Undetectable = Untransmittable

A Community Brief

Executive Summary

The International Council of AIDS Service Organizations (ICASO) developed this brief to provide the HIV community with current information and analysis of new and updated clinical data on the effectiveness of antiretroviral therapy (ART) in preventing HIV transmission to sexual partners of people living with HIV[i]. While the health benefits of treatment will always be the primary purpose of ART, it is vital that the secondary benefits to people living with HIV and their sexual partners be fully understood and communicated. The brief is organized as follows:

1. **Introduction**
   - Overview of the rationale for this brief as well as a glossary of key terms
2. **HIV Basics: Prevention, Sexual Transmission and the Dual Role of Antirretrovirals**
   - Overview of current global information on sexual transmission, combination HIV prevention packages and the dual role of ART in improving the health of people living with HIV and preventing sexual transmission to sexual partners
3. **The Science of HIV Transmission: What's New?**
   - Summary of clinical findings released in 2016 and early 2017 on the role of ART in preventing transmission to sexual partners of people living with HIV
   - Brief review of the clinical evidence regarding the use of ARVs as oral pre-exposure prophylaxis (PrEP) by HIV-negative people to prevent HIV acquisition
4. **Advocacy for Access to ART and HIV diagnostics**
   - Analysis of implications of new and updated clinical findings in developing advocacy strategies to address disparities in access to HIV diagnostics including viral load testing and ART.
5. **Advocacy for Accurate, Rights-based HIV Education: Challenging HIV Stigma**
   - Analysis of implications of new and updated clinical findings in developing rights-based HIV education for people living with HIV
6. **The Population Potential of ARVs as Prevention**
   - Analysis of the population potential of ARVs in reducing or eliminating sexual transmission of HIV
7. **Law Reform on Criminalization of HIV Non-Disclosure**
   - Implications for advocacy for law reform efforts aimed at ending the unjust, overly-broad application of general and HIV-specific laws which criminalize people living with HIV
   - ICASO's position is consistent with international guidance on restricting the use of criminal law to exceptional circumstances of intentional, actual transmission.

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1. Introduction

ICASO, in partnership with the Ontario HIV Treatment Network (OHTN), the Canadian AIDS Treatment Information Exchange (CATIE), The Global Network for People Living with HIV – North America (GNP+-NA), the Canadian Positive People's Network (CPPN) and the International Indigenous HIV & AIDS Community (IIHAC) developed this brief to provide the HIV community with updated information regarding the possibility of sexual transmission where the person living with HIV is on antiretroviral therapy (ART) and has an undetectable viral load for at least six months. The recent Undetectable = Untransmittable consensus statement, issued by the Prevention Access Campaign in conjunction with recent clinical findings, started an important global conversation on how the HIV community should respond to new information regarding sexual transmission in this context, including the importance of how communications about ART prevention benefits can and should reflect differences in access and experience of people living with HIV in different regions of the world. Globally, sexual transmission remains by far the most common route of HIV transmission. Delivering combination prevention packages and scaling up access to ART and viral load diagnostics is essential to meeting the 90-90-90 targets established by the United Nations Global Programme on HIV/AIDS (UNAIDS).[ii]

In January 2017, ICASO and the Māori, Indigenous & South Pacific HIV/AIDS Foundation (INA), released a joint statement endorsing the Undetectable = Untransmittable (U = U) Consensus Statement, issued by the Prevention Access Campaign. Many other community-based, scientific and legal advocacy organizations have also endorsed the Consensus Statement since it was issued and have become community partners of the U = U campaign. The statement was developed following the release of updated data from clinical studies evaluating the risk of sexual transmission between mixed status (sero-discordant) heterosexual and male same-sex couples when the partner living with HIV is on effective ART and has an undetectable viral load. The statement was based on these new clinical findings and other empirical evidence to date.

This brief provides a detailed analysis of the scientific, legal, policy and advocacy implications of U = U for people living with HIV and the broader HIV community sector. It also provides information on how this new scientific evidence can support civil society advocacy on scaling up access to ART and viral load diagnostics that are required to achieve the 90-90-90 targets.

