Dear Colleagues

The U=U campaign, which began in the United States in 2016, has become a global movement. We are both so proud that healthcare providers across Australia have taken up the message and the underlying strategy within U=U with such vigour and enthusiasm with their patients across the community.

In this update to the guidance from ASHM we cannot echo more loudly the absolute priority of getting people living with HIV onto effective anti-retroviral treatment as soon as possible after their diagnosis, to provide the support for optimal treatment adherence and long-term viral suppression, and to ensure that all patients living with HIV achieve the greatest treatment satisfaction from their ART regime.

In this version of the guidance you will find even more evidence regarding the impact that sharing the information regarding U=U has upon the relationship between healthcare providers and their patients and even more impressive is the evidence pointing towards the substantial impact that sharing this message has upon the health outcomes of patients including upon their self-reported mental health, sexual health and the overall satisfaction with their health in general.

We can feel increasingly confident that when we say to patients that maintaining a durable viral suppression (HIV RNA <200 copies/mL) eliminates the risk of the sexual transmission of HIV.

This guidance document is following international best practice by providing a set of five recommendations based upon clinicians’ guidelines from New York and adapted for the Australian context with the most up to date advice from other countries and international health agencies. As well, we encourage you to consider the infographic attached to this version of the guidance as an easy to access and comprehend guide for yourself, your colleagues and patients.

Australia has set a very high bar when it comes to ensuring that the community response to HIV and the healthcare workforce work in tandem to ensure the best possible health outcomes for people living with HIV.

We commend this guidance from ASHM to you and encourage you to reflect upon and consider how you can further spread the good news about U=U.

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Overview

This is the third version of guidance for healthcare providers (HCP) to better understand the message and evidence behind Undetectable = Untransmissible (U=U) that ASHM has developed in the past few years. As the evidence mounts and our understanding of how the message of U=U has implications which profoundly affects the lives of people living with HIV; ASHM remains committed to ensuring that clinicians and other healthcare service providers are kept abreast of the latest scientific developments on how antiretroviral treatment (ART) for people living with HIV prevents onward transmission of HIV to their sexual partners.

In this version of the guide, we have provided a set of overarching recommendations and an annotated bibliography of the latest research on U=U. This guide also provides a summary of the foundational evidence which explores the sexual transmission risks of HIV. In this version, we also provide a discussion of the growing implications that the U=U strategy has upon the psychological wellbeing of people living with HIV and the dynamic of healthcare providers discussing U=U with their patients.

Since the release of the ground-breaking research studies from 2016 which looked at how effectively antiretroviral treatment (ART) prevents the sexual transmission of HIV, we can state with confidence that people who take ART daily as prescribed and achieve and maintain an undetectable viral load cannot sexually transmit the virus to an HIV-negative partner. In a 2019 meta-analysis of the research to data, an "overwhelming body of evidence has emerged that a durable1 viral suppression (HIV RNA <200 copies/mL) eliminates the risk of sexual HIV transmission.2 The change in language reflected in this version of the guidance document may seem like a relatively minor change. However, as discussed in the previous guide, phraseology is significant and in the previous version, we recognised that there are different phraseologies (i.e. epidemiological) to describe the risk of HIV transmission and that, at the time the previous guide was issued, it was decided to use the language that there is "effectively no risk" of sexually transmitting the virus to an HIV-negative partner.

Words have both meaning and power. In the clinical setting, the emerging evidence suggests that the words we choose as healthcare providers and the advice we provide (or not) to patients with regard to U=U can have significant impacts upon their health outcomes.3 In a recent Viewpoint article in JAIDS (July 2020) the authors expressed significant concern that "when communication about viral suppression and risk does occur, some providers are inconsistent and/or unclear, continuing to use language such as "extremely low" or "negligible" (rather than "no" or "zero") to describe transmission risk, or incorrectly qualifying U=U as applicable only in the context of condom use." They go on to claim that, "withholding patient education around U = U or tempering the message to prevent unwanted behaviour is not medically justifiable. Furthermore, the decision to withhold or modify U = U messaging could be influenced by stigma towards patients."4

In the previous version of this guide we expressed concern that, at the time, many commentaries suggested that "an undetectable viral load needs to be sustained over at least six months" as an overly-conservative reading of the evidence. This guidance note confirms that consistent adherence to ART may be confirmed with:

- Two consecutive undetectable viral load test results separated by at least four weeks; or
- More conservatively, a full 6-month period during which all viral load test results are durably undetectable.5

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1 A viral load usually becomes undetectable in less than six months and is confirmed by two consecutive undetectable viral loads at least 4 weeks apart and this is considered to be a durable viral load. Further information on this matter is discussed in the following reference: Diepstra, Karen; Lu, Haifong; Macmanus, Kathleen A.; Rogawski Mcquade, Elizabeth T.; Rhodes, Anne G.; Westreich, Daniela What we talk about when we talk about durable viral suppression. AIDS. September 1, 2020 - Volume 34 - Issue 11 - p 1683-1686 doi: 10.1097/QAD.0000000000002612


