

# Role of viral suppression in HIV treatment and prevention and its potential in addressing harmful laws and discrimination

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## ABSTRACT

The World Health Organization's (WHO) global public health mandate includes a focus on expanding access to HIV testing, antiretroviral therapy (ART) and treatment monitoring to improve the clinical management of HIV, achieve sustained viral suppression, and prevent HIV-related incidence, morbidity, and mortality. This article documents key moments in research and WHO policies that have informed how ART is applied within HIV programs, including as a prevention tool with the potential to support efforts to address HIV-related discrimination. For more than 20 years, WHO has promoted the benefits of HIV treatment including as part of the approach to prevent the mother-to-child transmission (vertical transmission) of HIV. WHO guidance has followed, and continues to follow, the evolving evidence. In 2023, WHO continues to clarify that there is zero risk of sexual HIV transmission when a person living with HIV has an undetectable viral load and an almost zero or negligible risk of sexual transmission when a person living with HIV has a viral load of  $\leq 1000$  copies/mL – helping to evolve the focus of community campaigns and health worker training to include a focus on 'virally suppressed' while also continuing to emphasise the ultimate goal of achieving an undetectable viral load. This evolution does two things: first, it strongly reasserts the evidence around there being no chance of transmission if a person has an undetectable viral load; and second, it provides an extremely strong degree of confidence that, similarly, individuals who are virally suppressed will not pass on the virus sexually. WHO is now encouraging positive and clear messaging to highlight that the consistent use of ART prevents onwards HIV transmission.

**Keywords:** community interventions, HIV prevention, HIV/AIDS, human rights, legislation, patients' views, policy, public health, stigma and discrimination, viral suppression.

## Science and communities

Connecting people and science to give everyone an equal chance of a safe and healthy life drives the World Health Organization's (WHO) work across the world.<sup>1</sup>

WHO's global public health mandate includes a focus on expanding access to HIV testing, optimal antiretroviral therapy (ART) and viral load monitoring to improve the clinical management of HIV, achieve sustained viral load suppression, and prevent HIV-related incidence, morbidity, and mortality.

The global HIV response has particularly benefited from the connection between science and people, most specifically communities of people living with and affected by HIV, to drive the innovations required to respond to a global emergency that has so far killed more than 40 million people.<sup>2</sup> And the interface between science and affected communities was, and continues to be, a critical force behind the development and evolution of HIV treatment options.

Since the first clinical trials of individual antiretrovirals in 1985, affected communities rapidly understood the benefits, limitations and unintended consequences of treatment and have advocated for new science, participated in research studies and clinical trials, and have frequently become scientists themselves.

In 1995, the success of ‘highly active antiretroviral treatment’ (HAART) – a combination of three antiretroviral drugs (ARVs), was found to reduce AIDS-related deaths by between 60% and 80%. Since then, WHO has worked with scientists, civil society organisations and communities to continuously improve the quality, acceptability, and accessibility of treatment.<sup>3</sup> And, as discussed here, WHO’s close collaboration with civil society organisations and affected communities, including through the WHO advisory group of women living with HIV<sup>4</sup> and the Global Network of People living with HIV (GNP+), which is in official relations with WHO, has helped broaden the application of treatment beyond lifesaving and life-enhancing therapeutic use, for use in both HIV prevention and stigma-reduction efforts.

## Treatment, viral suppression, and prevention

For more than 20 years WHO has understood and promoted the benefits of HIV treatment as part of the approach to prevent mother-to-child transmission (vertical transmission) of HIV and developed various guidelines and strategies to support this work.<sup>5</sup>

In 2000, researchers examined the influence of viral load in relation to other risk factors for the heterosexual transmission of HIV-1 in a community-based study of 15 127 persons in the Rakai rural district of Uganda. The study followed serodiscordant couples for 30 months and found no cases of sexual transmission involving the 51 people with viral suppression at lower than 1500 copies per millilitre.<sup>6</sup>

Boosted by increasing evidence, in 2001, the United Nations General Assembly set a target for 80% of pregnant women and their children to have access to essential prevention, treatment and care by 2010 to reduce the proportion of infants infected by HIV by 50%.<sup>7</sup>

And as the science and evidence around the community-wide benefits of treatment on reduced incidence and mortality became increasingly clear,<sup>8</sup> WHO not only looked to expand its vertical transmission focus geographically and to include a focus on syphilis<sup>9</sup> (and later hepatitis B) as part of triple elimination of mother-to-child transmission,<sup>10</sup> it also started to explore the impact of treatment as a prevention tool in the context of other modes of transmission.

