

"UNDETECTABLE MEANS UNTRANSMITTABLE" (U=U): WHAT JUDGES NEED TO KNOW

INTRODUCTION

Since the discovery of the human immunodeficiency virus (HIV) and the identification of its transmission pathways, countries around the world began amending their legislation, seeking to use criminal law as a tool to curb the spread of the epidemic. However, substantial evidence now shows that this approach is ineffective, yet the criminalization of HIV transmission and exposure remains highly prevalent globally.

The Eastern Europe and Central Asia (EECA) region is no exception. In fact, the region leads in the prevalence of criminal laws penalizing HIV and in the prosecution of people living with HIV. Virtually all EECA countries have specific provisions in their criminal codes addressing HIV transmission and exposure. While in most countries the number of cases under these provisions is either negligible or nonexistent, some actively enforce these laws, with the number of convictions reaching dozens, if not hundreds.¹ The vast majority of these convictions are for "exposure to the risk of HIV infection," where no actual transmission has occurred. Moreover, due to the way these laws are formulated, convictions are often handed down even in cases where the "victim" has no complaints against the accused, and where the accused had no intent to infect the other person.² The situation is further complicated by the fact that the law fails to account for critical factors such as the actual degree of risk involved.

EVIDENCE GENERATION

It was observed as early as the late 1990s that antiretroviral therapy (ART) reduces the risk of HIV transmission. In 1998, results from a study conducted among HIV-positive pregnant women indicated that using triple ART reduced the risk of transmission to nearly zero, compared to a 30% risk before treatment.³ A landmark study that first established a clear connection between viral load (the amount of virus in the blood) and the risk of HIV transmission was conducted in Uganda in 2000. This 30-month study involved 415 serodiscordant⁴ heterosexual couples. Among the 415 HIV-positive partners, 51 had a viral load of fewer than 1,500 copies/ml. During the observation period, HIV transmission was recorded in 90 of the 415 couples. However, among the 51 couples where the HIV-positive partner had a viral load below 1,500 copies/ml, not a single case of transmission occurred. It lasted 30 months involving 415 serodiscordant⁴ heterosexual couples. Of the 415 partners living with HIV, 51 had a viral load of less than 1500 copies/ml. During the follow-up period, HIV transmission was documented in 90 couples out of 415. But there were no cases among those 51 couples where the partner living with HIV had a viral load of less than 1500 copies/ml.

¹ Since case statistics are not published in the countries of the region, accurate data on the number of criminal cases and sentences in this category of cases are not publicly available.

² Five countries in the region (Belarus, Kazakhstan, Kyrgyzstan, Moldova and Russia) have amended their criminal code articles on HIV to exempt HIV-positive people from liability if the "victim" was informed in advance of the person's HIV-positive status and voluntarily consented to the actions associated with the risk of infection.

³ Beckerman K et al. Control of maternal HIV-1 disease during pregnancy. Int Conf AIDS 1998 Jun 28-Jul 3; 12:41. Poster abstract 459, <https://i-base.info/ttfa/wp-content/uploads/2012/05/Beckerman-Abs459-IAS-geneva-1998.pdf>.

⁴ A serodiscordant couple is a couple where one partner is HIV-positive and the other is HIV-negative

In the following years, an impressive number of papers have accumulated that somehow link viral load to the frequency of HIV transmission. And in 2008, the Swiss National AIDS Commission issued the first public document, later called the Swiss Statement, which asserted that HIV-positive people with no other sexually transmitted diseases who are adherent to antiretroviral therapy do not sexually transmit HIV⁵. The Swiss statement was initially criticized, but subsequent large-scale studies have confirmed its validity. The findings of the Swiss Statement would later be supported by all reputable medical organizations, including the World Health Organization, the US Centers for Disease Control and Prevention (CDC) and many others.

Since the Swiss Statement was issued, a number of other seminal studies have been conducted. In particular, the HPTN-052 study (2011), which covered 9 countries with more than 1700 serodiscordant couples, identified 17 cases of HIV transmission, all 17 among HIV-positive people with detectable viral loads. Another study, PARTNER-1 (2014), also reported no HIV transmission from 58,000 unprotected sexual contacts from HIV-positive people with a viral load of less than 200 copies/mL.