Key Terms

- **HIV Diagnostics**: HIV infection is diagnosed using either laboratory-based or point-of-care (POC)/rapid HIV tests that detect HIV antibodies and viral antigens in the blood using a validated testing algorithm. If the initial screening test is reactive, a second confirmatory test is usually done to confirm HIV infection. Additional information on HIV diagnostic tests currently in use or in development is available at www.aidsmap.com.
- **Antiretroviral therapy (ART):** ART is a combination of three or more antiretroviral drugs (ARVs) taken by people living with HIV to block replication (reproduction) of HIV. Suppressing viral replication prevents HIV from infecting and damaging the white blood cells that the body needs to combat infections and disease.

- **Viral load testing**: viral load tests are used to determine the amount of virus in the blood, usually expressed as the number of HIV copies per milliliter (ml) of blood (e.g., 2,500 copies/ml). There are a number of different types of viral load tests or "assays" available, but most are sensitive enough to detect viral loads above 20 - 500 copies/ml. Viral load testing is the preferred method of monitoring HIV disease and determining the effectiveness of ART. At a minimum, a viral load test should be performed six months and 12 months after starting treatment, and then at least once every 12 months thereafter.[iii]
- **Undetectable viral load:** the amount of virus in the blood is known as "viral load". An undetectable viral load means that the amount of virus in the blood is below the limit of detection of the viral load test or "assay". An undetectable viral load means that treatment has been effective at suppressing viral replication. Significant increases in viral load, which are rare if the individual is adherent, likely means that a change in ART regimen is required. Most viral load assays in high-income countries have a limit of detection of 20 - 40 copies/ml. Most low and middle-income countries use viral load assays that have a limit of detection of 500 copies/ml. There is therefore some variance, depending on the sensitivity of the assay used in different jurisdictions, on what is "undetectable".[iv] For example a person living with HIV might have a viral load of 350 copies/ml, which would be below the limit of the detection of an assay used in a low-income country (and therefore be considered "undetectable" but the same amount of virus using the more sensitive assays in high-income countries, would be above the limit of detection and therefore "detectable" (although still very low). The important point is that the clinical evidence suggests there is no significant difference in terms of transmission risk once someone has a viral load below the limit of detection, irrespective of the sensitivity of assay.[v] Unless otherwise indicated, this brief uses the U=U campaign's threshold of 200 copies/ml as "undetectable".
- **Undetectable = Untransmittable Campaign (U=U):** U=U is shorthand for the campaign launched by the Prevention Access Campaign highlighting new and updated clinical findings that demonstrate if someone is on ART and has an undetectable viral load for at least six months, it is not possible to transmit the virus sexually: hence, Undetectable = Untransmittable.
- **CD4+ Testing:** CD4+ cells are a type of white blood cell that the body needs to fight infection; these cells are the primary target of HIV and, over time, are damaged and depleted by ongoing viral replication. CD4+ tests measure the quantity of these cells in the blood and are used, along with viral load testing, to monitor the impact of HIV on the immune system. The lower the number of CD4+ cells, the more difficult it is for the body to fight infections such as HIV, tuberculosis and other infections.
- **Clinical Trial**: a clinical trial is any research study that prospectively assigns groups of human participants who have consented to be in the trial to receive one or more health-related interventions over a period of time in order to evaluate the safety of the intervention and its efficacy in achieving specific health outcomes (such as reducing disease progression or rates of mortality). Interventions can include drugs, medical devices or other interventions.
- **Systematic Review and meta-analysis:** A systematic review summarizes the results of available health care studies (clinical trials) in peer-reviewed medical literature and provides a high level of evidence on the effectiveness of health care interventions because it analyzes results of

multiple trials evaluating the same intervention. A meta-analysis is the use of statistical methods to summarize the results of these studies.