In 2008, the Swiss National AIDS Commission issued a landmark statement noting that people on effective ART would not sexually transmit HIV to their partners. The statement was issued at the time of a global increase in criminal cases against people living with HIV for having sex with HIV-negative partners regardless of any subsequent transmission and was highly controversial at the time.<sup>11</sup>

Four years later, the groundbreaking clinical trial set up to study HIV transmission among partners (HPTN 052)<sup>12</sup> noted that the early initiation of antiretroviral therapy led to a 96% reduction in sexual transmission of HIV between

serodiscordant partners, indicating both personal and public health benefits from immediate ART for all, at a time when global guidance was to initiate ART for those with CD4 350 cells/ $\mu$ L, for preventing HIV transmission.<sup>12</sup> WHO responded quickly to the study’s findings in working with a range of partners, including community stakeholders, in developing new guidelines to issue the following recommendation in 2012:

People with HIV in serodiscordant relationships and who are started on antiretroviral therapy (ART) for their own health should be advised that ART is also recommended to reduce HIV transmission to the uninfected partner. (WHO 2012)

The guidance<sup>13</sup> also clearly noted that initiating treatment at any CD4 level was recommended to reduce HIV transmission to partners who were not living with HIV. The language of reduce, rather than prevent, reflected the data available at the time. Further evidence from the PARTNER<sup>14</sup> and Opposites Attract<sup>15</sup> studies led to WHO guidance emphasising both the prevention and treatment benefits of antiretrovirals, including through the announcement of its ‘treat all’ policy.<sup>16</sup>

## Politics, policies, and advocacy

Health policies developed for HIV and sexually transmitted infections, as with most policies related to sex, sexual and reproductive health and marginalised groups, benefit from referencing lived experience and community-led research and data that highlight significant issues as an important pillar of broader public health research.<sup>17</sup> These data sources should be further promoted as critical contributions to the broader evidence base to ensure further investment, political support, and the engagement of stakeholders for their optimal application and impact.<sup>18</sup> Increased understanding of the role of viral suppression and the prevention benefits of treatment, especially among policymakers, affected communities and health workers, may support increased testing uptake and treatment adherence and have a role in addressing stigma and ongoing community-led research is exploring these themes. Similarly, communities remind us that there may be important opportunities to strengthen science-driven advocacy against unfair criminal prosecutions targeting non-disclosure, exposure or transmission of HIV, including in instances when no harm was intended, HIV transmission did not occur, and HIV transmission was extremely unlikely or not possible.<sup>19</sup>

In recognition of the need for political and stakeholder support, several communities of people living with HIV, under the leadership of the Prevention Access Campaign, launched what *The Lancet HIV* described as the ‘simple but hugely important’ U=U campaign.<sup>20</sup> The history and

evolution of the campaign is well documented<sup>21</sup> and includes several references to the work of WHO and other partners.

In 2018, as a contribution to the policy dialogue generated by the campaign, WHO used stronger, unambiguous language to support that individuals who have successfully achieved and maintained viral suppression through ART do not transmit HIV to their HIV-negative partner(s).<sup>22</sup> The statement also noted that HIV transmission was still occurring in areas with high ART coverage – requiring further prioritisation of HIV testing, ART and treatment monitoring, and primary combination HIV prevention.

And in 2020, the WHO Regional Office for South-East Asia, with UNAIDS and the Ministry of Public Health of Thailand, noted the additional value of promoting U=U messaging in combatting stigma and discrimination in the health sector.<sup>23</sup>

## Engaging member states

While WHO has continued to promote the science and impact of treatment as a prevention tool in various science-informed guidelines<sup>24</sup> and statements,<sup>25</sup> in recent years it has also supported several negotiations among the Member States of different United Nations bodies on the subject. These spaces bring political and cultural considerations and discourse into discussions that sometimes highlight considerable and ongoing challenges and resistance to science and public health.

During extensive negotiations in advance of the 2021 United Nations General Assembly High Level Meeting on HIV and AIDS,<sup>26</sup> WHO engaged in several briefings with Member States, some of whom had questioned the science behind the use of treatment to prevent the onward sexual transmission of HIV. The final text of the Political Declaration<sup>27</sup> is endorsed by the 165 Member States that voted in its favour<sup>A</sup> and represents a significant tool in support of implementation and accountability.

