

RISK OF SEXUAL TRANSMISSION OF HIV FROM A PERSON LIVING WITH HIV WHO HAS AN UNDETECTABLE VIRAL LOAD Messaging Primer & Consensus Statement

Editor's Note 1/10/18: The term "negligible" is not effective in public health messaging to describe the risk of HIV sexual transmission when a person with HIV has an undetectable viral load and is taking ART as prescribed. "Negligible" is often misconstrued as still a risk to take into consideration in sexual and reproductive health decisions. Please see the <u>messaging guide</u> with examples of the words used in public health messaging to convey the risk including "no risk", "zero risk," "cannot transmit," and "do not transmit." It is imperative that language instills confidence and avoids promoting unnecessary fear about sexual transmission when a person with HIV has an undetectable viral load and is taking ART as prescribed. We recommend using the language referenced in the guide and not in this Consensus Statement which was an important and early advocacy tool in the U=U campaign but is no longer the most up to date language for use in public health communications.

There is now evidence-based confirmation that the risk of HIV transmission from a person living with HIV (PLHIV), who is on Antiretroviral Therapy (ART) and has achieved an undetectable viral load in their blood for at least 6 months is negligible to non-existent. (Negligible is defined as: *so small or unimportant as to be not worth considering; insignificant.*) While HIV is not always transmitted even with a detectable viral load, when the partner with HIV has an undetectable viral load this both protects their own health and prevents new HIV infections.[i]

However, the majority of PLHIV, medical providers and those potentially at risk of acquiring HIV are not aware of the extent to which successful treatment prevents HIV transmission.[ii] Much of the messaging about HIV transmission risk is based on outdated research and is influenced by agency or funding restraints and politics which perpetuate sex-negativity, HIV-related stigma and discrimination.

The consensus statement below, addressing HIV transmission risk from PLHIV who have an undetectable viral load, is endorsed by principal investigators from each of the leading studies that examined this issue. It is important that PLHIV, their intimate partners and their healthcare providers have accurate information about risks of sexual transmission of HIV from those successfully on ART.

At the same time, it is important to recognize that many PLHIV may not be in a position to reach an undetectable status because of factors limiting treatment access (e.g., inadequate health systems, poverty, racism, denial, stigma, discrimination, and criminalization), pre-existing ART treatment resulting in resistance or ART toxicities. Some may choose not to be treated or may not be ready to start treatment.



Understanding that successful ART prevents transmission can help reduce HIVrelated stigma and encourage PLHIV to initiate and adhere to a successful treatment regimen.

The following statement has been endorsed by:

- <u>Dr. Michael Brady</u> Medical Director of Terrence Higgins Trust and Consultant HIV Physician, London, UK
- <u>Dr. Myron Cohen</u> Principal Investigator, HPTN 052; Chief, Division of Infectious Diseases, UNC School of Medicine, North Carolina, USA
- <u>Dr. Demetre C. Daskalakis, MPH</u> Assistant Commissioner, Bureau of HIV/AIDS Prevention and Control New York City Department of Health and Mental Hygiene, New York, USA
- <u>Dr. Andrew Grulich</u> Principal Investigator, Opposites Attract; Head of HIV Epidemiology and Prevention Program, Kirby Institute, University of New South Wales, Australia
- <u>Dr. Jens Lundgren</u> Co-principal Investigator, PARTNER; Professor, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Denmark
- <u>Dr. Mona Loutfy, MPH</u> Lead author on Canadian consensus statement on HIV and its transmission in the context of the criminal law; Associate Professor, Division of Infectious Diseases, Women's College Hospital, University of Toronto, Toronto, ON, Canada
- <u>Dr. Julio Montaner</u> Director of the British Columbia Centre for Excellence in HIV/AIDS; Director of IDC and Physician Program Director for HIV/AIDS PHC, Vancouver BC, Canada
- <u>Dr. Pietro Vernazza</u> Executive Committee, PARTNER; Author, Swiss Statement 2008, Update 2016; Chief of the Infectious Disease Division, Cantonal Hospital in St. Gallen, Switzerland