- **Oral Pre-exposure prophylaxis (PrEP):** PrEP is a way for an HIV-negative person who is at risk of HIV infection to reduce their risk of acquiring HIV by taking ARVs prior to sex. The use of tenofovir (TDF) alone or in combination with emtricitabine (FTC) as PrEP is a highly effective HIV prevention strategy when used as prescribed. Like using ARVs for treating HIV, adherence is key to maximizing the preventive benefit of oral PrEP.

2. HIV Basics: Prevention, Sexual Transmission and the Dual Role of Antirretrovirals

Sexual intercourse involving exposure to HIV accounts for the vast majority of HIV infections worldwide. UNAIDS estimates that there are an estimated 36.7 million people living with HIV, of which only 60% are aware that they are HIV-positive; over 14 million people living with HIV are undiagnosed.[vi] Key populations have higher rates of infection (HIV incidence) and higher overall HIV prevalence (the total number of people in a specific population who are HIV-positive) compared to other populations. Key populations include sex workers, gay and other men who have sex with men, transgender populations and people who inject drugs; depending on the region, key populations may also include prisoners, migrants, youth, girls and women. For example, UNAIDS data suggests that more than 90% of new HIV infections in central Asia, Europe, North America, the Middle East and North Africa in 2014 occurred among people from key populations and their sexual partners.[vii] Although global HIV incidence and AIDS deaths are declining, there were 2.1 million new infections in 2015: effective prevention interventions, along with increased access to HIV testing, are critical to ending AIDS.

Global Combination Prevention Gaps

- Only 38% of people living with HIV are virally suppressed.
- Condoms available in sub-Saharan Africa cover less than one-half of the estimated need.
- Two-thirds of young people do not have correct knowledge of HIV.
- Condom use is too low across all populations at higher risk of infection.
- 43% of countries with documented injecting drug use do not have needle-syringe programs in place.
- Annual voluntary medical male circumcisions must nearly double to reach the 2020 target.
- PrEP coverage is less than 5% of the 2020 target.

UNAIDS, Prevention Gap Report 2016

There is a substantial body of clinical evidence demonstrating the health benefits of ART for people living with HIV, including significant improvements in life expectancy in a range of settings[viii].

ARVs are also highly effective at preventing HIV acquisition when used as prescribed by the HIV negative partner prior to sexual intercourse; this is known as oral pre-exposure prophylaxis or PrEP.[ix] Combination prevention packages, which may include VMMC[x], HIV education and counselling, condom programming[xi] and ARV-based interventions, are critical to reducing HIV transmission. ARVs have now been proven effective at dramatically improving the health of people living with HIV, reducing or

eliminating the possibility of transmission to sexual partners and preventing vertical (mother-to-child) transmission.

While most people who are newly diagnosed with HIV and start ART in high-income countries can expect a near-normal life expectancy, not all key populations (such as prisoners and people who inject drugs and their sexual partners) have equitable access to treatment and other evidence-based HIV interventions.[xii] As well, legal, institutional and structural barriers can limit access to HIV interventions. Recent studies have indicated similar life expectancy results can be achieved in low and middle-income countries such as South Africa.[xiii] However, diagnosis late in HIV disease, limited access to HIV education, diagnostics, free condoms and ART means this is far from reality for most people living with HIV in the global South.

3. The Science of HIV Transmission: What's New?

> "If you are durably virologically suppressed you will not transmit to your partner."
>
> *Carl W. Dieffenbach, Ph.D., Director, Division of AIDS, NIAID, NIH*