[Member States] welcome the recent scientific evidence related to the preventative benefits of antiretroviral drug therapy, demonstrating no evidence of sexual transmission of HIV within adult couples when the HIV-positive partner is on effective and sustained treatment, with undetectable viral loads, confirmed by routine testing at intervals as recommended by the World Health Organization and reflected in its updated 2021 guidelines, which is known as “Undetectable = Untransmittable (U=U)”, also recognising the continued need for further research processes. (Paragraph 39. United Nations General Assembly 75th Session, Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030)

At the same time, throughout 2021, WHO led a consultation process to develop global health sector strategies on HIV, viral hepatitis, and sexually transmitted infections for 2022–2030,<sup>28</sup> which include an action to ensure ART roll out, treatment monitoring and retention in care to achieve undetectable viral loads to prevent onward sexual transmission. Although some Member States requested clarification on the proposed action during negotiations, during the final deliberations, the action received full support and the Assembly passed a supportive resolution.<sup>29</sup>

The 2021 Political Declaration and the 2022 World Health Assembly Resolution offer insights into the political context and provide important accountability opportunities for advancing ART as a tool for treatment, prevention, and addressing discrimination – particularly in 2026, when 2025 targets of both instruments will be reviewed by Member States.

## Expanding efforts to challenge harmful laws and address discrimination in health settings

In recent years, WHO has been challenged to develop clearer materials and guidance in support of scaling-up treatment as an effective tool for both prevention and the reduction of stigma and discrimination.

Treatment literacy and adherence campaigns, including the ‘Flip the Script’ initiative,<sup>30</sup> have noted the importance of a strengthened role for WHO; in response, the Department of Global HIV, viral hepatitis, and sexually transmitted infections programs have convened a workstream across the organisation to address stigma and discrimination in the health sector, including through a focus on pre- and in-service training for health workers. This is particularly important given that knowledge about the prevention benefits of treatment is often disappointingly low among clinicians.<sup>31</sup> In December 2022, WHO also committed, through the UNAIDS Programme Coordinating Board, to organise consultations towards harmonising the key definitions that underpin this work.

Building on earlier consultations, in 2023 WHO continued to clarify that there is zero risk of sexual HIV transmission when a person living with HIV has an undetectable viral load and an almost zero or negligible risk of sexual transmission when a person living with HIV has a viral load of 1000 copies/mL or lower – helping to evolve the focus of community campaigns and health worker training towards more positive, consistent, and clear celebratory messaging for all people with an undetectable or suppressed viral load. This work has been supported by a systematic review of the evidence around the sexual transmission of HIV at lower

<sup>A</sup>Although four Member States voted against the instrument (Russian Federation, Belarus, Nicaragua, and the Syrian Arab Republic), the concerns they expressed during negotiations extended beyond questions about the role of antiretroviral therapy in prevention efforts.

levels of HIV viraemia,<sup>32</sup> which is supported by an updated policy brief.<sup>33</sup>

This evolution does two things: first, it strongly reasserts the evidence around there being no chance of transmission if a person has an undetectable viral load; and second, it provides an extremely strong degree of confidence that individuals who are virally suppressed (detected but  $\leq 1000$  copies/mL) will similarly not pass on the virus sexually. Expanded and simplified, yet appropriately nuanced, communication is required to promote the value of viral suppression. There are three key stages for HIV viral load measurements: unsuppressed ( $>1000$  copies/mL), suppressed (detected but  $\leq 1000$  copies/mL) and undetectable (viral load not detected by the test used). Given there is no robust evidence of sexual transmission when a person living with HIV has a viral load of  $\leq 1000$  copies/mL, people taking a preferred WHO-recommended antiretroviral therapy who are suppressed (detectable but  $\leq 1000$  copies/mL) can be advised that, as long as they take their medication as prescribed, there is almost zero risk of them transmitting HIV to their sexual partner(s). Everyone living with HIV should have access to viral load testing; however, even when this is not the case, viral load testing should not be seen as a barrier to positive messaging about the preventive benefits of treatment, particularly when people living with HIV are taking their medication as prescribed.

It is critical that information highlighting that *the consistent use of ART prevents onwards HIV transmission* is shared by healthcare workers with people living with HIV and disseminated in communities everywhere.

## Conclusion

Moving forward, civil society organisations focused on HIV and informed communities of people living with HIV will continue to embrace and promote the science around HIV and the power and potential of ART.<sup>34</sup> This work should rightfully challenge any notion that the clinical and treatment components of the HIV response operate independently of the social and structural components – they intersect deeply.

Greater investment in HIV therapy also directly supports efforts to strengthen primary prevention and efforts to reduce discrimination. Sharing the science behind the role of viral suppression in preventing HIV can help change harmful laws and policies, including those that seek to criminalise exposure to HIV or HIV transmission.

We must focus on leveraging the interdependencies built in to the 10 result areas of the multisectoral Global AIDS Strategy 2021–2026<sup>35</sup> and increasingly recognise the 95–95–95 targets<sup>B</sup> as a core goal that helps unite all aspects of the response to HIV, including all efforts focused on inequalities and the broader enabling environment, community engagement, prevention, testing and treatment, and care.

Ending AIDS requires broad understanding and recognition that achieving a suppressed viral load through ART is essential for both personal and public health.

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