The following statement has also been endorsed by over <u>1,045 organizations from</u> <u>102 countries</u> including:

- <u>ACT AIDS Committee of Toronto</u> Canada
- African and Black Diaspora Global Network on HIV/AIDS ABDGN Canada
- <u>AIDES</u> France
- AIDS ACTION NOW Canada
- <u>AIDS Alabama</u> United States
- <u>AIDS Foundation of Chicago</u> United States
- <u>AIDS United</u> United States
- <u>AIDS.center</u> Russia
- <u>All-Ukrainian Network of PLWH</u> Ukraine



- <u>APLA Health</u> United States
- AIDS Solidarity Movement Cyprus
- <u>Apoyo Positivo</u> Spain
- Australian Federation of AIDS Organizations Australia
- <u>Being Positive Foundation</u> India
- <u>Black AIDS Institute</u> United States
- <u>Blue Diamond Society</u> Nepal
- <u>Brazilian Network of People Living with HIV (RNP Brazil)</u> Brazil
- British Columbia Centre for Excellence in HIV/AIDS Canada
- <u>British HIV Association</u> United Kingdom
- <u>California Department of Public Health</u> USA
- Canadian AIDS Society Canada
- Canadian HIV/AIDS Legal Network Canada
- <u>Canadian Positive People Network</u> Canada
- CATIE Canadian AIDS Treatment Information Exchange Canada
- <u>Chicago Department of Health</u> United States
- Czech AIDS Help Society Czech Republic
- Desmond Tutu HIV Foundation South Africa
- <u>District of Columbia Department of Health</u> United States
- Equitas Health United States
- <u>Elton John AIDS Foundation</u> United States
- Getting to Zero United States
- <u>GMHC</u> United States
- <u>HIV Medicine Association</u> United States
- <u>Housing Works</u> United States
- <u>Human Rights Campaign</u> United States
- ICASO International Council of AIDS Service Organizations Canada
- INA Māori, Indigenous & South Pacific HIV/AIDS Foundation New Zealand
- International AIDS Society Switzerland
- International Association of Providers of AIDS Care -United States
- International Committee for the Rights of Sex Workers in Europe Amsterdam
- International Community of Women Living with HIV Kenya
- Latino Commission on AIDS United States
- League PLWHA from Moldova Moldova
- <u>LILA Italy</u>
- Love without Borders Foundation China
- <u>Michigan Department of Health & Human Services United States</u>
- <u>Minnesota Department of Health</u> United States
- <u>MSMGF (the Global Forum on MSM & HIV)</u> United States
- <u>NAM aidsmap</u> United Kingdom
- <u>National AIDS Trust</u> United Kingdom
- <u>National Alliance of State and Territorial AIDS Directors (NASTAD)</u> United States
- <u>National Black Justice Coalition</u> United States
- <u>New York City Department of Health and Mental Hygiene</u> United States
- <u>New York State Department of Health</u> United States
- <u>Positive People Armenian Network</u> Armenia
- <u>Positive Women's Network USA</u> United States
- <u>San Francisco AIDS Foundation</u> United States
- <u>Sensoa</u> Belgium
- <u>Sidaction</u> France
- Southern AIDS Coalition United States



- St. Petersburg City AIDS Center Russia
- <u>Terrence Higgins Trust</u> United Kingdom
- <u>Vietnam Network of People living with HIV (VNP+)</u> Vietnam
- <u>The Well Project</u> United States
- <u>Whitman-Walker Health</u> United States
- YouthCO HIV & Hep C Society Canada

(The full list and locations of organizational endorsements are here.)

People living with HIV on ART with an undetectable viral load in their blood have a negligible risk of sexual transmission of HIV. Depending on the drugs employed it may take as long as six months for the viral load to become undetectable. Continued and reliable HIV suppression requires selection of appropriate agents and excellent adherence to treatment. HIV viral suppression should be monitored to assure both personal health and public health benefits.

