



## Frequently Asked Questions about U = U

### 1. What is U = U?

Undetectable = Untransmittable (U = U) relates to the fact that people living with HIV who are on treatment and have a fully suppressed viral load have a **zero** risk of transmitting the virus to their sexual partners.

### 2. What do we mean by a fully “suppressed viral load”?

The viral load refers to the test that measures the amount of HIV virus in the blood. It is used in the monitoring of people living with HIV, primarily to assess response to treatment. HIV viral load is the single biggest determinant of HIV transmission: the higher the viral load the greater the risk of transmission and the lower the viral load the less likely a transmission is to occur.

HIV treatment works by preventing the virus from replicating and suppresses the virus in blood and other body tissues and fluids. The Partner 1 and Partner 2 studies demonstrated that when the viral load is suppressed below the level of 200 copies/ml there is a zero risk of sexual transmission.

Different laboratories use different assays, or machines, to measure HIV viral load and most will measure to levels lower than 200 copies/ml e.g. to < 40 or <20 copies/ml.

### 3. What is the difference between a “fully suppressed viral load” and an “undetectable viral load”?

A fully suppressed viral load is < 200 copies/ml. At this level there is a zero risk of HIV transmission as demonstrated by the Partner 1 and Partner 2 studies

An undetectable viral load is defined by the viral load assay used by the laboratory i.e. it is the lower limit of detection for that machine. For example, some will measure to < 40 and some will measure to < 20. So an individual living with HIV is virally suppressed and there is no risk of transmission to their sexual partners when the viral load is below 200 copies/ml and they are undetectable on the local assay when their viral load is < 20, for examples

For the purposes of U = U the definition of an undetectable viral load where there is no risk of transmission is < 200 copies/ml as this reflects the eligibility criteria of the Partner 1 and Partner 2 studies



#### 4. At what point would someone be defined as achieving U = U?

An individual living with HIV is defined as achieving U = U when they have ***been on treatment for 6 months and have achieved an undetectable viral load.***

Fundamental to this is their ability to maintain good adherence i.e. to take their medication regularly, around the same time each day as prescribed.

When someone has achieved an undetectable viral load and their adherence is good it is not necessary to wait another 6 months to confirm the viral load is still suppressed before reassuring them they have achieved U = U.

#### 5. If someone has an undetectable viral load after 3 months of treatment do I need to tell them to wait another 3 months before they have achieved U = U?

No. If their adherence is good they can be confident that they will maintain an undetectable viral load. Virological failure (defined as a rising viral load in someone who is on treatment) is rare in the context of someone who has achieved an undetectable viral load and has good adherence to treatment

#### 6. How can we be sure the risk of transmission is 'zero' and not 'negligible' or 'very low' and why is this important to patients?

The Partner 1 and Partner 2 studies proved beyond doubt that people living with HIV who are on effective treatment with a fully suppressed viral load (< 200 copies/ml) have a zero risk of transmission to their sexual partners. Over the two studies they observed around 135,000 condomless sex acts and there were no transmission from the HIV positive partner with an undetectable viral load to their HIV negative partner, even in the context of relatively high rates of reported sexually transmitted infections.

Language is important in how we communicate this message. For people living with or at risk of HIV it is essential that we use definitive language that there is no risk or a zero risk of transmission when they have an undetectable viral load to ensure they have confidence in this message.

#### 7. Does U=U work for everyone?

Yes. Everyone living with HIV who is on treatment and has achieved and maintains an undetectable viral load has a **zero** risk of transmitting the virus to their sexual partners. This is irrespective of their sex, gender, sexual orientation or the kind of sex they have.



