six-month period - before you can use your undetectable status as a **method of HIV prevention**.

10. **If I am undetectable and there is a ‘blip’ in my viral load, am I still untransmittable?**

Yes, you are still untransmittable. Sometimes, even when you take your medication every day, the HIV **viral load** test notes that it can ‘see’ or ‘detect’ virus in your blood. This is commonly known as a viral ‘blip’. Depending on the laboratory, a ‘blip’ is usually between 16 and 199 copies in some **viral load** tests. In other **viral load** tests this ‘blip’ would not have even been

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found or detected, which would still be in the negligible risk range. These 16 to 199 copy viral ‘blips’ have not been shown to increase the transmission of HIV, but the viral load test should always be repeated because sometimes it is an early sign that the ART medication is losing its power to suppress the virus. Most of the time, though, viral load goes back to undetectable levels without any changes in treatment.5

11. How often should I have my viral load checked?
A key part of U=U is remaining engaged in ongoing medical care. If you are using your undetectable status as an HIV prevention method, it is advisable that you check with your doctor and consider having your viral load tested with the frequency they recommend. No matter what your HIV status is, your sexual health is important and deserves regular attention. If your partner is on pre-exposure prophylaxis (PrEP), consider scheduling your quarterly medical visits at similar times. If either of you has other sexual partners, these quarterly visits are a good chance to get checked for sexually transmitted infections (STIs) and keep up to date with your other health screenings.

12. If I am HIV negative and my HIV-positive sexual partner is undetectable, do we still need to use condoms or PrEP?
In the age of U=U, prevention and safer sex now means an undetectable viral load, condoms, PrEP, or a combination of these, depending on your needs and feelings. If your partner is undetectable, they cannot transmit HIV through sex. However, your decisions about condoms should be based on your sexual behavior and your partner(s)’ sexual behavior. Remember that U=U only protects against HIV transmission! Condoms are still the best way to prevent STIs and pregnancy. If you are HIV negative and have other partners, you should consider PrEP and condoms or emergency PEP (post-exposure prophylaxis). However, if you are in a monogamous relationship (neither one of you is having sex with other people) and your partner is undetectable, you could choose not to use any other forms of protection. It is very important to have an open and honest conversation with your sexual partner(s) and your doctor about which prevention methods are right and most comfortable for you.

13. How is PEP different from PrEP?
PrEP and PEP are both forms of HIV prevention for people who are HIV-negative. A big difference between PrEP and PEP is that PrEP is taken before potential exposure, while PEP is taken after possible exposure to HIV. While PEP is prescribed in emergency situations and should be taken within 36 hours of exposure, PrEP is a daily pill that people can take to protect themselves against HIV if they think they will be sexually exposed.

14. I am HIV negative. My partner has been undetectable for over 6 months, and now we want to have a baby. Why does our doctor say I should take PrEP?
The research on HIV transmission risk in couples trying to conceive (get pregnant) when the

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HIV-positive partner is **durably virally suppressed** is still limited.⁶ If you are HIV negative and are trying to get pregnant with an HIV-positive partner’s sperm, it is generally recommended that you be on **PrEP**, regardless of your partner’s **viral load**.⁷ This is, however, a **clinical judgment** and a decision you and your doctor(s) should make considering what is best for you, your partner, and your future child.

15. **I am HIV negative. My partner was recently diagnosed with HIV and has just started antiretroviral therapy (ART). How does U=U apply to us?**

It is great that your partner has started **ART**, but until they have been undetectable for 6 months you should consider **PrEP** and/or condoms for prevention.

16. **What if I am undetectable and I use injection drugs?**

If you are undetectable and use injection drugs, your chances of **sexually** transmitting HIV are negligible. However, even with an undetectable **viral load**, anyone who injects drugs should always use clean/new equipment and never share **works**. **U=U** does not apply at all to HIV **transmission** with shared **works**. While **stigma** as well as inadequate and intermittent health care remain challenges for many people with a history of injection drug use who are living with HIV, it is still important for them to remain engaged in medical care to become **virally suppressed**.

17. **What if I am undetectable and I want to breastfeed?**

At this time, **U=U** does not apply to HIV **transmission** during breastfeeding. While the risk of mother-to-child **transmission** of HIV is significantly reduced with the effective use of **ART** and an undetectable **viral load**, neither **infant antiretroviral prophylaxis** nor **fully suppressive maternal ART eliminate** the risk of HIV **transmission** through breastmilk. It is, therefore, recommended that women in the United States who are living with HIV refrain from breastfeeding and feeding their expressed breastmilk to their **infants**.⁸⁻⁹

18. **What does U=U mean for people living with HIV who are not ‘undetectable’?**

Everyone with HIV in New York State should get into treatment and get the services they need to be as healthy as possible. Being adherent to **ART** reduces **transmission** risk and comes with many important health benefits. It is important to understand that many people living with HIV may not be in a position to reach undetectable **viral load** status due to factors that are beyond their control. These reasons may include problems accessing treatment, past **ART** treatment that led their HIV virus to develop **resistance** or cause **toxicities**, and other **comorbidities**.

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References


Appendix A: Definitions for U=U FAQ

**ART**: antiretroviral therapy (ART) refers to the medicine that stops human immunodeficiency virus (HIV) from making copies of itself in the body

**Clinical judgement**: a conclusion made by a medical professional based on actual observation of a patient; clinical reasoning

**Clinical trial**: a research study of human volunteers that is designed to add to medical knowledge

**Combination**: using two or more prevention methods at the same time – such as PrEP and condoms

**Comorbidities**: in medicine, when a patient has more than one additional disease or condition at the same time as their primary condition

**Confirmatory tests**: a second test that is needed to double check the results of a first test. Confirmatory tests are used to either make or rule out a diagnosis.