3 Okoli C, Van de Velde N, Richman B, Allan B et al Undetectable equals untransmittable (U = U) awareness and associations with health outcomes among people living with HIV in 25 countries. Sexually Transmitted Infections Published Online First: 30 July 2020. doi:10.1136/sextrans-2020-054551


5 Blackstock G, Myers J et al U=U Guidance for Implementation in Clinical Settings New York State Department of Health AIDS Institute, June 2019
Certainly, the data is strongest for complete elimination of transmission with greater than six months of virological suppression. However, in individuals with rapid suppression and more than one undetectable viral load test during this time, transmission is likely to be eliminated much earlier. The main purpose of the U=U campaign is to disseminate accurate and unambiguous information to people with HIV and those at risk, and also challenge government, civil-society and the private sector, to promote awareness and understanding of the far-reaching implications of what U=U means to quality public health and disease prevention. After more than four years after being introduced in the global public psyche the messages embodied in the U=U strategy remains unclear, misunderstood and unrecognised by upwards of 1/3 of people living with HIV globally.6

Some advocates have expressed concern that “our collective celebration of U=U is undermined if access to testing, treatment, care, and support — and viral suppression — is not universal.”7 These guidelines by no means negate the call for universal access to HIV testing, treatment, care and support which is often compromised by a variety of systemic risk factors such as colonialism, race, class, gender, gender identity, sexual orientation, immigration status, incarceration history, and other factors.

The intersection of these issues can profoundly affect access to healthcare and we support all efforts to respect the dignity and diversity of every person living with HIV regardless of their capacity to achieve or maintain an undetectable viral load. We encourage all health care professionals to be aware of these issues and be fluent in what has been posed as the 4th level of health literacy8 when faced with the challenges of working together with the patient towards their optimal adherence and treatment satisfaction.

ASHM remains steadfast in ensuring that the healthcare workforce across Australia is informed by evidence and maintains the highest level of provider and patient confidence. Australian healthcare professionals working in HIV have always understood the central role played by people with HIV in ending new HIV infections. These U=U guidance updates are a demonstrable commitment to people living with and the communities across Australia affected by HIV.

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Recommendations

These recommendations have been created and refined for the Australasian context based upon a number of sources, however particular thanks must go to New York State Department of Health for their outstanding work in the creation of their guidelines for clinicians which have served as the inspiration for this guidance document.

HEALTHCARE PROVIDERS SHOULD INFORM ALL PATIENTS OF THE FOLLOWING:

1. People who keep their HIV viral load at an undetectable level by consistently taking HIV medications will not pass HIV to others through sex.

2. Encourage patients newly diagnosed with HIV and those previously diagnosed but not taking ART to think about starting (or restarting) HIV treatment as soon as possible.

- Explain that doing so will help them avoid damage to their body and immune system and will prevent transmission of HIV to their sexual 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.
- Evidence is emerging that 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.

9 These recommendations are derived from and supported by a number of recent publications including:

- Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV. US CDC, November 2019
- Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. US Dept. Health and Human Services, December 2019
- U=U Guidance for Implementation in Clinical Settings. New York State Department of Health, June 2019
- 10 Things to Know About HIV Suppression. United States National Institutes of Health, June 2020

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.

Counsel patients to share information about the research on U=U as follows (proposed script provided below):

- Recent research studies that has involved thousands of couples both gay and straight, no one who was on HIV treatment and whose HIV was undetectable passed HIV to their HIV-negative sexual partner.

Healthcare 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.
- Frequent testing of those who are most at risk of infection ensures that any HIV infection is diagnosed as soon as possible and minimises the risk of unknowingly passing on their HIV infection.
- It is also important to inform patients that common STIs may be asymptomatic.
FAQ

What is Undetectable = Untransmittable?

Undetectable = Untransmittable, often shortened to U=U, is the health promotion campaign to promote understanding of the updated clinical findings that demonstrate if someone is on ART and has a sustained undetectable viral load is unable to sexually transmit the virus to an HIV-negative partner. According the Prevention Access Campaign\footnote{https://www.preventionaccess.org} the U=U message is an unprecedented opportunity to transform the lives of millions of people living with, and affected by, HIV and to radically transform the field. It argues that message of U=U has the potential to:

- Improve the lives of people with HIV by dramatically reducing the shame and fear of sexual transmission, and opening up possibilities for conceiving children without alternative means of insemination.
- Dismantle HIV stigma at community, clinical, and personal levels.
- Encourage people living with HIV to start and stay on treatment, which keeps them and their partners healthy.
- Strengthen advocacy efforts for universal access to treatment, care, and diagnostics to save lives and bring us closer to ending the epidemic.

What is the clinical evidence behind the message?

To date there have been four major studies published which provide robust support for the assertion that if someone takes ART daily, as prescribed, and achieves and maintains an undetectable viral load there is unable to sexually transmit the virus to an HIV-negative partner.

The four studies are the HPTN052 study, the PARTNER study (both Partner 1 and Partner 2) and the Opposites Attract study. The summary of these studies can be found in Appendix B of this guidance.

Why is this message so important?

