

Treatment as Prevention: Arriving at Community Consensus

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At a satellite meeting preceding the 2013 Controlling the HIV Epidemic With Antiretrovirals evidence summit in London, England, a group of organizations and advocates discussed and formulated the final draft of a document, the Community Consensus Statement on the Use of Antiretroviral Therapy in Preventing HIV Transmission, that succinctly outlines a set of principles that should be followed in the provision of antiretroviral therapy to people with living with human immunodeficiency virus (HIV) for the purposes of preventing HIV, particularly as a public health measure. The satellite meeting's conclusions were subsequently outlined in a presentation and panel discussion at the evidence summit.

Keywords. community; rights; policy; guidelines; standards.

The primary goal of human immunodeficiency virus (HIV) treatment is prevention of mortality and morbidity; through early treatment initiation, the occurrence of other diseases such as tuberculosis [1] and liver cirrhosis [2] is reduced. However, a considerable secondary benefit is the prevention of HIV transmission.

The issue of using antiretroviral therapy (ART) specifically to prevent HIV transmission (ie, treatment as prevention) has been one that has given rise to varied and sometimes polarized opinions within the worldwide community of people living with HIV and among policymakers.

THE BENEFITS OF TREATMENT AS PREVENTION

The ability of virally suppressive ART to render people with HIV essentially noninfectious has, as well as its public health benefit, the potential to relieve people living with HIV of a burden of guilt, anxiety, and fear of

prosecution at the prospect of transmitting HIV to others. HIV remains an intensely stigmatized condition, but as the news diffuses through affected populations about the significant reduction in the risk of HIV transmission conferred by full viral suppression, the reason to justify stigmatizing attitudes starts to become less valid in people's minds including, in some cases, those of lawmakers [3].

This was the spirit in which organizations representing people with HIV received the first professionally written declaration of the prevention possibilities of ART. This so-called "Swiss Statement" of January 2008 stated that, within certain criteria that included full adherence, freedom from sexually transmitted infections, and having had a fully suppressed viral load for at least 6 months, "an HIV-infected person on antiretroviral therapy with completely suppressed viraemia . . . cannot transmit HIV through sexual contact" [4].

At the 17th International AIDS Conference in Mexico City that year, community delegates wrote a "Mexico Manifesto," which drew attention to the potentially destigmatizing effects of ART as prevention which, it said, "favours quality of life and—even more—social integration of people with HIV" [5].

Similarly, in the wake of the result of the HIV Prevention Trials Network (HPTN) 052 study [6] in 2011, a group of HIV prevention advocates and organizations

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Clinical Infectious Diseases 2014;59(S1):S35–40

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DOI: 10.1093/cid/ciu268

issued a statement that hailed earlier initiation of ART as “a powerful, potentially cost-saving tool that can help end the AIDS epidemic” [7].

Some commentators have questioned whether people with high CD4 counts who start ART may have poorer adherence because the medication is not “of direct personal benefit” [8]. This assumes that people with HIV do not perceive becoming almost negligibly infectious as a direct personal benefit.

People living with HIV sometimes cite fear of side effects as the primary reason they postponed starting therapy, as does a perception that having to take drugs signifies failure or “losing” to the virus [9]. However, the fact that freedom from the risk of infecting others is something earnestly desired is attested to by 2 surveys of opinion on the benefits of a hypothetical cure for HIV infection.

In both cases, respondents were asked to rank in order what would be the most important improvement that becoming HIV negative would make to their lives. In one survey, a community sample rated “the risk of infecting someone” as the third most important disadvantage of having HIV, behind the general risk to their own health but ahead of fear of side effects, fatigue, stigma, and the impact on relationships [10]. In the second survey, a group of people who had taken an experimental drug as part of HIV cure research rated “not passing the virus on to others” as the most important advantage of a hypothetical cure for HIV, ahead of reverting to HIV-negative serostatus, being able to stop medications, and no longer having to see a doctor [11]. Respondents rated it even more highly than a cure that could also prevent reinfection.

THE MISUSE OF ART AS PREVENTION

Enthusiasm for the possibilities offered by using ART for prevention is tempered by concerns about its possible abuse.

First, there are concerns that although the prevention potential of ART is to be welcomed, its active promotion is less welcome, because it might erode the motivation to maintain condom use in at-risk populations. Concerns have also been raised that the findings from HPTN 052 could lead to HIV testing and treatment that was not only universal, but compulsory.

A mathematical modeling article from 2008 found that achieving the ultimate goal of universal HIV testing and treatment for everyone diagnosed with HIV would reduce annual HIV incidence from 2% to 0.1% within 10 years and would reduce prevalence by 95% by 2050 [12]. This article and similar modeling exercises raised alarm. In April 2009, a Civil Society Consultation on ART for Prevention attended by delegates from 7 African countries met in Johannesburg, South Africa. The delegates’ statement declared that they had “fundamental concerns about the flawed and optimistic assumptions on which the model is based, its shortcomings from a human rights perspective and its inattention to vulnerable and marginalised groups . . . the authors’ argument that the benefits of eradicating AIDS

outweigh the potential violations of individual rights that this may occasion is hard to accept” [13].

An Open Society Foundation seminar in October 2009 reiterated these concerns [14]. In its report it said: “It is neither desirable nor possible to scale up voluntary HIV testing and treatment sustainably to implement ART as prevention without addressing . . . human rights [and] health-systems challenges. Strengthening civil society organizations in affected communities is crucial to achieve this goal.”

These very different reactions to the idea of using ART for prevention, and how practicable its application might be, threatened to split the HIV activist community into 2 opposed camps.