NOTE: An undetectable HIV viral load only prevents HIV transmission to sexual partners. Condoms also help prevent HIV transmission as well as other STIs and pregnancy. The choice of HIV prevention method may be different depending upon a person's sexual practices, circumstances and relationships. For instance, if someone is having sex with multiple partners or in a nonmonogamous relationship, they might consider using condoms to prevent other STIs.

"NEGLIGIBLE" = so small or unimportant as to be not worth considering; insignificant.

To sign-on as a Community Partner and endorse the Consensus Statement please visit <u>Community Partners.</u>

ADDITIONAL EXPERT QUOTES, SOURCES, AND EXPLANATIONS [iii]

1. "I just want to pay tribute to the U=U campaign, it has been astonishing. I think the time for excuses are over. I think it is very, very clear that the risk is zero. I very much think we have to promote this... if you are on suppressive ART you are sexually noninfectious and the time for excuses is over." -Dr. Alison Rodger, lead author of PARTNER2 at the International AIDS Conference - AIDS 2018 presentation (July, 2018)

2. "When ART results in viral suppression, defined as less than 200 copies/ml or undetectable levels, it prevents sexual HIV transmission. Across three different studies, including thousands of couples and many thousand acts of sex without a



condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIVnegative partner were observed when the HIV-positive person was virally suppressed. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner." U.S. Centers for Disease Control & Prevention (CDC), <u>Dear Colleague Letter</u> (September, 2017)

3. "The science really does verify and validate U=U." Anthony S. Fauci, M.D., Director, NIAID, NIH, <u>Speech at the United States Conference on AIDS</u> (September, 2017)

4. "Last month, the global medical and scientific community at the forefront of HIV research and care came together in Paris for the ninth International AIDS Society Conference, where they announced – unequivocally – that an undetectable HIV viral load means HIV is untransmittable." Dr. Julio Montaner, UBC-Killam Professor of Medicine; UBC-St. Paul's Hospital Foundation chair in AIDS Research, <u>Editorial</u> (August, 2017)

5. "In addition to the positive impact upon the health of people living with HIV, there is increasing consensus among scientists that people with undetectable HIV in their blood do not transmit HIV sexually. This knowledge can be empowering for people living with HIV. The awareness that they are no longer transmitting HIV sexually can provide people living with HIV with a stronger sense of being agents of prevention in their approach to new or existing relationships." <u>UNAIDS Explainer</u> (July, 2017)

6. "If you diligently take your medicine and keep your viral load to below detectable levels, you will not be dangerous to your partner. We now have the scientific data to say you may be "infected" but you are not "infectious". That goes a long way toward eliminating the stigma associated with HIV." Anthony S. Fauci, M.D., Director, NIAID, <u>NIH Video interview</u> (July, 2017)

7. "Scientists never like to use the word 'Never' of a possible risk. But I think in this case we can say that the risk of transmission from an HIV-positive person who takes treatment and has an undetectable viral load may be so low as to be unmeasurable, and that's equivalent to saying they are uninfectious. It's an unusual situation when the overwhelming evidence base in science allows us to be confident that what we are saying is fact." Anthony S. Fauci, M.D., Director, NIAID, NIH <u>NAM aidsmap</u> (July, 2017)

8. "People who take their ART effectively and in whom the virus is suppressed to undetectable levels are no longer infectious. A massive public health and social justice response has led to unprecedented scale up of this miraculous treatment." <u>UNAIDS Science</u> <u>Report, Issue #6</u> (July, 2017)



9. "As the UK's leading voice for HIV health professionals, our backing for U=U is unequivocal. There should be no doubt about the clear and simple message that a person with sustained, undetectable levels of HIV virus in their blood cannot transmit HIV to their sexual partners. This fact is a testament to the preventive impact of effective HIV treatment and highlights the need to maximise access to treatment in order to minimise and ultimately eradicate HIV transmission. Spreading the U=U message is also an important way to help reduce the stigma experienced by people living with HIV, whose sexual partners may fear infection unnecessarily." British HIV Association Chair, Professor Chloe Orkin, statement from <u>BHIVA</u> (July, 2017)