The implications of U=U are highly significant. For so long, being HIV positive has carried stigma, stemming largely from the person with HIV being perceived as a risk to others. This negative characterisation, which has been around since the beginning of the epidemic, has also been internalised by some people with HIV.

The message of U=U has provided an opportunity to transform the lives of people with, and affected by, HIV. An understanding of U=U can go a long way to alleviating HIV transmission-related anxiety. It can empower people with HIV to be comfortable in the totality of who they are and have a greater confidence to achieve sexual and reproductive health and a higher quality of life overall.

Clinicians are likely the first professionals with whom a newly-diagnosed person will be able to safely speak. Amidst the understandable fear and concern they may experience, the message of U=U is crucial. This will be particularly so if it gives people with HIV the confidence to disclose their status. It can help substantially address any already existing HIV-related stigma and can also serve as a significant additional incentive to consider starting ART.

What about those who do not have a sustained undetectable viral load?

There are range of factors that will affect whether an individual will have an undetectable viral load (and be able to sustain it). Some people who have access to treatment may choose not to be treated or may not be ready to start. Others who start treatment may have challenges with adherence for a variety of reasons such as stigma, mental health challenges, substance use issues, unstable housing, difficulty affording medications, drug resistance, and/or intolerable side effects.\footnote{14}
It is very important to explain clearly to all patients that in order not to sexually transmit HIV, a person with HIV must have an undetectable viral load and remain treatment adherent. More intensive support from the clinician will likely be needed for individuals with cognitive issues, limited health literacy, and differences in language and cultural norms.

In order to assist people who may have limited health literacy, language and/or cognitive abilities, consideration should be given to whether a support person or carer should attend services with the individual. HIV peer- support organisations and AIDS councils can be the best place for referral if the individual does not already have their own support system or people around them that they can trust.

For individuals who have had intensive support to optimise antiretroviral adherence but who remain unable to achieve sustained adherence and who are placing others at risk of HIV, it may be appropriate for the clinician to contact sexual health contact tracers at local health department or in New Zealand, the local Public Health Unit. As a last resort, the clinician may wish to confer with the relevant state/territory health department contact responsible for overseeing the National Guidelines for the Management of People with HIV Who Place Others at Risk (POAR Guidelines).

What is the HIV-negative partner still wants to take PrEP?
Some partners of people with HIV who have a sustained undetectable viral load may express a wish to be prescribed PrEP due to anxiety about HIV transmission. This is unnecessary from a clinical point of view, with the ASHM PrEP clinical guidelines stating that, “individuals are not considered to be a high or medium risk of HIV acquisition (and thus eligible for PrEP) if the person they have had sexual contact with has an undetectable viral load”.

However, other issues may be need to be explored such as anxiety around sex with their positive partner, or sexual partners outside of the relationship. In such circumstances, a clinician may decide to offer PrEP.

Is there still a role to suggest a course of PEP?
According to the Australian National Guidelines for Post-Exposure Prophylaxis after Non-Occupational and Occupational Exposure to HIV, “PEP is no longer routinely recommended for non-occupational exposure when an HIV-positive source has an undetectable viral load”.

What about HIV RNA in genital secretions?
There is no evidence that detectable virus in genital secretions while plasma viral load is undetectable is associated with transmission.

What about breastfeeding?
Studies demonstrate that ART greatly reduces the risk of HIV transmission from individuals who breastfeed their babies. However, research has not established that people whose HIV is undetectable do not transmit HIV during breastfeeding.

What about injection drug use?
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.

Does this apply to Needlestick injuries?
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.

What is the role of condom use in this era of U=U?
Without doubt condoms help to protect against other STIs, such as gonorrhoea, chlamydia, and syphilis, and help prevent pregnancy. What is important is that patients find a prevention strategy that works for them. If an individual who does not have HIV and/or 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 emphasise that no one should ever be compelled to have sex without condoms.

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12 https://www.cdc.gov/actagainstaids/campaigns/hivtreatmentworks/stayincare/treatment.html
Viral load testing
Viral load testing is the preferred method of monitoring HIV disease and determining the effectiveness of ART.\textsuperscript{16} Viral load tests are used to determine the amount of virus in the blood, usually expressed as the number of HIV copies per millilitre (ml) of blood (e.g. 2,500 copies/ml). Most viral load tests used in Australia and New Zealand have a lower limit of detection of HIV virus between 20-75 copies/ml\textsuperscript{17} while most low and middle-income countries use viral load assays with a limit of detection of 500 copies/ml.\textsuperscript{18} Regardless, the clinical evidence suggests there is no significant difference in terms of transmission risk once someone has a viral load below the limit of detection, irrespective of the sensitivity of assay.

Undetectable viral load
When an HIV viral load is below the level of detection on a specific assay, typically HIV RNA <20 copies/mL but as high as 50 copies/ml.

Durably undetectable
When a person has maintained an undetectable viral load for at least 6 months—indicating that their HIV is at a stable, undetectable level and that they will not pass HIV through sex if they continue to adhere to treatment.

Untransmittable
The finding—established by various clinical trials and observational studies—that people who maintain an undetectable viral load have so little HIV in their blood and other secretions that they have “effectively no risk” of passing HIV to others through sex.