THE N=N CAMPAIGN AND ITS SIGNIFICANCE IN THE CONTEXT OF HIV CRIMINALISATION

Accumulating clinical evidence led to the concept of "Undetectable means non-transmissible", or N=N, being formulated in 2016 and then validated scientifically. N=N means that people with HIV *cannot sexually transmit the virus to* others if, through daily⁶ intake of effective antiretroviral therapy (ART), they have achieved and maintained an *undetectable* viral load (i.e., an amount of virus in the blood that is too low to be detected by World Health Organization-approved diagnostic tests). The concept of H=H is of particular importance to people living with HIV, including in the context of criminalization of endangerment HIV infection. However, despite the consolidation of partners' efforts around the H=H campaign, there was no normative guidance on the issue.

A relative breakthrough was the 2018 Expert Consensus Statement on the Scientific Evidence on HIV in the Criminal Law Context⁷. This document was designed to ensure that existing scientific knowledge is correctly and fully understood by professionals involved in HIV-related cases and officials working in the criminal justice system.

⁵ Vernazza P et al. *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), 30 January 2008.

https://i-base.info/qa/wp-content/uploads/2008/02/Swiss-Commission-statement_May-2008_translation-EN.pdf

⁶ Effective treatment regimens using prolonged-acting injectables that do not require daily administration are now available.

⁷ F. Barré-Sinoussi et al, Expert Consensus Statement on the Scientific Evidence on HIV Infection in the Criminal Law Context. 2018 r., https://onlinelibrary.wiley.com/action/downloadSupplement?doi=10.1002%2Fjia2.25161&file=jia225161-sup-0004-Sup_MaterialS4.pdf

Despite its importance, the Expert Consensus Statement did not solve the main problem: it could not fully compensate for the lack of a normative document on this issue. There was no separate WHO document on the degree of risk of HIV transmission, and WHO experts referred to data from other organizations, such as the US Centers for Disease Control, and studies.⁸ This gap was noted by participants at several meetings of the Eastern Europe and Central Asia Judges Forum on HIV, Human Rights and the Law; they recommended that WHO develop a document that clearly states that there is no risk of HIV transmission among people living with HIV, taking ART and having an undetectable viral load. The United Nations Development Programme (UNDP), as the secretariat of the Forum, discussed the possibility of developing such a document with the WHO Regional Office for Europe.

Nevertheless, already in 2017 (i.e. even before the publication of the Statement of Expert Consensus), the Republican Public Association "People PLUS" (Belarus) appealed to the WHO Country Office in Belarus with a request for an opinion on the case of putting at risk of HIV infection. The official response of WHO, together with other evidence, allowed the court to give the most lenient sentence possible. In the future, People PLUS has repeatedly asked WHO for clarification, and the organization's responses have helped HIV-positive people receive minimal sentences and, in some cases, acquittals.⁹

After many years of work, in July 2023 WHO published a policy brief¹⁰, providing updated data, conclusions and recommendations. The document contains key messages that are of key importance to people living with HIV.

The document distinguishes between three main categories of HIV viral load measurement:

- lack of suppression (>1000 copies/ml),
- suppression (viral load is detectable but ≤1000 copies/ml)
- undetectable viral load (the test used did not detect a viral load).

