

UNDETECTABLE VIRAL LOAD AND RISK OF HIV TRANSMISSION: THE 'SWISS STATEMENT'

References:

- [1] Vernazza P, Hirschel B, Bernasconi E & Flepp M (2008) Les personnes séropositives ne souffrant d'aucune autre MST et suivant un traitement antirétroviral efficace ne transmettent pas le VIH par voie sexuelle. *Bulletin des médecins suisses* 89(5), 165–169.
- [2] Epidemiology is the study of disease among populations of people. In this case, the authors of the Swiss Statement looked at epidemiological studies of PLHIV in Europe. They noted that there had not been reports of cases of sexual transmission of HIV where the positive partner had an undetectable viral load. Critics of this position argue that this is not a reliable data source, as the data collection processes for such studies may not reliably identify all the factors involved in individual cases of HIV transmission.
- [3] Stürmer M, Doerr HW, Berger A, & Gute P (2008) Is transmission of HIV-1 in non-viraemic serodiscordant couples possible? *Antiviral Therapy*, 13(5), 729–732
- [4] Depending on the set-up of their testing procedures, some Australian laboratories measure to 40 viral copies per millilitre of plasma, while others measure to 50 viral copies per millilitre of plasma. These numbers of viral copies per millilitre are the lowest levels that currently available viral load tests can detect.
- [5] Persson A, Richards W, Barton D, & Reakes K (2009) Men and women living heterosexually with HIV: Straightpoz study, Volume 2 (Monograph 1/2009). Sydney: National Centre in HIV Social Research, The University of New South Wales, 39.
- [6] These numbers of viral copies per millilitre are the lowest levels that currently available viral load tests can detect.

Acknowledgement:

This factsheet is partly based on an article that appeared in the April–May 2009 edition of *Talkabout*, a publication of Positive Life NSW (<http://www.positivelife.org.au>). AFAO gratefully acknowledges permission from Positive Life NSW to re-use parts of the text.

IN SUMMARY

If you have decided to take the risk of not using condoms with your regular partner and to rely on an undetectable viral load, then you should certainly monitor your situation closely. Remember that an undetectable viral load only decreases the risk of passing on or getting HIV—it does not eliminate it. And remember, undetectable viral load **decreases the risk ONLY** if:

1. **You never miss a treatment dose.**
2. **Your viral load has been consistently undetectable throughout the previous six month period.**
3. **You and your partner are both certain neither of you has an STI (with or without symptoms) and that you both test for STIs regularly.**

Condoms, however, can take the stress out of all these uncertainties and are proven to be the safest way to avoid passing on or getting HIV.

Dr Darren Russell, a leading Australian sexual health specialist, has this advice for couples who don't always use condoms where the HIV-positive partner has an undetectable viral load.

It is vital that the HIV-positive partner avoids missing doses of HIV treatments and is having regular viral load tests. If some doses are missed, then condoms should be used again until undetectable viral load can be confirmed.

Where one or both partners have casual sex, the risk of getting an STI is increased, so regular sexual health checks are very important. If casual sex is frequent, then sexual health checks should be more frequent too. If one or both partners have herpes, then herpes treatment should be considered, and it is important to avoid sex or use condoms when herpes sores are present.

INFORMATION FOR HIV-NEGATIVE PARTNERS

The decision to dispense with condoms on an ongoing basis is a very serious one. It is important that both you and your partner talk openly and honestly about this, and are comfortable with all aspects of such a decision, and that you understand the increased risks involved. You may want to talk to your doctor, or your partner's doctor for more advice. Information and advice is also available from the AIDS council in your state or territory.

You need to be confident that your partner has regular viral load tests and takes his or her HIV treatments on time. You should also be able to talk openly with each other about sex with other partners. You may wish to have an agreement that you both return to condoms when anything about your situation changes or if you just feel more comfortable using condoms.

INFORMATION FOR HIV-POSITIVE PARTNERS

The decision to dispense with condoms on an ongoing basis is a very serious one. It is important that both you and your partner talk openly and honestly about this, and are comfortable with all aspects of such a decision, and that you understand the increased risks involved. You will need to maintain regular monitoring of your viral load levels, be adherent to your HIV treatments, be open and honest with your partner about sex with other partners, and be prepared to return to condoms if the need arises. You may want to talk to your doctor or to a treatments officer at the AIDS council in your state or territory.



napwa

Australian Federation of
AIDS Organisations
PO Box 51 Newtown
NSW 2042

www.afao.org.au

December 2009

WHAT IS THIS FACTSHEET ABOUT?

This factsheet addresses the relationship between HIV treatments, viral load levels, and the risk of sexual transmission of HIV. These issues have recently received a lot of attention in the HIV and community media and among people living with HIV (PLHIV) due to the publication of a statement from the Swiss Federal Commission for HIV/AIDS, which has subsequently become known as 'the Swiss Statement'.

WHO IS THIS FACTSHEET FOR?

This information is for people in serodiscordant relationships (where one person is HIV positive and the other is HIV negative).

This fact sheet may also be of interest to all PLHIV and to HIV-negative gay men, and other men who have sex with men, who want to understand more about the implications of the Swiss Statement. It is important to understand that **the Swiss Statement was explicitly developed to address the situation of people in serodiscordant monogamous relationships, not casual sexual partnerships.**

WHAT IS AFAO'S POSITION ON THE SWISS STATEMENT?

AFAO does not endorse anal or vaginal sex without condoms between people with a different HIV status. While AFAO does believe that the risk of HIV transmission is reduced when the HIV-positive person meets the criteria of the Swiss Statement, some risk of HIV transmission still remains. This factsheet has been produced because a significant number of serodiscordant couples have decided to sometimes or regularly have sex without condoms. This information is provided to help them understand the risks that remain—even when viral load is undetectable—and how to reduce those risks as much as possible.