Viral load suppression
When a person with HIV has a measured quantitative HIV RNA viral load <200 copies/mL of blood.

Viral blips
Patients on previously suppressive ART with newly detectable viral loads may be experiencing 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; still, there was no transmission from people whose measured HIV viral load was consistently suppressed.

Virological failure
Some individuals who initiate ART will not reach an undetectable viral load, also known as virological failure. Factors that can contribute to virological failure include drug resistance, drug toxicity, and poor treatment adherence.\textsuperscript{19} To be able to establish this, viral load testing should be undertaken every 3-4 months.

Infographic
The attached infographic has been produced as a visual cue for health care professionals and is something that has proven to work well in other settings.\textsuperscript{20} The simple, clear visuals and text illustrates the basics of U=U in a way that is meant to assist providers and enable them to feel confident sharing this information with their patients.

This infographic has been created to provide empirically supported, scripted language to help explain the concept of U = U. As a prompt for you to display in your clinical setting it can be used to cue conversations about U = U.\textsuperscript{21} Informational pamphlets, closed-circuit waiting room videos, and other patient-targeted education materials can further stimulate and reinforce patient–provider conversations about U = U and we encourage you to reach out to your local AIDS Council or PLHIV organisation to locate such items that are appropriate to your clinical service setting.

\textsuperscript{16}\url{https://apps.who.int/iris/bitstream/handle/10665/255891/WHO-HIV-2017.22-eng.pdf?sequence=1}
\textsuperscript{17}\url{https://www.labtestsonline.org.au/learning/test-index/hiv-viral-load}
\textsuperscript{20}Undetectable = Untransmittable (U=U) to drive stigma reduction and epidemic control in Vietnam: A global model for political and program innovation.
\textsuperscript{21}Sibigra impedes HIV prevention by stifling patient-provider communication about U=U.
Stamp out Scepticism about U=U

STAY HEALTHY
Emphasise that remaining HIV undetectable means you cannot transmit HIV and helps you live a better quality of life.

MAINTAIN UNDETECTABLE
A durable undetectable viral load requires high levels of adherence and regular viral load testing.

AVOID VIRAL REBOUND
If you stop taking HIV treatment, viral rebound can occur within 1-2 weeks and you may pass HIV to your sexual partners.

ACHIEVE UNDETECTABLE
It may take up to 6 months of HIV treatment to bring HIV down to undetectable.

THINK ABOUT STARTING (OR RESTARTING) HIV TREATMENT AS SOON AS POSSIBLE
Both newly diagnosed with HIV and those previously diagnosed but not taking ART should get on treatment.

SUPPORT THOSE LIVING WITH HIV

INFORM ALL PATIENTS

THE NEED FOR REGULAR STI TESTS
Even if they believe they have no symptoms, this keeps themselves and their sexual partners healthy.

U=U
People who keep their HIV viral load at an undetectable level by consistently taking HIV medications will not pass HIV to others through sex.

THE EVIDENCE BASE BEHIND U=U
The research is clear, no HIV-positive person who was HIV undetectable and on treatment passed HIV to their HIV-negative sexual partner.

www.ashm.org.au

Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine
“People living with HIV don’t just need to hear about U=U, we need to believe it. That’s why it is so important that healthcare professionals who diagnose and care for us expertly communicate just what an undetectable viral load means. We need you to believe it, so we do too. Anything less keeps us under stigma’s thumb.”

Nic Holas
Founder, The Institute of Many
Appendix A – Prior ASHM Comments & Guidelines

Undetectable = Untransmittable Position Statement
An HIV undetectable status means HIV cannot be transmitted – ASHM Conference 2017
November 2017

Australian guidance for clinicians and other health care providers discussing Undetectable = Untransmittable (U=U) with people living with HIV
July 2018

Updated Australian guidance for clinicians and other health care providers discussing Undetectable = Untransmittable (U=U) with people living with HIV — now available
September 2018

Understanding Undetectable=Untransmissible (U=U) for Women Living with HIV – Media Release
September 2018

ASHM, AIDA and NAPWHA congratulate the Australian Government’s release of new National BBV and STI Strategies
November 2018

World AIDS Day: Responding to the HIV epidemic both in Australia and throughout the Asia and Pacific regions
December 2018

Singapore WAD 1st Congress on HIV 2019 “U=U: Science, Not Stigma”
November 2019

Research presented at AIDS 2020 highlights ASHM’s work in educating healthcare providers about U=U
July 2020
Appendix B - Foundational Research

Antiretroviral Therapy for the Prevention of HIV-1 Transmission: A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples

September 2016

HTPN 052 was a Phase III, two-arm, randomized, controlled, multi-centre trial to determine whether antiretroviral therapy (ART) can prevent the sexual transmission of HIV-1 in HIV-1 serodiscordant couples.

This was a landmark study proving that early ART can prevent HIV transmission. Following the interim results of the HPTN 052 study, the World Health Organization recommended that antiretroviral treatment be offered to all people living with HIV who have uninfected partners to reduce HIV transmission in 2016.