Clinical study findings, released in 2016, have added to prior evidence demonstrating that HIV cannot be sexually transmitted if the person living with HIV is on fully suppressive ART and has an undetectable viral load. In 2011, the HIV Prevention Trials Network 052 (HPTN 052) clinical trial reported that the risk of transmission is dramatically reduced if the HIV-positive partner is on effective ART.[xiv] Updated findings (five years of follow-up from initial enrolment) were reported in 2016, indicating that there were no cases of transmission among sero-discordant heterosexual couples where effective ART reduced viral load below the limit of detection.[xv] ART reduced the risk of transmission by 93%; the risk reduction was not higher because genetically linked transmissions occurred either within days of ART initiation or following failure of an ART regimen.[xvi] A 2014 systematic review of studies evaluating the heterosexual risk of transmission on a per-act basis with the person living with HIV on ART found that the risk was less than 13 in 100,000, although that risk would be significantly reduced if the one transmission event noted in the review occurred prior to full viral load suppression (i.e., prior to six months from ART initiation).[xvii] Preliminary findings, released in 2015 from the Opposites Attract observational study of 234 male same-sex sero-discordant couples in Australia, Brazil and Thailand, reported no phylogenetically linked transmissions where the HIV-positive partner was on suppressive ART, despite almost 6,000 acts of condomless anal intercourse.[xviii] A recent Spanish study of a prospective cohort of 202 heterosexual HIV sero-discordant couples found no HIV transmission among the 199 couples where the person living with HIV was on effective ART, despite 7,600 condomless sex acts and 85 natural pregnancies which occurred over the course of the study.[xix]

In January 2016, an author of the 2008 Swiss Federal AIDS Commission statement published an editorial, *HIV is not transmitted under fully suppressive therapy: The Swiss statement eight years later*, based on updated scientific evidence and the authors' experience with the long-running Swiss Cohort Study.[xx] The updated statement was released in part due to the authors' concerns regarding unjust criminal prosecutions of potential or perceived HIV exposure in Switzerland and also to reaffirm the original

advice to Swiss clinicians that sero-discordant heterosexual couples do not require artificial reproductive technology (e.g., artificial insemination) in order to conceive, provided the HIV positive partner was on ART and had an undetectable viral load. A recent consensus statement, based on a number of clinical studies and consultations, underscores the safety of natural conception and pregnancy for people living with HIV who are on ART and have an undetectable viral load.[xxi] In July 2016, the Partners of people on ART – a New Evaluation of Risk (PARTNER) study, a prospective, observational cohort trial evaluating transmission risk among both heterosexual and same sex male couples, reported no transmission over four years of the study when the HIV-positive partner was on ART and had an undetectable viral load.[xxii] The findings were based on approximately 22,000 condomless sex acts between male same sex couples and approximately 36,000 condomless sex acts between heterosexual couples. Both HPTN 052 and the PARTNER study were large, longitudinal, multi-site international cohorts, providing robust evidence from both developing and developed setting contexts of the efficacy of ART in eliminating the risk of transmission.

The clinical studies and meta-analyses of peer-reviewed scientific literature provide robust scientific evidence that ART dramatically reduces transmission risk, irrespective of the sexual act. As a result of these and additional scientific findings regarding the health benefits of early ART initiation, the World Health Organization (WHO) updated its clinical guidelines in 2016 to recommend starting ART immediately following HIV diagnosis.[xxiii] WHO also recommends viral load testing as the preferred monitoring tool for people who are taking ART.

4. Advocacy for Access to ART and viral load diagnostics

Some community activists and organizations have raised legitimate concerns that "treatment as prevention" (or "TasP") messages and slogans place inordinate focus on the issue of "undetectability" and do not address the fact that many people living with HIV do not currently have access to ART, viral load testing and quality, rights-based health care.[xxiv] The most recent data available (to the end of 2015) indicates that only 46% of adult people living with HIV are on ART (18.2 million people) and that, of those on ART, access to viral load diagnostics is limited.[xxv] An estimated 38% of people living with HIV have an undetectable viral load. Access to rights-based HIV services is even more limited for key populations, many of whom face programmatic, social and legal barriers to accessing HIV diagnostic and treatment services.[xxvi]