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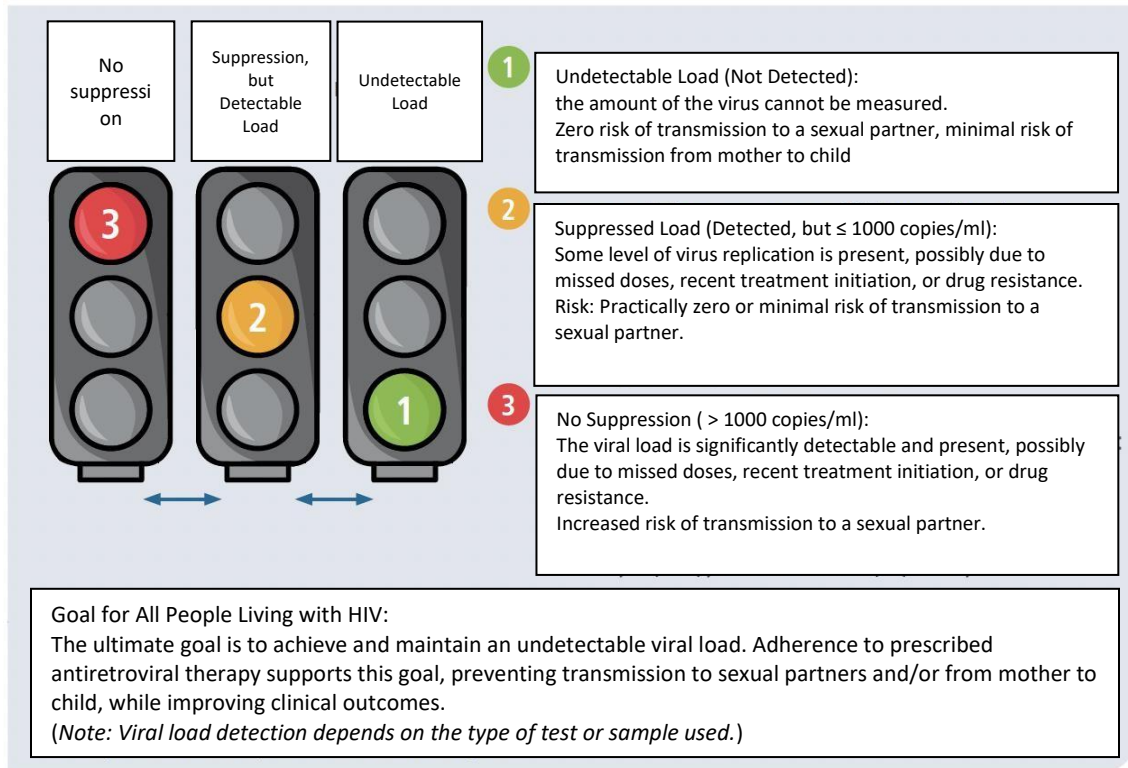
In doing so, two important conclusions are contained:

- People living with HIV who have an undetectable viral load and continue taking medication as prescribed **have a zero risk of transmitting HIV** to their sexual partner(s).
- People living with HIV who have a suppressed but detectable viral load and are taking medication as prescribed **have little or no risk of transmitting HIV** to their sexual partner(s).

⁸ See, e.g., Report of the Third Meeting of the Eastern European and Central Asian Judges Forum on HIV, Human Rights and the Law (p. 5), 11-12 November 2021, https://www.forum-sudey.org/wp-content/uploads/2021/12/Report_3rd-EECA-regional-judges-forum_RUS_FINAL.pdf.

⁹ Data from ROO "People PLUS".

¹⁰ WHO, *The role of HIV viral suppression in improving human health and reducing the risk of transmission. Policy brief*. 2023, <https://apps.who.int/iris/bitstream/handle/10665/372690/9789240077409-rus.pdf>.



It should be noted that the viral load measurement categories used in this document have one important limitation: tests are now available and in use whose sensitivity can detect even minimal concentrations of virus in the blood, i.e. a viral load that is not detectable by one test may be detectable by another test - provided both tests are reclassified, i.e. approved, by WHO. In this regard, the document lacks a viral load threshold below which viral load should be considered "undetectable". Based on the studies referenced in the document, such a threshold is a viral load below **200 copies per ml of blood**.

CONCLUSIONS AND RECOMMENDATIONS

WHO has explicitly confirmed that an undetectable viral load excludes the possibility of sexual transmission of HIV. Courts should also take note of the WHO's conclusion that "viral loads of less than 1000 copies/ml do not indicate an obvious link to sexual transmission of HIV". In this regard, viral suppression should be considered as a circumstance that eliminates the risk of HIV transmission, which, in conjunction with other circumstances (such as taking ART or using a condom), should mean that a conviction should be inadmissible.

In this regard, we call on judges not to convict people with viral suppression and undetectable viral loads in cases of HIV exposure. In doing so, we are convinced that States should move away from criminalizing HIV exposure altogether and remove HIV-specific articles from criminal codes and, where necessary, apply general articles on health harms.