July 2016

This study posed the question “What is the risk of HIV transmission through condomless sex from an HIV-positive person taking suppressive ART?” In this observational study in HIV-serodifferent heterosexual and MSM couples having ongoing condomless sex over 1238 couple-years of follow-up in which the HIV-positive partner was using suppressive ART and who reported condomless sex, during median follow-up of 1.3 years per couple, there were no documented cases of within-couple HIV transmission (upper 95% confidence limit, 0.30/100 couple-years of follow-up). Additional longer-term follow-up is necessary to provide more precise estimates of risk.


Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study

August 2018

In the Opposites Attract observational cohort study, serodiscordant male homosexual couples were recruited from 13 clinics in Australia, one in Brazil, and one in Thailand. Evidence on viral load and HIV transmission risk in HIV-serodiscordant male homosexual couples is limited to one published study. We calculated transmission rates in couples reporting condomless anal intercourse (CLAI), when HIV-positive partners were virally suppressed, and daily pre-exposure prophylaxis (PrEP) was not used by HIV-negative partners.

HIV treatment as prevention is effective in men who have sex with men. Increasing HIV testing and linking to immediate treatment is an important strategy in HIV prevention in homosexual men.


Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study

April 2019

The level of evidence for HIV transmission risk through condomless sex in serodifferent gay couples with the HIV-positive partner taking virally suppressive antiretroviral therapy (ART) is limited compared with the evidence available for transmission risk in heterosexual couples. The aim of the second phase of the PARTNER study (PARTNER2) was to provide precise estimates of transmission risk in gay serodifferent partnerships.

Our results provide a similar level of evidence on viral suppression and HIV transmission risk for gay men to that previously generated for heterosexual couples and suggest that the risk of HIV transmission in gay couples through condomless sex when HIV viral load is suppressed is effectively zero. Our findings support the message of the U=U (undetectable equals untransmittable) campaign, and the benefits of early testing and treatment for HIV.

Rodger AJ et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. Lancet 2019;
Appendix C – Recent Research & Reports

U=U: A Destigmatizing Message Inconsistently Communicated by Clinicians to PLHIV
June 2018

This presentation from the 2018 Adherence Conference was based upon a 45-question survey to gauge clinician perspectives on HIV, HBV, and HCV clinical management between December 2017-March 2018 with over 1000 providers from 35 countries.

suggests U=U is a simple but hugely important campaign based on a solid foundation of scientific evidence. However, U=U is not consistently integrated into practice by clinicians (notably PCPs); HIV-positive patients with undetectable viral loads are thus not hearing message.

It is recommended that Education/support regarding the science behind U=U and how to communicate message to HIV-positive patients with undetectable viral loads is needed.

U=U – A Destigmatizing Message Inconsistently Communicated by Clinicians to PLHIV (Abstract 223). José M. Zuniga, PhD, MPH President/CEO, IAPAC

Science Validates Undetectable = Untransmittable HIV Prevention Message
July 2018

People living with HIV whose virus is completely, durably suppressed by treatment will not sexually transmit the virus to an HIV-negative partner, according to NIAID Director Anthony S. Fauci, M.D. The success of this HIV prevention strategy is contingent on achieving and maintaining an undetectable viral load—the amount of HIV genetic material in the blood—by taking medication to treat HIV daily as directed.


Brief Report: No HIV Transmission from Virally Suppressed Mothers During Breastfeeding in Rural Tanzania
September 2018

To what extent antiretroviral therapy (ART) reduces mother-to-child HIV transmission (MTCT) during breastfeeding remains unclear. We assessed the MTCT risk from mothers on ART to their infants during breastfeeding. We found no MTCT from mothers who were retained in care and had suppressed VL. Breastfeeding signifies a very low risk when mothers adhere to ART. Adherence counselling, VL monitoring, and strategies to trace back those LTFU should be a priority


BHIVA encourages universal promotion of Undetectable=Untransmittable (U=U)
November 2018

Consistent use of ART by people living with HIV to maintain an undetectable viral load is a highly effective strategy to prevent the sexual transmission of HIV. We urge health care professionals to discuss U=U proactively with all people living with HIV at appropriate points during care including, but not limited to: diagnosis, when initiating treatment, to encourage adherence, when undetectable, and if planning to conceive.

We recommend consistent and unambiguous terminology when discussing U=U such as “no risk” or “zero risk” of sexual transmission of HIV, avoiding terms like “negligible risk” and “minimal risk.”


Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV
December 2018

The data [from HTPN-025, Partners and Opposites Attract] 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 persons with HIV remain virally suppressed.

HIV viral load and transmissibility of HIV infection: undetectable equals untransmittable.
January 2019

In this Viewpoint of JAMA, there is an examination of the underlying science-based evidence supporting this important concept and the behavioural, social, and legal implications associated with the acceptance of the U=U concept.

In 2016, the Prevention Access Campaign, a health equity initiative with the goal of ending the HIV/AIDS pandemic as well as HIV-related stigma, launched the Undetectable = Untransmittable (U = U) initiative. U = U signifies that individuals with HIV who receive antiretroviral therapy (ART) and have achieved and maintained an undetectable viral load cannot sexually transmit the virus to others.