WHO currently recommends beginning ART immediately after an HIV diagnosis, based on extensive clinical evidence that early initiation optimizes long-term health outcomes and reduces the risk of other infections.[xxvii] Although viral load monitoring is now the standard of care and has been incorporated into most low and middle-income country clinical guidelines, it has yet to be widely implemented in many settings. Our ability to meet the 90-90-90 targets depends on scaling up HIV testing, ART and viral load diagnostics, particularly for key populations who remain consistently underserved in current national HIV programming. Innovations in diagnostics, such as the use of dried blood spot (DBS) technology for early infant diagnosis and viral load quantification, have the capacity to significantly expand access to viral load monitoring in low and middle-income countries and further reduce AIDS-related morbidity and mortality.[xxviii] Ensuring access to both is one of the most important advocacy goals for community

leaders and our allies in the medical and scientific communities. The recent clinical findings provide community leaders with additional evidence to incorporate in their advocacy strategies for the resources required to scale up access to ART and viral load testing.

In addition to challenging the donor community and national governments to adequately invest in ART and viral load technologies, civil society must call on manufacturers of viral load testing technologies to make them more affordable in low- and middle-income countries. The Diagnostics Access Initiative, launched in 2014, recently announced a new pricing agreement of a US$9.40 ceiling per unit cost of a viral load test which significantly lowers its cost in low and middle-income countries, as well as price reduction on DBS assays to reduce the cost of early infant diagnosis.[xxix] While these are important steps, additional advocacy is required to ensure access to affordable, reliable POC technologies in all low and middle-income countries. Current intellectual property regimes have placed additional barriers to expanding access to ART and viral load diagnostics for people in low and middle-income countries. Few countries struggling with limited technical capacity and resources are willing or able to employ the available flexibilities in the TRIPS agreement for fear of reprisal by both pharmaceutical companies and World Trade Organization (WTO) proceedings initiated by high-income countries, where the pharmaceutical industry lobby has driven international trade policy on this issue.[xxx]
We also need better quality global data on cost and access to viral load diagnostics. While it is important to recognize that U = U is not a reality for most people living with HIV and to balance "treatment as prevention" messaging with the paramount importance of ART for individual health, the new findings can and must inform civil society advocacy. The more people living with HIV who are able to access ART and achieve an undetectable viral load, the closer we are to ending AIDS.

5. Advocacy for Accurate, Rights-based HIV Education: Challenging HIV Stigma

Many – perhaps most – of the millions of people living with HIV who are currently on ART and have an undetectable viral load do not know that they cannot transmit HIV to sexual partners through vaginal or anal sex. Not only does this information provide an added incentive for adherence, and therefore help to maximize the individual health benefits of ART, it has important implications for self-esteem (including internalized HIV stigma) as well as potentially difficult HIV disclosure conversations. Community activists, counsellors and educators may not be aware that information about the possibility of sexual transmission of HIV if someone is on effective ART is still widely unknown outside of those working in the HIV field. A 2015 study in the United States found that even people in care and on effective ART overestimated their risk of transmission, with African-Americans and people who inject drugs more likely to over-estimate the possibility of HIV transmission than other populations living with HIV.[xxxi]

While the clinical benefits of immediate ART initiation after diagnosis is clear, it is vitally important that post-diagnosis treatment and prevention counselling be accurate, rights-based and responsive to the social and psychological context of individual people living with HIV. Individual autonomy in decisions regarding treatment is paramount. Initiating ART immediately following diagnosis may ultimately not be clinically optimal if an individual is not prepared for long-term adherence to ART. Ensuring that post-diagnosis counselling includes accurate information regarding transmission risk, other prevention interventions and the importance of adherence are key to ensuring accurate, rights-based information is

in the hands of individual people living with HIV. The clinical evidence and U = U campaign should not be interpreted as undermining proven public health interventions, such as condom programming; it is about providing accurate information to people living with HIV that there is an important new prevention tool in the HIV prevention package.

Updated scientific information regarding the prevention benefits of ART also has important implications for sero-discordant partners who want to have children. As the number of natural pregnancies in the Spanish study demonstrates, conception is possible without the need for costly reproductive technologies that are out of reach for most people living with HIV in the global South. The impact of ART on transmission risk when breastfeeding is an area which requires further study to be definitive.