**Diagnosis**: a medical diagnosis is the identification of a disease or condition someone may have (verb: diagnose). A variety of medical tests can be used to diagnose someone with HIV.

**Discrimination**: any distinction, exclusion, restriction, or preference based on what one believes to be an undesirable characteristic. Some people living with HIV face discrimination because of a lack of knowledge on how HIV is spread.

**Durably virally suppressed**: when an individual is on antiretroviral medication and has stayed virally suppressed for at least 6 months

**Eliminate**: completely remove or get rid of; exclude or rule out

**Enrolled**: the formal process of being registered to participate in a scientific study or trial

**Enrollment eligibility criteria**: in scientific studies, the people who organize and run the study decide which factors are needed for individuals to participate. These factors (enrollment eligibility criteria) generally involve the illnesses or conditions that are being studied, as well as demographic characteristics.

**Epidemic**: when the number of people in a community with the same disease is much more than would be expected. That number varies depending on many factors. In order to end the HIV epidemic in New York State, the number of people who get HIV (are newly diagnosed) needs to go down.

**Evidence**: scientific evidence refers to proof; interpretation in accordance with scientific facts

**Fully suppressive maternal ART**: antiretroviral drugs that make the HIV-positive mother have an undetectable viral load in her blood

**Groundbreaking**: something original and important; revealing new ideas or a new way of doing or thinking about things
Health screenings: examinations usually involving several medical tests and procedures to check for health conditions, generally to identify any conditions or diseases early when they are easier to treat

Infant antiretroviral prophylaxis: antiretroviral drugs given to babies with HIV positive mothers for a short time after birth to reduce their chances of getting HIV

Insertive anal sex: when a person has insertive anal sex (“top”), they are inserting or putting their penis into their partner’s anus

Interchangeably: words or objects used in the place of each other to mean the same thing, such as ‘test’ and ‘assay’

Internalization: to accept an idea, attitude, belief so that it becomes part of your identity or the person see yourself as. Internalization happens even if the idea, attitude or belief is not true.

Laboratory viral load assay: refers to HIV viral load lab tests that measure the amount of HIV in a sample of blood. Note that there are different types of test methods and techniques (assays).

Method of HIV prevention/HIV prevention method: an HIV prevention method is an action or tool to protect against passing on HIV or getting HIV

Milliliter (mL): metric measurement of volume: one thousandth of a liter or 0.338 fluid ounces

Narratives: stories; tales; accounts

Oral sex: stimulating a partner’s genitals using the mouth, lips or tongue

PLWH: people living with HIV

Post-Exposure Prophylaxis (PEP): a method of preventing HIV infection. It involves using a short course of the drugs used to treat HIV, taken very soon after a person may have been exposed to the virus.

Pre-Exposure Prophylaxis (PrEP): a daily medication people who are HIV-negative can take to protect themselves from getting HIV

Pre-seminal fluid: also known as pre-cum, is a fluid released from the urethra prior to ejaculation, which is less likely to contain sperm

Randomized Control Trial: the term applied to the kind of scientific study in which the participants are assigned by chance (randomly) to separate groups. One of the groups is given or uses the treatment being tested; the other, the “control” group, does not. At the end of the trial study the results/outcomes between the two groups can be compared to learn if the tested treatment was effective. Find out more about Randomized Control Trials here (https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0025811/)

Receptive anal sex: when a person has receptive anal sex (“bottom”), their partner’s penis is being put into their anus

Rectal fluids: secreted fluids released from the rectum/anus
**Reported 58,213 sexual encounters:** the number of times the study participants said they had anal or vaginal sex

**Resistance:** drug resistance can occur in HIV when the virus in someone’s blood changes shape or mutates. This means that certain types of anti-HIV drugs may not work anymore to treat that person’s HIV. Some people with long-term HIV may have developed resistance to multiple HIV treatments, making it difficult for them to suppress their HIV completely.

**Semen:** also called seminal fluid, is a thick, whitish fluid released from the male reproductive organs via the urethra. Semen contains sperm cells and secretions of the testes, seminal vesicles, prostate and bulbourethral glands.

**Sensitivity:** a sensitive lab test is one that is very likely to correctly identify what is being tested in a sample

**Sero-different couples:** couples in which one partner is HIV positive (sometimes called the “index” partner) and the other partner is HIV negative. Sometimes referred to as ‘sero-discordant’ couples.

**Stigma:** a characteristic, such as HIV, that links an individual to a stereotype that society or a group of people believes to be undesirable. This can lead to separation, status loss, and discrimination.

**Suppressed:** when a person has very low levels of HIV virus in their blood, which reduces the function and replication of the HIV virus, they are said to be suppressed

**Toxicities:** when a drug, or mix of drugs, become harmful (toxic) leading to adverse effects on the body. This can be due both to incorrect prescriptions or a negative reaction to medications.

**Transmission:** HIV transmission is when HIV is passed from one person to another

**Transmit:** pass on; spread; cause something to pass to another

**Vaginal fluids:** any fluids released from the vagina, also known as vaginal discharge. Vaginal discharge is a mixture of liquids, cells and bacteria that lubricates the vagina.

**Vaginal sex:** vaginal sex (intercourse) involves inserting the penis into the vagina

**Viral load:** HIV viral load is a measurement of the amount of HIV virus in a person’s bloodstream (plasma), usually stated as copies per milliliter of blood (copies/ml)

**Works:** equipment used for injecting drugs, including needles, syringes, cookers/caps, cotton, alcohol prep pads, etc.