This concept, based on strong scientific evidence, has broad implications for treatment of HIV infection from a scientific and public health standpoint, for the self-esteem of individuals by reducing the stigma associated with HIV, and for certain legal aspects of HIV criminalization.


Providers should discuss U=U with all patients living with HIV
February 2019

As scientific knowledge surrounding the link between HIV viral suppression and transmission risk evolves, messaging to patients must be updated accordingly. Presenting the results of the multisite, observational PARTNER2 study at the 22nd International AIDS Conference, Alison Rodger reported that no phylogenetically linked infections occurred following more than 76 000 condomless sex acts between virally suppressed men and their HIV-negative male partners. This finding reinforces existing consensus by WHO and more than 750 other organisations worldwide that people whose HIV viral load is stably suppressed cannot sexually transmit the virus. With evidence supporting undetectable=untransmittable (U=U) now overwhelming providers should be routinely communicating the message to all of their patients living with HIV.


Strategies used by gay male HIV serodiscordant couples to reduce the risk of HIV transmission from anal intercourse in three countries
April 2019

There are few data about the range of strategies used to prevent sexual HIV transmission within gay male serodiscordant couples. We examined HIV prevention strategies used by such couples and compared differences between countries. Couples used condoms, PrEP or perceived undetectable VL for prevention in the majority of anal intercourse acts. Only a very small proportion of events were not protected by these strategies. Variation between countries may reflect differences in access to HIV treatment, education, knowledge and attitudes.


Undetectable is Prevention

Poster Resource for HCP with the key message being that by educating patients about the value of treatment as prevention can help them manage their HIV. Engaging patients in routine, brief conversations about treatment as prevention can also help health care providers become more familiar with each patient, including their adherence and transmission risk.


Awareness, understanding and impact of U=U: views from patients and staff
April 2019

This presentation found that there were mixed levels of understanding and that staff U=U explanations varied. Whilst there was broad agreement that U=U can have a positive impact in multiple areas (disclosure, sex and medication) and most staff are mostly aware of these positives, but may under-estimate complexities, or incorrectly assume knowledge / relevance.

It recommended that:

○ U=U can have a positive impact on both individuals and prevention
○ HIV clinics are well placed to proactively check and promote understanding.
○ Information must be clear, consistent and accessible.

Most UK clinic staff now tell people about U=U, but not always in the same way
April 2019

Two presentations at this month’s British HIV Association (BHIVA) conference in Bournemouth show that most specialist healthcare workers are now informing people with HIV that if their viral load becomes undetectable as a result of taking antiretroviral therapy (ART), they can no longer transmit the virus (‘Undetectable equals untransmittable’, or ‘U=U’).

However, the healthcare workers told the patients at different times – on diagnosis, after starting therapy, once they were undetectable – and also phrased the information in different ways. The inconsistent practice highlighted in BHIVA’s survey of its members prompted the organisation to issue a public statement about U=U on World AIDS Day, 1 December, last year.


Understanding the perception and potential promise of U=U and TasP among sexual minority men (SMM) in the U.S.
June 2019

In this poster demonstrated that a greater proportion of HIV-negative and unknown men believed in U=U in 2017-18 than the prior year. For those that question the notion of U=U it appears that it centred upon their understanding of TasP not in the message of =U itself. Among HIV+ men, fewer than half understood that TasP was associated with “essentially no risk” of transmission and concerning that virtually no SMM living with HIV had heard about TasP/U=U from their medical providers. This is in light of the finding that the vast majority of HIV+ SMM said U=U made them feel better about their HIV status.

Rendina H, Cenfuegos-Szalay J, Carter J et al Understanding the perception and potential promise of U=U and TasP among sexual minority men (SMM) in the U.S.

U=U in Practice: Results from a Midwest Provider Survey, MATEC and Minnesota Department of Health
September 2019

Most HCP (n=403) had heard of U=U and self-reported that they discussed U=U with their patients with 1/2 concerned about potential clinical ramifications and 1/3 concerned about potential legal ramifications of discussing U=U with their patients. A third of respondents thought patients would be more likely to engage in sexual risk-taking behaviours if they discussed U=U with them.

Lots of differences among professions in feeling comfortable counselling a durably undetectable patient about U=U in absence of condoms or PrEP: with physicians most comfortable, PAs and Nurses the least comfortable. It was recommended that workforce development & education for HCP that do not have many years of experience or large # HIV patients is needed.

https://drive.google.com/file/d/0B730_D8IzgZ8cWlmNUFMN05VMHg5QZltha0NknhUMcBIIWz1pN/view

WHO Policy Brief: Consolidated guidelines on HIV testing services for a changing epidemic
November 2019

In this update to the WHO guidelines, the HIV testing services guidelines suggest that at the time of diagnosis, providers should educate patients that “people with HIV on [antiretroviral therapy] who achieve and maintain viral suppression cannot transmit HIV to their partners.”

https://www.who.int/publications/i/item/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic

U=U Guidance for Implementation in Clinical Settings
June 2019

These guidelines emanate from the New York State Department of Health (NYSDOH) and their efforts to destigmatize HIV and to support innovative biomedical and social efforts to improve the health and well-being of all PLHIV. The guidelines provide practical advice to HCP on how to counsel individuals and couples with regard to U=U and provide the guidelines in several easy to access formats.