10. "This is a landmark development in the response to HIV and too many people are not hearing this message and receiving its full benefit. A person living with HIV with a sustained suppressed viral load poses no risk of transmitting HIV. This development puts each one of us living with HIV at the forefront of stopping new infections, and gives everyone strong, clear and direct language to stop the stigma and move all communities faster towards ending the epidemic." Jesse Milan, Jr., President & CEO, statement from <u>AIDS United</u> (March, 2017)

11. "Research demonstrating that people living with HIV who are virally suppressed cannot transmit HIV to others is one of the most important developments in HIV prevention in the last decade. It is now more important than ever that we ensure universal access to antiretroviral therapy and educate our communities about the public health benefits of effective HIV treatment." Craig E. Thompson, Chief Executive Officer, statement from <u>APLA Health</u> (March, 2017)

12. "Desmond Tutu HIV Foundation strongly endorses the Prevention Access Campaign core message: Undetectable HIV is Untransmittable HIV (U=U). An HIV-positive person who maintains an undetectable viral load with the aid of regular, successful treatment cannot transmit HIV sexually. This knowledge has the potential to alter negative perceptions around the disease, yet the message still hasn't reached everyone." Statement from <u>Desmond Tutu HIV Foundation</u> (March, 2017)

13. "NAM aidsmap, one of the foremost sources of HIV information in the world, strongly endorses the 'Undetectable Equals Untransmittable' (U=U) Consensus Statement issued by the Prevention Access Campaign. The scientific evidence is clear. Someone who has undetectable levels of virus in their blood does not pose an infection risk to their sexual partners. This understanding transforms the way that HIV is considered with enormous implications for what it now means to live with HIV and the best ways to prevent it." Statement from <u>NAM aidsmap</u> (February, 2017)



14. "NASTAD joins public health experts and leaders in affirming that there is now conclusive scientific evidence that a person living with HIV who is on antiretroviral therapy (ART) and is durably virally suppressed (defined as having a consistent viral load of less than <200 copies/ml) does not sexually transmit HIV." Statement from <u>NASTAD</u> (February, 2017)

15. "All of us here at CATIE, and indeed around the world, are celebrating the most significant development in the HIV world since the advent of effective combination therapy 20 years ago – people living with HIV with sustained undetectable viral loads can confidently declare to their sexual partners "I'm not infectious!" This is an absolute game-changer and those who live with HIV can proudly share this information. At the same time, service providers working in HIV must get up to speed fast and share this far and wide with their communities." Laurie Edmiston, Executive Director, Statement from <u>CATIE -</u><u>Canadian AIDS Treatment Information Exchange</u> (January, 2017)

16. "The scientific evidence is clear and unequivocal: effective treatment reduces HIV transmission risk to zero. The Consensus Statement highlights unprecedented scientific consensus that early diagnosis and treatment with antiretroviral therapy (ART) not only restores people living with HIV to a normal life expectancy, but it also has far-reaching public health impacts." Joint statement from <u>ICASO (International Council of AIDS Service Organizations) and INA (Māori, Indigenous & South Pacific) HIV/AIDS Foundation (January, 2017)</u>

17. "...studies have proven that when an individual living with HIV is on antiretroviral therapy and the virus is durably suppressed, the risk that he or she will sexually transmit the virus is negligible." Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases; Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID. <u>NIH</u> <u>Statement on World AIDS Day 2016</u> (December, 2016)

18. "If you are durably virologically suppressed you will not transmit to your partner... I'll say this again, for somebody who is in a discordant couple, if the person [with HIV] is virologically suppressed, 'durably' --there is no virus in their system, hasn't been for several months -- your chance of acquiring HIV from that person is ZERO. Let's be clear about that: ZERO. If that person the next day stops therapy for two weeks and rebounds, your chance goes up. That's why we talk about 'durable' viral suppression...You're as durably virologically suppressed as good as your adherence." Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH. <u>NIH Video interview</u> (November, 2016)