HIV stigma has driven public fear and perpetuated dangerous misconceptions about HIV transmission risk that have negative consequences for the HIV community, including driving unjust criminal prosecutions. Recent clinical findings add important evidence to counteract those fears and misconceptions. Community HIV educators have a unique opportunity to provide additional reassurance to people living with HIV regarding both their individual health and the health of their sexual partners. This incentives retention in care across the HIV cascade; people are more likely to get tested if the stigma associated with HIV is reduced, more likely to disclose if on effective ART, more likely to remain adherent and more likely to be retained in care.

6. The Population Potential of ARVs as Prevention

ARVs, whether as treatment for people living with HIV or as PrEP, are an important part combination prevention. While condom programming and VMMC will remain key HIV prevention interventions, it is important that the prevention benefits of ART be incorporated into post-diagnosis prevention, treatment and adherence counselling. The United States Center for Disease Control and Prevention (CDC) recently estimated that reaching the National HIV/AIDS Strategy (NHAS) targets for HIV testing and treatment and expanding the use of daily PrEP would prevent an estimated 185,000 new HIV infections in the USA by 2020 – a 70 percent reduction in new infections over 5 years.[xxxii] A recent retrospective modelling study in The Lancet HIV found that the combination of ART and harm reduction interventions (such as needle and syringe programs) averted 3204 infections (2402–4589) between 1996 and 2013 in British Columbia.[xxxiii]

ARVs, along with other proven prevention strategies, have the potential to fundamentally alter the course of the epidemic as both primary and secondary prevention interventions.

7. Advocacy for Law Reform: HIV Science and Criminal Law

There are few areas where updated scientific evidence is needed more desperately than in reforming or repealing laws which criminalize people living with HIV for non-disclosure of their HIV status, even in cases where there is no transmission or no risk of transmission. In other cases, HIV-positive individuals have been charged and convicted in connection with workplace incidents, such as needlestick injuries, where the risk of transmission is negligible. In July 2012, the Global Commission on HIV and the Law recommended against enacting laws that criminalize HIV exposure or HIV non-disclosure and repealing

general or HIV-specific laws that have this effect.[xxxiv] The Commission stated that the impact of criminalizing otherwise consensual adult behavior was both disproportionate and counterproductive to public health measures. The two main reasons advanced for criminalizing HIV transmission are to punish harmful conduct by imposing criminal penalties, and to prevent HIV transmission by deterring or changing risk behaviors. However, as UNAIDS and UNDP guidance on this issue notes, except in the very rare cases of intentional HIV transmission, applying criminal law to HIV transmission does not serve these goals.[xxxv]

> "My life will not be the same after facing HIV criminalization. My 30 years working as a nurse and dedicated to saving lives have been erased. I have spent almost a year in prison. I have been branded a criminal and a killer even though I have harmed no one."
>
> *Rosemary Namubiru, Ugandan nurse*

Many jurisdictions at both the national and state or provincial level have passed laws providing for serious sentences that criminalize HIV non-disclosure, potential or perceived exposure and/or unintentional transmission, despite no evidence that such laws reduce HIV transmission or have public health benefits.[xxxvi] General laws used to criminalize non-disclosure are usually the most serious charges available to law enforcement, such as sexual assault, aggravated sexual assault and attempted murder. A 2015 review of HIV-specific legislation in 27 sub-Saharan African countries found that many HIV-specific laws violated basic human rights protections, such as laws providing for compulsory HIV testing, involuntary partner notification and criminalization of HIV exposure or non-disclosure.[xxxvii] Some laws include significant penalties for conduct that has a negligible or no risk of transmission, such as oral sex, biting or spitting. Many of these laws were passed prior to scientific evidence of the efficacy of ARVs in preventing HIV transmission or do not consider condom use, which is 100% effective when used correctly and no breakage occurs. These laws also do not take into account the fact that the risk of HIV transmission on a per-act basis, even in the absence of ART, is low.[xxxviii]