Blackstock O, Myers J, Kisriak P, Dasakakis D with the Medical Care Criteria Committee U=U Guidance for Implementation in Clinical Settings NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE June 2019

U=U: ASHM GUIDANCE FOR HEALTHCARE PROFESSIONALS // October 2020
The survey of 239 women living with HIV illustrates the need for the HIV community to expand notions of optimal outcomes beyond viral suppression to include measures of broader health and quality of life. Nearly all participating women living with HIV faced high levels of stigma, violence and trauma, and behavioural health issues, all of which complicated their ability to manage their overall health.

Key findings regrading U=U:
- 85% of women surveyed were either very familiar or extremely familiar with U=U
- 78% were very confident or extremely confident in U=U
- 72% said U=U had a significant or tremendously positive impact on their lives
- 64% had not heard it from their healthcare providers

https://www.thewellproject.org/news-press/well-project-user-survey-results-together-we-are

Undetectable viral load and HIV transmission dynamics on an individual and population level: where next in the global HIV response?

This purpose of this review was to examine recent literature on the efficacy and effectiveness of HIV treatment in preventing HIV transmission through sexual exposure, at both an individual and at a population level. Factors contributing to the disconnect between individual high-level efficacy and population-level effectiveness of TasP [U=U] include undiagnosed infection, delays in linkage to care, challenges in retention and adherence to antiretroviral therapy (ART), time between ART initiation and viral suppression, and stigma and discrimination. Suppressive ART renders people living with HIV sexually non-infectious. However, epidemic control is unlikely to be achieved by TasP [U=U] alone.


IAS statement on U=U: Putting the science into action

In this letter from the IAS, advocates from across the HIV response have raised their concerns that despite the unequivocal scientific evidence, those who have spoken publicly in support of U=U in Thailand have recently received an extreme backlash for ensuring this science is put into practice. They have recommended that to avoid misinformation, medical associations and establishments must uniformly and openly recognize U=U. The pre- and in-service training of a range of healthcare practitioners must ensure that the principles of U=U are understood across a range of diverse settings. Including an evidence-based U=U message within all client interactions will ensure that everyday prevention and the choices people make are grounded in science.

https://www.iasociety.org/The-latest/News/ArticleID/244/IAS-statement-on-U-U-Putting-the-science-into-action

Implementing U=U in clinical practice: results of a British HIV association members survey

In 2016, the Prevention Access Campaign, launched the Undetectable=Untransmittable statement. U=U is arguably the single most important communication for people living with HIV and is based on a solid foundation of scientific evidence. The zero risk of sexual transmission represents a significant change in messaging. The British HIV Association (BHIVA) conducted an anonymised member’s questionnaire on U=U. Members could select different answer options, submit free text and opt out of answering questions. The survey was emailed to members in October 2018.

The majority were discussing U=U routinely. However, inconsistencies were observed. The BHIVA U=U position statement was devised, recommending proactive discussion and use of the word ‘zero’ to describe risk. The BHIVA monitoring guideline was updated, highlighting that U=U applies in the presence of STI’s. Healthcare providers have a duty to disseminate clear, accurate and unambiguous information to maximise well-being and dismantle stigma.

“I just believe there is a risk” understanding of undetectable equals untransmissible (U = U) among health providers and HIV-negative partners in serodiscordant relationships in Kenya

March 2020

Sustained HIV viral suppression resulting from antiretroviral therapy (ART) eliminates the risk of HIV transmission, a concept popularly framed as Undetectable = Untransmittable (U = U). We explored knowledge and acceptance of information around the elimination of HIV transmission risk with ART (U = U) in Kenya.

Despite awareness that effective ART use eliminates HIV transmission risk, there is both a lack of in-depth knowledge and conviction about the strategy among health providers and HIV-negative partners in serodiscordant relationships. New strategies that go beyond communicating the science of U = U to consider the local social and clinical environments could maximize the effectiveness of U = U.


Undetectable equals untransmittable (U = U): awareness and associations with health outcomes among people living with HIV in 25 countries

July 2020

‘Undetectable equals Untransmittable’ (U=U) is an empowering message that may enable people living with HIV (PLHIV) to reach and maintain undetectability. We estimated the percentage of PLHIV who ever discussed U=U with their main HIV care provider, and measured associations with health-related outcomes. Secondarily, we evaluated whether the impact of the U=U message varied between those who heard it from their healthcare provider (HCP) vs from elsewhere.

HCP discussion of U=U with PLHIV was associated with favourable health outcomes. However, missed opportunities exist since a third of PLHIV reported not having any U=U discussion with their HCP. U=U discussions with PLHIV should be considered as a standard of care in clinical guidelines.