19. "When an HIV positive person first starts on treatment, it takes a few months before viral growth is completely suppressed. During that short window of time, the couple should use condoms. Alternatively, the HIV negative partner might use antiretroviral agents as



pre-exposure prophylaxis [PrEP]." Dr. Myron Cohen Chief, Division of Infectious Diseases, UNC School of Medicine, North Carolina, USA; Principal Investigator, HPTN 052. <u>POZ</u> <u>magazine</u> (September, 2016)

20. Suppressing the viral load of a person living with HIV to undetectable levels "not only saves their lives but prevents them from infecting others. So the higher percentage of people who are on treatment, in care and get their viral loads to undetectable, the closer you get to literally ending the epidemic." Anthony S. Fauci, M.D., Director, NIAID, NIH. <u>NIH</u> <u>Video Interview</u> (August, 2016)

21. "Once you begin therapy, you stay on therapy, with full virologic suppression you not only have protection from your own HIV…but you also are not capable of transmitting HIV to a sexual partner. With successful antiretroviral treatment, that individual is no longer infectious." Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH. <u>NIH</u> <u>Video</u> interview (August, 2016)

22. "We can now say with confidence that if you are taking HIV medication as prescribed, and have had an undetectable viral load for over six months, you cannot pass on HIV with or without a condom." <u>Dr. Michael Brady</u>, Medical Director, <u>Terrence Higgins</u> <u>Trust</u>, London, England (July, 2016)

23. "The force of evidence in both real world and clinical trial experience confirms that individuals with suppressed viral loads have a negligible risk of transmitting HIV. Treatment as prevention, pre-exposure prophylaxis, and traditional prevention measures, like condoms, make up an HIV prevention toolkit based in harm-reduction that allows individuals to make personalized and enlightened decisions to both maintain their health and prevent HIV and STI transmission." Dr. Demetre C Daskalakis, MPH - Assistant Commissioner, Bureau of HIV/AIDS Prevention and Control New York City Department of Health and Mental Hygiene (July, 2016)

24. "Does this work over a long period of time for people who are anxious to be suppressed? The answer is absolutely yes, we now have 10,000 person years (of follow-up) with zero transmissions from people who are suppressed." Dr. Myron Cohen. <u>Medpage:</u> <u>NEJM</u>. (July, 2016)

25. "Among serodifferent heterosexual and MSM couples in which the HIV-positive partner was using suppressive ART and who reported condomless sex...there were no documented cases of within-couple HIV transmission" among 58,000 condomless sex acts. Reporting on PARTNER study, <u>Dr. Alison Rodger</u>, et al. JAMA. (July, 2016)



26. "These results are simple to understand – zero transmissions from over 58,000 individual times that people had sex without condoms...[PARTNER study] provides the strongest estimate of actual risk of HIV transmission when an HIV positive person has undetectable viral load – and that this risk is effectively zero." <u>Simon Collins</u>, Steering Committee, PARTNER, <u>i-BASE</u> (July, 2016)

27. "The [Swiss] statement [was the first position statement that] addressed the infectiousness of an HIV-positive person once the virus was stably suppressed for at least 6 months with ART. [T]he [Swiss Federal Commission for AIDS-related Issues] felt, based on an expert evaluation of HIV transmission risk under therapy, that the risk of HIV transmission in such a situation was negligible." <u>Dr. Pietro Vernazza</u>, chief of the Infectious Disease Division, Cantonal Hospital in St. Gallen, Switzerland; Executive Committee, PARTNER <u>Swiss Medical Weekly</u> (Jan., 2016, confirming the original 2008 Swiss statement)'

28. "[T]he HPTN 052 study saw only cases of transmission during ART that occurred shortly (days) after the initiation of therapy. If only transmissions after the first six months of ART are considered (as stipulated in the Swiss statement) the efficacy would have been 100% with a transmission risk of zero." <u>Dr. Pietro Vernazza</u>, <u>Swiss Medical Weekly</u> (Jan., 2016)

29. "Achieving viral suppression protects the body's immune system, helps people living with HIV stay healthy and prevents transmission of HIV to other people." <u>UNAIDS - Joint</u> <u>United Nations Programme on HIV/AIDS</u> (2016)

