

<p>Needlestick injuries?</p> <p>Research has not established that people with an undetectable HIV viral load do not transmit HIV to people who are stuck by a needle containing their blood. HIV PEP may be indicated.</p>	<p>Injection drug use?</p> <p>Studies demonstrate that ART greatly reduces the risk of HIV transmission through sharing of injection drug use equipment. However, research has not established that people with an undetectable HIV viral load do not transmit HIV through needle sharing.</p>	<p>Breastfeeding?</p> <p>Studies demonstrate that ART greatly reduces the risk of HIV transmission from individuals who breastfeed their infants. However, research has not established that people whose HIV is undetectable do not transmit HIV during breastfeeding.</p>	<p>HIV RNA in genital secretions?</p> <p>There is no evidence that detectable virus in genital secretions while plasma viral load is undetectable is associated with transmission.</p>	<p>Virologic "blips"?</p> <p>Patients on previously suppressive ART may occasionally experience low-level transient viremia ("blips") and not virologic failure. Virologic blips likely occurred in individuals participating in HPTN 052, PARTNER, PARTNER 2, and Opposites Attract, yet there was no transmission from people whose measured HIV viral load was consistently suppressed.</p>
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WHAT ABOUT U=U AND...

U=U BEST PRACTICES

Adherence:

- Carefully address all likely barriers to adherence, which may include poverty, housing instability, and other key social factors, and offer all available adherence supports, referrals for assistance, and other interventions, along with HIV prevention strategies that do not rely on viral suppression.

Viral load monitoring:

- Follow existing NYSDOH AI guidelines for monitoring viral load in patients on treatment.
- Encourage all patients to get tested for STIs. Consider offering STI screening every 3 months (as with PrEP) for all individuals with HIV who rely on U=U as a sole strategy to prevent the sexual transmission of HIV.

Screening and treatment for STIs (other than HIV):

- Encourage all patients to get tested for STIs. Consider offering STI screening every 3 months (as with PrEP) for all individuals with HIV who rely on U=U as a sole strategy to prevent the sexual transmission of HIV.

APPLYING U=U TO CLINICAL PRACTICE

U=U is grounded in adherence:

- Maintaining an undetectable viral load is foundational to the U=U strategy and may be functionally challenging for many individuals with HIV. It is recommended that consistent adherence to ART is demonstrated before relying on U=U as a sole, effective HIV prevention strategy.
- Adherence may be confirmed with:
 - Two consecutive undetectable viral load test results separated by at least several weeks; or
 - More conservatively, a full 6-month period during which all viral load test results are undetectable.

U=U is grounded in monitoring:

- Per NYSDOH AI guidelines, viral load testing should be performed:
 - Every 4 months after an individual achieves an undetectable viral load.
 - If viral suppression and stable immunologic status are maintained for > 1 year, then viral load testing can be extended to every 6 months in select patients thereafter.



← Use this code with your phone's QR code reader to go directly to a mobile-friendly version of the guideline.

■ This 1/4-Folded Guide is a companion to the *U=U Guidance for Implementation in Clinical Settings*: Shauna H. Gunaratne, MD, MPH, and Jessica Rodrigues, MS; in collaboration with the Medical Care Criteria Committee, April 2023, available at www.hivguidelines.org.

HIV CLINICAL RESOURCE ■ 1/4-FOLDED GUIDE
 VISIT HIVGUIDELINES.ORG TO LEARN MORE OR VIEW COMPLETE GUIDE

U=U GUIDANCE FOR IMPLEMENTATION IN CLINICAL SETTINGS

NYSDOH AIDS INSTITUTE HIV CLINICAL GUIDELINES PROGRAM APRIL 2023

WHAT IS U=U?

People who achieve and maintain an undetectable HIV viral load do not sexually transmit HIV.

This scientific finding, called “Undetectable = Untransmittable,” or “U=U,” has been promoted as a health equity initiative by the Prevention Access Campaign since 2016 and has been endorsed by the CDC, the NYC Health Department, the NYSDOH, and many other health departments and experts. U=U asserts that individuals who keep their viral load below the level of assay detection (typically HIV RNA <20 copies/mL) do not pass HIV through sex. Leading scientists have assessed the evidence base as “scientifically sound” [Eisinger RW, Dieffenbach CW, Fauci AS. HIV viral load and transmissibility of HIV infection: undetectable equals untransmittable. *JAMA* 2019;321(5):451–52.]

EVIDENCE BASE SUPPORTING U=U

- The HPTN 052, PARTNER, PARTNER 2, and Opposites Attract studies followed thousands of male and heterosexual HIV-serodiscordant couples.
- There were no genetically linked HIV transmissions when the partner with HIV was taking ART and was virally suppressed (HIV RNA <200 copies/mL).
- These studies provide robust evidence that individuals *do not* sexually transmit HIV if they are virally suppressed or have an undetectable viral load.

ENSURING EQUITABLE ACCESS TO KNOWLEDGE ABOUT U=U

Research has established that certain groups, including sexual and racial or ethnic minority groups, report decreased awareness of or are less likely to be counseled on U=U (see full guideline for references). Care providers are encouraged to make an extra effort to ensure that all patients with HIV are made aware of the importance of U=U and its implications.