‘... if U equals U what does the second U mean?': sexual minority men’s accounts of HIV undetectability and untransmittable scepticism

July 2020

The everyday meaning and use of HIV ‘undetectability’ raises significant questions about the social and sexual significance of this state of viral suppression. These in-depth, semi-structured interviews with 25 sexual minority men living in Vancouver, Canada, including men living with HIV illustrated that most participants understood being undetectable to signify that someone living with HIV is at a ‘low’, ‘lower’, or ‘slim to no’ risk of sexually transmitting HIV, as opposed to meaning ‘uninfectious’ or ‘untransmittable’. Men discussed how undetectability was communicated in-person and online, including via sexual networking apps, and revealed how it is sometimes confused or conflated with another biomedical advance in HIV prevention, namely pre-exposure prophylaxis (PrEP). HIV-negative men expressed significant scientific scepticism, a reluctance to incorporate a partner’s low viral load or undetectable HIV status into their sexual decision-making, and an enduring fear associated with knowingly having sex with someone who is HIV-positive. We describe this as a form of ‘untransmittable scepticism’. While international campaigns have worked to communicate the scientific message that ‘undetectable equals untransmittable’ (U = U), the sexual stigma attached to HIV remains durable among some gay, bisexual, queer and other men who have sex with men.

Daniel Grace, Ronita Nath, Robin Parry, James Connell, Jason Wong & Troy Grennan (2020): ‘... if U equals U what does the second U mean?’ sexual minority men’s accounts of HIV undetectability and untransmittable scepticism, Culture, Health & Sexuality
Stigma impedes HIV prevention by stifling patient–provider communication about U = U

July 2020

In this viewpoint article the authors contend that stigma – that is, social devaluation based on one or more distinguishing characteristics – could be a key reason underlying the lack of consistent U = U patient education. The authors further suggest that the withholding of patient education around U = U or tempering the message to prevent unwanted behaviour is not medically justifiable. Furthermore, the decision to withhold or modify U = U messaging could be influenced by stigma towards patients.

The viewpoint stresses that additional research is needed to assess the impact of provider stigma, evaluate culturally tailored interventions, and ultimately optimize U = U communication between patients and providers. Nonetheless, immediate action can and should be taken to encourage providers to routinely communicate about U = U with all of their patients and to ensure that stigma does not stifle these critical conversations.

Recommended Strategies for Encouraging Universal U = U Patient Education include:

- Establish universal U = U patient education in normative guidelines dictating clinical practice
- Incorporate U = U into clinical education for all HIV service providers
- Facilitate patient–provider conversations about U = U with concrete tools
- Broaden public awareness through public health messaging

Implementing a Status-Neutral Approach to HIV in the Asia-Pacific

July 2020

Globally, “undetectable equals untransmittable (U=U)” and “pre-exposure prophylaxis (PrEP)” have become crucial elements in HIV treatment and prevention programs. This review focuses upon the implementation of U=U and PrEP among countries in the Asia-Pacific region. To advance U=U and PrEP in the Asia-Pacific, strategies targeting changes to practice norm through wide-scale stakeholders’ training and education, making use of online health care professional influencers, and utilizing financial mechanism should be further explored through implementation research.

What we talk about when we talk about durable viral suppression

September 2020

As policies built on ‘Undetectable = Untransmittable’ become more popular, use of durable viral suppression (DVS) as an outcome in analyses is increasing. We identified a case series of recent HIV-related publications that study the DVS outcome. The majority did not distinguish between a definition of DVS and the operationalization of that definition. Clearer discussion of DVS, including a formal definition, is needed to ensure better comparability across studies and ultimately better public health outcomes.

Diepstra, Karen; Lu, Haidong; McManus, Kathleen A; Rogawski McQuade, Elizabeth; Rhodes, Anne G; Westreich, Daniel. What we talk about when we talk about durable viral suppression.
Appendix D – Patient Resources

Increasingly there are a number of sites online where patients can find further information regarding U=U.

The following sites and resources have been designed and developed within Australia for the Australian healthcare consumer.

**TIM - The Institute of Many**

The Institute of Many (TIM) is a peer-run movement for People Living with HIV. Acting as a social umbrella and advocacy platform, we bring HIV positive people together to share their experience of living with HIV in an informal, confidential environment - in person and online.

The site contains videos from a variety of people speaking about U=U.

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**NAPWHA – National Association of People Living with HIV Australia**

NAPWHA is Australia’s peak non-government organisation representing community-based groups of people living with HIV. It is a membership of national networks and state-based organisations reflecting the diverse make-up of the HIV-positive community and represents the positive voice in Australia.

The site contains stories and updates about living with HIV and the impact of U=U.

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**EMEN8**

Emen8 is Australia’s biggest and boldest online sexual health and wellbeing initiative for gay men, bisexual men and other men who have sex with men.

This site contains videos and information for gay, bisexual and men who have sex with men about U=U.

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A comprehensive listing of resources and materials from other countries, in languages other than English and providing information to specific sub-populations and on a variety of topics related to U=U can be found at The Prevention Access Campaign.
“I might be the odd nurse out, but even when vaccinating people for HPV or shingles, I want a handout that has valuable information for me and that the patient can understand as well. Something that is eye-catching and concise is the way to go.

And this resource does just that.”

Brianna Rizzuti, RN