> Now that we have data that clearly demonstrates people with HIV with undetectable viral loads are at basically zero risk of infecting their partners, it's past time for the law to catch up with the science
>
> *Ryan Peck, HIV & AIDS Legal Clinic Ontario*

These laws, and the sensationalist media attention that often surrounds HIV-related prosecutions, drive public fear, misconceptions and HIV stigma. The risk of transmission is negligible to zero if a condom is used properly or if a person living with HIV is being successfully treated with antiretroviral medications. Such prosecutions also undermine the shared responsibility for sexual decision-making between people living with HIV and their sexual partners. It is past time for the law to catch up with these realities. Community leaders, legal advocacy groups, clinicians and scientists have spoken out repeatedly against the overly broad use of the criminal law in HIV non-disclosure cases.[xxxix]

It is important that the law not distinguish between people living with HIV who have an undetectable viral load and those who do not, thereby punishing people living with HIV who may not have access to ART or viral load diagnostics or who choose not to go on treatment. The position of ICASO is consistent with international recommendations that the criminal law should not be applied outside of the exceptional circumstances regarding intentional, actual transmission, noted above. However, the recent clinical evidence regarding the possibility of sexual transmission when on suppressive ART provides additional scientific evidence for advocacy to repeal or reform unjust laws that criminalize and further stigmatize people living with HIV.

8. Conclusion

The recent clinical evidence regarding the effectiveness of ART in eliminating the possibility of sexual transmission can be used to advocate for better access to ART, viral load testing and other proven HIV interventions. These efforts are particularly critical in the global South, where access to ART and viral load diagnostics is still well short of the levels required to reach the 90-90-90 targets and realize U = U for individual people living with HIV.

It is also important to recognize concerns from organizations advocating for people living with HIV that U=U messaging not eclipse the importance of treatment for individual health and to guard against the use of "treatment as prevention" messaging to coerce people onto treatment. Individual autonomy in treatment decision-making remains a fundamental human rights principle. As this brief makes clear, current access to ART and viral diagnostics is limited and unevenly distributed, across and within regions and populations. However, this new information has important implications for community activism and advocacy in a number of areas critical to reaching the 90-90-90 targets. It needs to be shared by public health authorities, clinicians and community workers to ensure people living with HIV have current, evidence-based information. On an individual level, it is also about providing accurate, rights-based information to people living with HIV so that they can make informed decisions about their social, sexual and reproductive health needs.

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[i] This brief is intended to provide a summary and analysis of new and updated clinical findings on the effectiveness of ART in preventing sexual transmission. Therefore, this brief does not address, among other issues, other routes of transmission, reproductive health issues or ART as treatment.

[ii] By 2020, 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained ART and 90% of all people receiving ART will have viral suppression: UNAIDS, 90-90-90: An Ambitious Treatment Target to Help End the AIDS Epidemic, 2014.

[iii] Guidelines developed for high-income settings generally recommend more frequent ongoing viral load testing of at least once every six months following viral suppression: Günthard HF, Saag MS, Benson CA et al. IAS-USA Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2016 Recommendations of the International Antiviral Society–USA Panel. JAMA. 2016;316(2):191-210.

[iv] No genetically linked transmissions have been recorded in the clinical literature when the HIV-positive partner was on ART and had an undetectable viral load for at least six months, but there are four studies in the literature where one-two genetically linked transmission occurred when the person living with HIV was on ART and had an undetectable viral load at some point during the study. However, the design of these studies meant that it was not clear whether the transmission occurred within the six-month period: Globerman J, Gogolishvili D, Rourke SB.

Evidence Review: HIV sexual transmission risk by people with suppressed HIV viral load. Ontario HIV Treatment Network: Toronto, ON, May 2017.

[v] Attia S, Egger M, Müller M, et al. Sexual transmission of HIV according to viral load and antiretroviral therapy: systematic review and meta-analysis. *AIDS* 23:1397-1404, 2009 [the HIV positive partner was not on ART at the time of transmission]

[vi] UNAIDS, UNAIDS Global AIDS Update 2016 [Global Update 2016]; WHO, HIV/AIDS Fact Sheet (updated November 2016).

