ACON Position Statement 2014

Undetectable Viral Load, Treatment and HIV Transmission

ACON's Position

Having an undetectable viral load (UVL) greatly reduces the risk of HIV transmission. This was first outlined in the 2008 Swiss Statement and has since been clearly established in large international studies.

HPTN 052 (1) looked at two treatment strategies to prevent the sexual transmission of HIV in heterosexual HIV-serodiscordant couples, and the European PARTNER study investigated HIV transmission in couples where an HIV positive partner was taking effective HIV treatment.

Both studies have shown the effectiveness of antiretroviral treatment (ART) in preventing HIV transmission, with the interim results of the PARTNER study showing that no cases of HIV were transmitted either by anal or vaginal sex where the HIV positive partner had an UVL. Importantly, 40% of PARTNER study participants were gay men (2).

There are multiple benefits associated with obtaining and maintaining an UVL, especially for individuals but also for the broader community. These benefits are primarily improved health outcomes for people living with HIV (PLHIV) and a low risk of onward transmission of HIV.

While gay and other homosexually active men (GHAM)in NSW have maintained high rates of condom use, sex without condoms still happens in our community, in a variety of contexts. ACON believes that achieving an UVL can significantly reduce the risk of onward transmission of HIV infection in situations where sex without condoms occurs.

ACON believes the law in NSW should recognise contemporary understandings of having and maintaining an UVL and the strength of the evidence that this significantly reduces the risk of transmission of HIV.

This should be taken into consideration when police, prosecutors and courts are implementing and interpreting the law.

Science has demonstrated that PLHIV who are well informed and closely monitor their viral load could be considered taking a 'reasonable precaution' in remaining treatment adherent and are confident they are maintaining an UVL, although it is unsure whether the law has kept up to date with the science. This places PLHIV in an uncertain position in relation to legality.

Purpose

New evidence on the reduced risk of transmission associated with having an UVL and the considerable public interest has prompted this updated position statement reflecting new developments. ACON recognises that the relationship between viral load, treatment and HIV transmission is multifaceted, with viral load affected by serious illness, poor adherence to treatment and STIs.

This position paper aims to highlight ACON's stance on the complex issue of what a contemporary understanding of safe sex means, and the evolving evidence on obtaining and maintaining an UVL for GHAM in NSW, and the interplay between viral load and HIV transmission offences.

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Background

The notion that UVL can reduce the risk of onward transmission was first articulated publicly in the 2008 *'Swiss Consensus Statement'* which stated that when heterosexual couples maintained suppressed viral loads for 6 months or more and absent of STIs, HIV transmission was deemed "*unlikely*". (14)

Subsequent large scale studies, in particular HPTN 052 (1), a randomised control trial, that looked at two treatment strategies in preventing the sexual transmission of HIV in serodiscordant couples, and the European PARTNER, an ongoing observational cohort study which is looking at HIV transmission when an HIV positive partner is taking effective HIV treatment, have shown the effectiveness of ART in preventing HIV transmission.

Key results from HPTN 052 suggest a 96% reduction in risk when study participants had suppressed viral loads. Similarly the interim results from the European PARTNER study reports that no cases of HIV were transmitted either by anal or vaginal sex where the HIV positive partner had an UVL, though this does not meant that there is zero risk of transmission. Importantly, 40% of PARTNER study participants were gay men (2).

In light of this recent evidence, ACON recognises that having an UVL, achieved through the use of ART by the HIV-positive partner, drastically reduces the risk of HIV transmission during sex.

We also acknowledge that there is some evidence to suggest that viral load may fluctuate over time depending on the presence of certain STIs and strong evidence suggesting that treatment adherence can influence viral load and that regular monitoring of UVL is important to prevent HIV transmission.

ACON acknowledges that the HIV landscape in NSW is changing. A range of risk reduction strategies can now be employed to reduce the transmission of HIV. However, condoms remain the most effective strategy to reduce transmission of HIV as well as other STIs, which may in turn facilitate HIV transmission. ACON acknowledges that the majority of gay men in NSW continue to use condoms and lubricant in casual sex settings.

ACON recognises that for the goals contained in the NSW HIV Strategy to be met, particularly the reduction of HIV transmission amongst gay men by 80% by 2020 (3), high levels of condom use with casual partners of unknown or serodiscordant HIV status will need to be maintained or increased, along with greater testing and treatment uptake.

Recent changes to Australia's Pharmaceutical Benefits Scheme (PBS), have removed impediments to the early availability of ART. We believe that this will provide PLHIV with greater opportunity to initiate treatment when they wish to and to maintain an UVL.

Legal issues surrounding the transmission of HIV still exist in NSW, and ACON believes there is a lack of clarity on how the defence of taking 'reasonable precautions' under Section 79 of the Public Health Act 2010 will be interpreted by the courts, particularly in accordance with recent evidence on the reduced risk of HIV transmission in the context of an UVL.