**8. Does U=U work with all HIV drugs?**

Yes. It doesn't matter what treatment or which HIV drugs an individual is taking. What determines whether or not someone can pass the virus on to their sexual partners is whether or not they are virologically suppressed, not what treatment they are taking

**9. Does U= U work for all types of sex?**

Yes. All people living with HIV who are on effective treatment with a fully suppressed viral load have a zero risk of passing the virus on to their sexual partners. It does not matter what type of sex they have. The Partner 1 and Partner 2 studies included both heterosexual and homosexual partners, observed around 135,000 condomless sex acts over the course of the studies and demonstrated a zero risk of transmission where the HIV positive partner had a undetectable viral load

**10. Does U=U mean my patients no longer need to use condoms?**

U = U means that people living with HIV who are on effective treatment with a fully suppressed viral load do not need to use condoms to prevent HIV transmission. In this situation there is a zero risk of HIV transmission.

Effective HIV treatment prevents the transmission of HIV, but it does not prevent the transmission of other sexually transmitted infections. People living with HIV should use condoms when they need to prevent the transmission of STIs and may choose to use condoms as their method of contraception

**11. Do Sexually Transmitted Infections affect U = U and the risk of HIV transmission?**

No. Sexually transmitted infections (STIs) do not increase the risk of HIV transmission when someone living with HIV is on effective treatment and has an undetectable viral load. The Partner 1 and Partner 2 studies demonstrated the zero risk of HIV transmission when the HIV positive partner has a fully suppressed viral load despite high rates of reported STIs during the course of the study.



## 12. What if my patient forgets to take their medication one day?

Good adherence to taking medication as prescribed is essential to maintain a fully suppressed viral load and to be confident that there is a zero risk of HIV transmission to sexual partners. However, occasional missed, forgotten or late doses will not affect this. It is not unusual for people living with HIV to occasionally forget a dose and this does not impact on their viral suppression or their transmission risk.

If someone is struggling to take their medication as prescribed, regularly missing or forgetting doses or at risk of poor adherence they should see their HIV clinician to check their viral load, access adherence support to address any problems they are having and, in the meantime, use condoms for sex until we are able to confirm that their viral load is suppressed and their adherence has improved.

## 13. What about viral load blips?

A viral load blip is not infrequently seen in people who are adhering well to their medication and have previously had undetectable viral loads. A blip is a transient small rise in the viral load (usually to a level < 100 copies/ml) that returns to undetectable levels when it is repeated. As long as the viral load remains below 200 copies/ml there is no concern about HIV transmission and you can reassure the individual that there are still U = U.

If the viral load rises above 200 copies/ml then U = U no longer applies and condoms should be used to prevent HIV transmission until the viral load is fallen back below 200 copies/ml

## 14. Does U=U apply to breastfeeding?

No, U = U and the definitive language that, in the context of a suppressed viral load (< 200 copies/ml), there is a zero risk of HIV transmission only applies to sexual transmission of HIV as this is where we have the data to support this message. It does not apply to other settings e.g. breastfeeding

There have been a few cases of women who have an undetectable viral load transmitting the virus to their babies during breastfeeding so although we know that HIV therapy prevents mother to child transmission we cannot say the risk of transmission is zero. BHIVA guidelines recommend that HIV positive people do not breastfeed because of this very low risk as we have access in the UK to clean water and formula feed. However, they recognise that some women may choose to breast feed and they should be supported to do this as safely as possible



### **15. Does U=U apply to sharing drug injecting equipment?**

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Having said that we know that viral load is the single biggest determinant of HIV transmission so the transmission risk in this setting when an individual living with HIV has a fully suppressed viral load is extremely low.

The British Association of Sexual Health and HIV guidelines on the use of post-exposure prophylaxis (PEP) do not recommend prescribing PEP in this scenario.

### **16. Does U=U apply to needlestick injuries?**

No, U = U and the definitive language that, in the context of a suppressed viral load (< 200 copies/ml), there is a zero risk of HIV transmission only applies to sexual transmission of HIV as this is where we have the data to support this message. It does not apply to other settings e.g. a needlestick injury.

Having said that we know that viral load is the single biggest determinant of HIV transmission so the transmission risk in this setting when an individual living with HIV has a fully suppressed viral load is extremely low.

The British Association of Sexual Health and HIV guidelines on the use of post-exposure prophylaxis (PEP) do not recommend prescribing PEP in this scenario.