BACKGROUND: THE SWISS STATEMENT AND CONTROVERSY

In January 2008, the Swiss Federal Commission for HIV/AIDS released a statement outlining its view that **under certain conditions** PLHIV on effective antiretroviral therapy were not sexually infectious¹. The release of this statement caused a global sensation among PLHIV, scientists and clinicians involved in HIV research and care, and those involved in HIV prevention work. **Many HIV experts disagree with the authors of the Swiss Statement about their analysis, in particular its relevance for gay men with HIV.** The statement was mainly based on a review of evidence from studies of serodiscordant heterosexual couples, and epidemiological studies².

One of the most debated questions has been whether anal sex can be included in the scope of the Swiss Statement, and thus whether the statement applies to gay men. The evidence reviewed by the authors of the Swiss Statement did not include studies that looked at the specific HIV transmission risks of anal sex.

Importantly for gay men and heterosexuals who practise anal sex, **there has recently been a case report of HIV transmission occurring in a serodiscordant gay couple, where all of the conditions of the Swiss Statement had been met**, that is, the HIV-positive man had undetectable plasma viral loads, no other sexually transmissible infections (STIs), and good adherence to antiretroviral drugs³.

Another key question concerns how the Swiss Statement should be interpreted by PLHIV who are on treatments but who *do not meet all* of the required conditions. We know that in Australia, some serodiscordant couples do not always use condoms, including in instances and at times where they do not meet all of the conditions of the Swiss Statement.

In the sections below we will explore the key issues for people who do or do not meet the conditions in the statement.

THE CONDITIONS IN THE SWISS STATEMENT

The authors of the Swiss Statement claimed that PLHIV are not sexually infectious

- the HIV-positive person must be taking antiretroviral therapies and be perfectly adherent to their treatments (i.e. take all pills at the correct dose and on time, every time);
- there should be regular monitoring of HIV viral load by the treating physician;
- HIV viral load must have been undetectable (i.e. below 40 or 50 copies/ml⁴) for at least the six previous consecutive months; and
- there must be no other sexually transmissible infections (STIs) present.

SOME LIMITATIONS IN THE SWISS STATEMENT

The Swiss Federal Commission for HIV/AIDS added a caution in its statement: viral load in blood rises rapidly just a few days or weeks after stopping antiretroviral drugs. There have been cases of HIV transmission during this period of viral rebound. As stated above, the statement also required that the HIV-positive person should have no other concurrent STIs.

Critics of the Swiss Statement have also pointed out that viral load can rise quickly or unexpectedly due to factors such as having other illness (e.g. having the flu), vaccinations, and the development of resistance to HIV drugs. STIs can also cause viral load to rise in blood and semen, and PLHIV may not be aware of the presence of an STI as many can be present without noticeable symptoms. STIs can also cause inflammation of mucosal membranes (e.g. the lining of the rectum), or broken skin (such as with a herpes outbreak). These conditions allow HIV to be transmitted more easily.

The requirement that the HIV-positive person should have no other STIs is important for PLHIV in Australia. This condition can only be met by couples in a monogamous relationship, as any couple where one or both partners have sex outside the relationship are at risk of contracting other STIs. In Australia, most PLHIV are gay men who report having both casual and regular partners. STIs can be contracted even when safe sex is practised, and the high prevalence of STIs among Australian gay men means that men having casual sex risk regular exposure to sexually transmissible infections. Herpes is another problem, even for monogamous couples, as outbreaks of herpes can recur regularly, and herpes lesions can be present before being noticed. Herpes is very common among PLHIV in Australia.

WHAT ABOUT PLHIV IN AUSTRALIA?

Some serodiscordant couples feel that the Swiss Statement provides them with added assurance that HIV transmission is unlikely to occur (e.g. in situations such as when the condom breaks), rather than providing them, with 'permission' to forego condoms and safe sex. Tom, who is HIV negative and has been in a relationship with Greg (HIV positive) for fifteen years, said:

[My] first couple of [HIV tests] were very stressful, especially the first time. But after that, it hasn't worried me much at all and I just consider it a routine check. Safe sex, using condoms, obviously does work. Greg also takes HIV treatments and his viral load is undetectable, and that gives us an added sense of security, if we needed one

Other couples had already been having sex without condoms before the release of the Swiss Statement. Some large Australian research studies of gay men's behaviour have shown that between one-quarter and one-third of serodiscordant gay couples either sometimes or regularly have anal sex without condoms.

Another study of HIV-positive heterosexuals in Australia collected many accounts of couples who were no longer using condoms when the positive partner was on treatments and had an undetectable viral load⁵.

ADVICE FROM LOCAL SEXUAL HEALTH EXPERTS

Dr Robert Finlayson is a Sydney-based HIV and sexual health expert with over twenty years experience says:

It's been known for years that HIV infectiousness is related to HIV viral load, so that a person with a high viral load will be more infectious when having unprotected sex than someone with a low or 'undetectable' viral load.

'Undetectable' viral load means there are less than 40 or 50 copies/ml of HIV⁶ in the plasma [the fluid part of blood], but the virus may still be in some blood cells, and even more often still, be in semen [cum] and rectal mucous. This is why there could still be some risk when you have unprotected sex with someone whose viral load is 'undetectable'.

The risk of transmitting HIV is much greater if there is any inflammation in the genitals, the presence of a sexually transmissible infection or trauma. Also, someone may have been 'undetectable' at their last test but not have taken their pills 100% of the time since, so their viral load might be higher than it was when they were tested. Safer sex is still recommended even if your partner is 'undetectable'.