Evidence Base

HPTN 052, which began in April 2005, enrolled 1763 HIV serodiscordant couples, most of whom (97%) were heterosexual (1). The purpose was to measure whether early or standard treatment initiation would reduce transmission of HIV to the negative partner.

The study was also designed to evaluate whether beginning ART earlier would benefit the health of the HIV-positive partner. The key finding was that prevention efficacy of treatment was 96% (1).

Recent outcomes from the first two years of the European PARTNER study, which involves 1110 serodiscordant couples, have to date been consistent with the results of HPTN 052. While the final results of the study are due to be released in 2017, interim results from the first two years of the study show that no cases of HIV were transmitted either by anal or vaginal sex where the HIV positive partner had an UVL (under 200 copies/ml) (2).

Sexually Transmissible Infections

ACON acknowledges that evidence concerning the role STIs have on the facilitation of HIV transmission is contested and ever-changing. Some recent smaller studies have shown that a significant minority of men with UVL in their blood had detectable viral load (200 – 2500 copies/ml) in their semen (15).

The authors surmise that this was due to urethral inflammation as a result of an STI. This was also associated with men taking the insertive position during anal sex. This research suggested that even if an STI is asymptomatic, there is potential for fluctuation of a person's viral load without that individual being aware- and this has important HIV prevention implications especially for GHAM in NSW.

However, interim results from the PARTNER study in Europe report that despite high prevalence of STIs among the gay participants of the study, no transmissions of HIV have occurred, suggesting that STIs may only facilitate HIV transmission when HIV infection is left untreated. ACON acknowledges the need for more research in this area to better understand the role of STIs on UVL.

ACON maintains that regular testing for STIs is important for all gay and homosexually active men, irrespective of HIV status. ACON encourages all sexually active men to test for HIV and STIs at least twice a year, or up to four times per year in the context of sex without condoms, more than 10 partners in the past six months, or group sex with or without recreational drugs during sex (7).

Sexually active gay men living with HIV should consider testing for STIs at each occasion of CD4/viral load monitoring (7).

Adherence to antiretroviral treatments

As a result of recent advances in ARTs, PLHIV are leading longer and healthier lives. Adherence to antiretroviral treatment is strongly correlated with HIV viral suppression, reduced rates of drug

resistance, an increase in survival and an improved quality of life (8). However, suboptimal adherence can have many negative implications such as fluctuation in viral load, drug resistance, viraemia, and can increase the risk of transmitting a drug-resistant strain of HIV to sexual partners (8).

Efficacy of Undetectable Viral Load against HIV Transmission

Although most evidence to date suggesting individual and population-based benefits of having an UVL load has been derived from studies of heterosexual populations, there is now emerging evidence to suggest the same benefits will be observed if applied to gay men.

The interim results coming from the first two years of the European PARTNER study show that no cases of HIV were transmitted by either anal or vaginal sex where the HIV positive partner had a UVL (under 200 copies/ml) (2). The final results of the study are due to be released in 2017.

In Australia and Brazil, The Kirby Institute is undertaking a study called 'Opposites Attract' which is looking into the effect of a UVL on HIV transmission in serodiscordant gay couples, with the findings due to be reported in 2016.

Recent research states that decisions regarding sex with or without condoms should be based on viral load measurements taken no more than six months prior (9). The study recognises that viral loads can fluctuate. Therefore if men are using UVLs as a risk reduction strategy, regular patient monitoring is necessary (9).

Research from Sydney's Gay Community Periodic Survey 2014 suggests that the proportion of men having unprotected anal intercourse with regular partners has slightly decreased between 2012 and 2013, however, the proportion of men reporting any sex without condoms in casual encounters has been stable since 2010 at approximately 35% of those that reported any casual sex (10).

In addition, well over half of all men who are living with HIV are in serodiscordant or sero-nonconcordant relationships (10). Taking this into consideration, ACON stresses the importance of informing our community about the benefits of treating early and subsequently maintaining an UVL, while maintaining regular testing for HIV and STIs for men regardless of HIV status.

Structural Barriers

ACON has been working with non-government organisations, government agencies, Local Health Districts and other parts of the HIV sector to advocate for treatment guidelines that provide sufficient scope and flexibility to accommodate patient/physician treatment choices based on best practice evidence and individual circumstances.

As of April 2014, Australia's PBS has removed existing impediments to early availability of ARTs. We believe that this will provide PLHIV with a greater ability to initiate treatment and with more affordable treatment options to manage their health and viral load.