[vii] *Ibid*.

viii Teeraananchai S, Kerr SJ, Amin J, Ruxrungtham K, Law MG. Life expectancy of HIV-positive people after starting combination antiretroviral therapy: a meta-analysis. *HIV Med.* 2017 Apr;18(4):256-266.

[ix] ARVs have also been tested using a variety of formulations and mechanisms for administration, such as vaginal gels and microbicides, but the most robust results to date are findings from clinical trials studying oral PrEP (taken orally in pill form). Drug level studies have found that PrEP taken as prescribed is near-100% effective (three undisputed global cases of PrEP failure in over 100K people taking it). See http://www.aidsmap.com/Four-doses-of-PrEP-a-week-may-be-enough-to-protect/page/2279465/

[x] Voluntary medical male circumcision (VMMC) reduces the risk of female to male transmission by approximately 60% (WHO, HIV/AIDS Fact Sheet (updated November 2016).

[xi] Consistent and "correct" use of condoms, if no breakage occurs, provide 100% protection against infection because condoms provide an impermeable physical barrier to HIV and other sexually transmitted infections. See http://www.aidsmap.com/Do-condoms-work/page/1746203/ and http://www.aidsmap.com/CDC-researchers-publish-estimate-of-effectiveness-of-condom-use-in-anal-sex/page/2930716/.

xii Samji H, Cescon A, Hogg RS, et al. Closing the Gap: Increases in life expectancy among treated HIV-positive individuals in the United States and Canada. *PLoS One.* 2013 Dec 18;8(12) [average life expectancy is lower if the PLHIV injects drugs, is non-white or lives in the United States rather than Canada]; Katz IT, Maughan-Brown B, Improved life expectancy of people living with HIV: who is left behind? *The Lancet HIV*,10 May 2017.

[xiii] Johnson LF, Mossong J, Dorrington RE, et al. Life expectancies of South African adults starting antiretroviral treatment: collaborative analysis of cohort studies. PLoS Med. 2013; 10: e1001418.

[xiv] Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365:493-505.

[xv] Cohen MS, Chen YQ, McCauley M, et al, Antiretroviral Therapy for the Prevention of HIV-1 Transmission, *N Engl J Med,* Sept 2016; 375:830-839.

[xvi] Eshleman SH, Hudeelson, SE, Red AD, et al, Treatment as Prevention: Characterization of Partner Infections in the HIV Prevention Trials Network 052 Trial, *J Acquir Immune Defic Syndr,* Jan 2017; 74(1): 112-116.

[xvii] Supervie V, Viard JP, Costagliola D, Breban R, Heterosexual risk of HIV transmission per sexual act under combined antiretroviral therapy: systematic review and bayesian modeling, *Clin Infect Dis*, Jul 2014;59(1):115-22.

[xviii] Grulich AE, Bavinton BR, Jin F, et al. HIV Transmission in Male Serodiscordant Couples in Australia, Thailand and Brazil, Conference on Retroviruses and Opportunistic Infections, 13 – 14 February 2015, Abstract 1019LB.

[xix] Del Romero J, Río I, Castilla J, Baza B, Paredes V, Vera M, Rodríguez C, Absence of transmission from HIV-infected individuals with HAART to their heterosexual sero-discordant partners, *Enferm Infecc Microbiol Clin*, December 2015;33(10):666-72.

[xx] Vernazza PL, Bernard E, HIV is not transmitted under fully suppressive therapy: The Swiss Statement – eight years later, *Swiss Med Wkly*, January 2016, 146:w14246 [Swiss Statement].

[xxi] Matthews, LT, Beyeza-Kashesya J, Cooke I, Davies N, et al. Consensus Statement: Supporting Safer Conception and Pregnancy for Men and Women Living with and Affected HIV. *AIDS Behav* (2017).

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