COUNSELING INDIVIDUALS WITH HIV ABOUT U=U

Share the message that people who keep their HIV viral load at an undetectable level by consistently taking HIV medications will not pass HIV to others through sex. Sharing this message with *all* patients can help accomplish the following:

- Diminish stigma associated with having HIV
- Reduce barriers to HIV testing and treatment
- Increase HIV testing uptake
- Inform choices about whether or not to start or continue an HIV prevention method
- Increase interest in starting and staying on ART
- Improve self-esteem by removing the fear of being contagious
- Support healthy sexuality regardless of HIV status
- Reduce sex partners' concerns

Encourage patients newly diagnosed with HIV and those previously diagnosed but not taking ART to immediately start (or restart) treatment.

- Explain that doing so will help them avoid damage to their body and immune system and will prevent transmission of HIV to their sex partners.
- The importance of ART should be framed primarily in terms of helping the individual with HIV maintain personal health. Prevention of transmission is a secondary, fortuitous effect of HIV self-care.
- Initiation of ART as soon as possible after diagnosis, even on the same day as diagnosis or at the first clinic visit, improves long-term outcomes, such as virologic suppression and engagement in care at 12 months.

Counsel patients to share information about the research on U=U as follows (proposed language in italics):

- *In 4 research studies that involved thousands of couples, no one who was on HIV treatment and whose HIV was undetectable passed HIV to their HIV-negative sex partner.*

Counsel patients with virologic blips that U=U still applies to them:

- Reassure patients who may be worried or concerned about virologic blips. Explain that people who have virologic blips do not transmit HIV sexually as long as they continue to take ART consistently.

Advise patients that they can share the following personal information with current or potential sex partners:

- When they last had a viral load test and if their viral load was undetectable.
- **Note:** Individuals should tell partners that their HIV is undetectable only if they have taken HIV medicines consistently since their last test with an undetectable viral load.

Care providers should encourage all sexually active patients and their partners, particularly those who do not use condoms consistently, to get tested regularly for bacterial STIs.

- Regular testing and prompt treatment can reduce transmission of bacterial STIs among individuals and throughout the population.
- It is also important to inform patients that common STIs may be asymptomatic.

WHAT TO SAY TO PATIENTS ABOUT U=U (PROPOSED SCRIPT)

- *Keeping your HIV undetectable helps you live a long and healthy life.*
- *To get your HIV to an undetectable level and to keep it undetectable, take antiretroviral medicines as prescribed.*
- *It may take up to 6 months of taking HIV treatment medicines to bring your HIV down to an undetectable level.*
- *If your HIV is undetectable and you are taking your medications as prescribed, you can be sure you will not pass HIV through sex.*
- *People who keep their HIV at an undetectable level will not pass HIV to others through sex.*
- *If you stop taking HIV medicines, your HIV can rebound to a detectable level within 1 to 2 weeks, and you may pass HIV to your sex partners.*
- *Keeping your HIV at an undetectable level helps you safely conceive a child with your partner.*

COUNSELING COUPLES ABOUT U=U

- **HIV treatment:** Couples may decide that ART and an undetectable viral load for the partner with HIV provides sufficient protection against HIV transmission.
- **PrEP:** PrEP is a safe and effective daily pill that prevents HIV infection. The partner without HIV may decide to take PrEP if they:
 - Are unsure that their partner's HIV viral load is undetectable, especially if their partner has only recently started ART.
 - Have more than 1 sex partner.
 - Feel more secure with the added perception of protection provided by PrEP. (See the NYSDOH AI guideline **PrEP to Prevent HIV and Promote Sexual Health** for more information.)
- **PEP:** After a possible HIV exposure (e.g., if a sex partner with HIV has not consistently taken ART or is not virally suppressed), the immediate initiation of emergency PEP can prevent HIV infection. (See the NYSDOH AI guideline **PEP to Prevent HIV Infection** for more information.)
- **Condom use:** Condoms protect against other STIs, such as gonorrhea, chlamydia, and syphilis, and help prevent pregnancy.
- **Counsel patients to find a prevention strategy that works for them.**
 - If an individual who does not have HIV is unsure if their partner has an undetectable level of virus or is anxious about acquiring HIV, care providers should encourage that person to choose a prevention strategy that works for them, whether that is use of PrEP, emergency PEP, condoms, or a combination of these strategies.
 - Care providers should emphasize that no one should ever be compelled to have sex without condoms.

GLOSSARY

Viral load suppression: A measured quantitative HIV RNA level <200 copies/mL in blood

Undetectable viral load: An HIV viral load that is below the level of detection on a specific assay, typically HIV RNA <20 copies/mL to 50 copies/mL

Durably undetectable: An undetectable viral load maintained for at least 6 months. This indicates that an individual's undetectable HIV viral load is stable and *they will not transmit HIV* through sex if they continue to adhere to treatment.

Untransmittable: As established by various clinical trials and observational studies, individuals who maintain an undetectable viral load have so little HIV in their blood and other secretions that they have no risk of passing HIV to others through sex.

Virologic blip: When an individual's HIV is initially undetectable on a viral load test, then is at a low but detectable level on a repeat viral load test (usually HIV RNA of 20 to 200 copies/mL, but can be higher), and is again measured at an undetectable level shortly thereafter.