Despite this, there are still PLHIV who are legally living in Australia with no access to subsidised ARTs through the PBS or alternative funding arrangements. These groups include: international

students, people on working visas, and partners of Australian citizens. Other international jurisdictions including the UK, Portugal, Canada and Brazil have public health funding that ensures free ARTs to all PLHIV. ACON would like to see a similar public health funding model for PLHIV in Australia.

Transmission and the Law

ACON does not support laws that explicitly criminalise HIV transmission, HIV exposure or failure to disclose HIV status, as they are counterproductive to public health outcomes. This is especially the case when dealing with cases of consensual private adult sex.

The vast majority of gay men actively seek to protect their own, and their partner's, sexual health. Everyone, regardless of HIV status, has a mutual responsibility to ensure that HIV and other STIs are not passed on. In these circumstances, legal intervention is neither needed nor appropriate.

ACON acknowledges that there is a limited place for criminal and public health law provisions in circumstances that are not specific to HIV, and which may apply in a very small number of cases where people deliberately or recklessly expose others to the risk of HIV transmission.

In NSW there are very few situations where a person is legally required to disclose their HIV status. The Public Health Act 2010 (NSW) includes the longstanding requirement for all people with HIV to disclose their status before a sexual encounter.

An amendment of this Act in 2010 introduced a defence of taking 'reasonable precautions' to avoid transmission in cases of non-disclosure. The courts have yet to determine what constitutes 'reasonable precautions'. It is likely that condoms and water-based lube will constitute a 'reasonable precaution', however it is less certain that attaining and sustaining a UVL will be recognised as 'reasonable precaution' by the courts (13).

The relationship between HIV transmission and the law varies throughout differing international jurisdictions. The first country to consider risk of HIV transmission and one's viral load was the Netherlands in 2005.

Since then, Austria, Switzerland, Germany and more recently the province of Nova Scotia, Canada, have seen individual cases where UVL was considered as part of a defence to non-disclosure and where a person was acquitted, although these decisions have not been confirmed in the higher courts.

In 2008, Professor Pietro Vernazza of the Swiss Federal AIDS Commission stated that, in his view and that of his co-authors, where PLHIV who have been on effective antiretroviral therapy for at least six months and in the absence of concurrent STIs, they are no longer sexually infectious (14).

Furthermore in Austria, the Ministry of Justice has recommended that if a person living with HIV has a UVL and consistently adheres to an effective ART regime then sexual intercourse without a condom does not constitute a criminal offence- given that the person is no longer sexually infectious. However, this suggestion is not yet binding of Austrian courts.

In light of the research that has been conducted, medical evidence of maintaining an UVL should play an important role in cases of non-disclosure, exposure and transmission. ACON believes that maintaining a UVL should be considered when assessing whether a person has taken 'reasonable precautions' by the NSW courts.

It is worth noting that as a reasonable precaution is an action, it is likely that courts will need to look at the actions a person has taken to achieve and maintain a UVL and whether this should be considered the reasonable precaution. Furthermore, reasonableness is subjective, having regard to all circumstances, and therefore varies from case to case based on circumstances.

Under the Crimes Act 1900, a person who recklessly causes another person grievous bodily harm (GBH) can be imprisoned for up to 10 years. This can include causing someone to be infected with HIV. A person is generally deemed as reckless when they are aware that there is a risk that another person may be caused GBH as a result of their actions, but they proceed to act anyway. There have been two criminal prosecutions for sexual transmission of HIV in NSW – one in 2004 and the other in 2008.

Although not specified as a defence, the use of condoms is likely to mean that a person was not being reckless if transmission occurred. Whether achieving and maintaining a UVL would be seen in the same light is yet to be tested in Australia, though international cases point to this being an arguable point in a criminal court.

Until there is clarity from NSW Courts regarding the *Public Health Act (2010)* and the *Crimes Act 1900*, ACON can only confidently recommend consistent use of condoms and lubricant with partners of unknown HIV status and/or full disclosure.

While the vast majority of people with HIV are unlikely to come into contact with the criminal justice system in relation to their HIV status, prosecutions for HIV transmission do occur. Individuals who recklessly or intentionally endanger others by exposing them to the risk of HIV need to be aware of the criminal and health implications of their actions.

Endnotes

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Viral Load

Viral load refers to the amount of HIV in your body. It is routinely measured in blood, not other body fluids such as seminal fluids. Although the amount of viral load is normally similar between both blood and semen, they can be different. Obtaining an UVL may not be possible for all PLHIV; however a reduced viral load is likely. There is varying evidence suggesting that STIs and other infections may also result in an increase in a person's seminal viral load. As with HIV negative men, it is important for PLHIV to be diligent when experiencing STI-like symptoms, as it is possible that there will be an effect on the viral load, particularly when HIV is untreated.

Note: This paper contains general commentary and does not constitute medical or legal advice.