30. "We have...rigorous confirmation that treatment prevents the spread of HIV and improves the health of infected people." <u>Dr. Thomas R. Frieden</u>, Center for Disease Control Director, USA <u>New England Journal of Medicine</u> sourcing HPTN 052 & PARTNER studies (Dec., 2015)

31. "EATG calls for much better public information to be made available in Europe and globally about the prevention benefits of antiretroviral therapy (ART), and in particular (about) the fact that HIV-positive people with undetectable viral loads are not infectious. Widespread ignorance of this fact helps perpetuate stigma against and criminalisation of people living with HIV and it should be the subject of a funded public awareness campaign, possibly to run in conjunction with a PrEP awareness campaign." <u>European AIDS</u> <u>Treatment Group (EATG)</u> (October, 2015)

32. "If people are taking their pills reliably and they're taking them for some period of time, the probability of transmission in this study is actually zero." <u>Dr. Myron Cohen</u>, Chief,



Division of Infectious Diseases, UNC School of Medicine, North Carolina, USA; Principal Investigator, HPTN 052 Interview with <u>plus</u> (August, 2015)

33. "[People with HIV] will not pass on the infection, if the virus is undetectable, to their partners..." <u>Professor David Cooper</u> - Director of the Kirby Institute for Infection and Immunity in Society. University of NSW, Australia; <u>ABC AU interview</u> (May, 2015)

34. When asked what the study tells us about the chance of someone with an undetectable viral load transmitting HIV, presenter Alison Rodger said: "Our best estimate is it's zero." Reporting on PARTNER study interim results. <u>Dr. Alison Rodger</u>, University College London, United Kingdom; Lead Author PARTNER, <u>NAM -AIDSMap (March</u>, 2014)

35. People living with HIV "are leading lives that are normal in quality and length. With effective treatment, they are not infectious." Health care workers on effective HIV treatment are "totally safe." <u>Professor Dame Sally Davies</u>, Chief Medical Officer, England. <u>The Telegraph</u> (Aug., 2013)

36. "Many people want to know their status, because they want to be rendered not contagious, because of confidence in living their lives normally. So I've heard dozens of stories of people who came in and said, 'I want to be tested, because if I'm infected I don't want to be transmissible.' Inspiring." <u>Dr. Myron Cohen</u>, Chief, Division of Infectious Diseases, UNC School of Medicine, North Carolina, USA; Principal Investigator, HPTN 052; <u>MEDPAGE Today</u> (Jan., 2013)

37. "In reality, if you give the treatment the opportunity to get on with its work, you will have zero transmission." Dr. Julio Montaner, Director of the British Columbia Centre for Excellence in HIV/AIDS; Director of IDC and Physician Program Director for HIV/AIDS PHC: <u>TED Talk</u> referring to HPTN 052 (Nov., 2011)

[i] Much of the current prevention messaging refers to this as Treatment as Prevention or TasP. As of the writing of this primer, there have been no confirmed cases of HIV transmission from a person with an undetectable viral load in any studies. The official cut-off point for an undetectable viral load as defined by the WHO ranges from <50 copies/ml in high-income countries to <1,000 copies/ml in low to middle-income countries. For the purposes of this statement, an undetectable viral load is defined as under <200 copies/ml, which is also the measurement for viral suppression.

[ii] Only a small proportion of people living with HIV in a large US treatment study regarded themselves as non-infectious after up to three years on antiretroviral therapy (ART), and a third of participants regarded their chance of transmitting HIV to a partner as still 'high', even though only 10% of participants actually had a detectable viral load." <u>NAM aidsmap</u> (2016)

[iii] Acknowledgements: In addition to PAC's Founding Task Force and Bruce Richman (PAC Executive Director), Professor Carrie Foote (Indiana University-Indianapolis; <u>HIV Modernization Movement</u>) and Edwin Bernard (<u>HIV Justice Network</u>) reviewed and provided valuable input on the Primer.