Advocates for biomedical prevention, many of whom started as HIV treatment activists, felt that some of the human rights concerns were due to the mathematical model being misread as a policy recommendation rather than a test of assumptions. They also felt that some fears about the toxicity of antiretroviral drugs were outdated and that assumptions that wider ART provision would lead to behavioral compensation were unproven.

Civil society organizations with more of a history of human rights campaigning feared that the “universal test and treat” model might serve as encouragement for agencies and leaders to implement or advocate for whole-population screening and treatment programs that could be oppressive and coercive—or worse, could serve as covers to persecute key affected populations.

These concerns are not entirely misplaced, and are connected to wider concerns about the overly broad criminalization of HIV transmission. Several countries in Africa have enacted or proposed measures that would allow for broad, compulsory HIV testing. In 2013, the government of Botswana signed off on a new public health act [15] that included the following provisions:

- empowering medical practitioners to force their patients to undergo HIV tests without their consent;
- empowering doctors to test patients without their knowledge;
- allowing surgeons or dentists to test a patient for HIV before deciding on whether to carry out a nonurgent procedure;
- mandating HIV disclosure to all potential sexual partners or caregiver(s) and allowing prosecution for placing another at risk;
- empowering doctors to disclose their patient’s HIV status to their sexual partner without their consent; and
- limiting the right to freedom of movement for people with HIV without sufficient legal checks and balances.

Similar measures have been proposed by Tanzania [16] and Uganda [17] and were seriously explored as a policy by a meeting of southern African leaders in Malawi in August 2013 [18].

In addition, as overall HIV prevalence falls in high-prevalence countries, being HIV infected may more than ever threaten “deductive disclosure,” the assumption that the person belongs to a stigmatized minority, as men who have sex with

men (MSM) attested to in responding to the 2012 Global Men's Health and Rights Survey [19, 20]. These concerns have only intensified recently with the passage of legislation in Nigeria and Uganda that intensifies the criminalization of homosexuality, and in Russia of legislation that forbids its promotion.

Instituting HIV therapy in people who feel coerced into or obliged to start ART risks poor adherence and high levels of loss to follow-up; there is some evidence of this in pregnant women offered ART as part of the Option B+ scheme developed by the World Health Organization (WHO), whereby all pregnant women start ART and have it provided lifelong [21, 22].

Such considerations are not just an issue in resource-poor settings. A qualitative study conducted with people who have tested HIV-positive but never had HIV medical care in the United States [23] found that many of these individuals had poor experiences with testing, counseling, and referral services, and health professionals were not always perceived to be compassionate, helpful, or available. In the United Kingdom, African men and nonpregnant women still present, on average, much later for testing than other groups, and this may be related to high levels of concern about being stigmatized that have been documented in this community [24, 25].

VARIANCE IN TREATMENT GUIDELINE RECOMMENDATIONS

Since the mid-2000s, international HIV treatment guidelines have diverged in their recommendations for when to start HIV treatment, partly due to the need to take into account the prevention aspect of ART, and partly due to differing views of the risk/benefit ratio of starting and continuing ART for people with high CD4 counts.

The 2 US guidelines, those from the Department of Health and Human Services [26] and the International Antiviral Society–USA [27], recommend universal ART on diagnosis, as do the French national guidelines [28].

In contrast, the WHO guidelines [29] recommend that ART not be started until patients' CD4 count is <500 cells/ μL , and the European AIDS Clinical Society (EACS) [30] and British HIV Association (BHIVA) [31] guidelines recommend a CD4 level of <350 cells/ μL .

The WHO, however, adds that treatment should also be offered to "HIV-positive people in serodiscordant relationships"; BHIVA says that it is a matter of good clinical practice to discuss the prevention possibilities of ART with all patients and prescribe it if requested for this reason; and EACS recommends that treatment is "considered" for all patients for whom it is not positively indicated.

The differences between these guideline recommendations may not only be driven by genuine differences of opinion about the risk/benefit ratio of ART; they may also reflect

professional differences about the balance of physician responsibility vs patient choice in the doctor–patient relationship. A recommendation of universal treatment may stem from a desire not to leave treatment up to patients who may eventually only decide to take it too late; other guidelines may reflect physicians' experiences of the futility of prescribing treatments to patients who are overtly or covertly not ready to take them.

A COMMUNITY CONSENSUS STATEMENT

Because the issue of treatment as prevention was creating so much debate within the global community of people infected with and affected by HIV, the European AIDS Treatment Group (EATG), a European advocacy organization (www.eatg.org), in collaboration with the international nongovernmental organization NAM (formerly the National AIDS Manual [www.aidsmap.com]), decided to devise its own short set of general principles to be followed when considering ART as prevention.

Initially these were developed because the EATG's previous policy paper on HIV prevention, published in 2009 [32], had no section on the use of ART as prevention. This was a starting point for a statement of principles for the use of ART as HIV prevention. This could be signed on to and used as basic guidance in devising ART provision and HIV prevention programs, and to help community prevention advocates critique such programs.

The consensus statement was developed throughout 2013, starting in March 2013, when a first draft was written by NAM and edited by an EATG writing group. In June 2013, the statement was put up for public consultation and comment on www.aidsmap.com, and on 22 September 2013 the International Association of Providers of AIDS Care (IAPAC) created space for a community satellite meeting at its Controlling the HIV Epidemic With Antiretrovirals evidence summit in London, England. The satellite meeting brought together 50 advocates from prominent HIV organizations, largely from Europe, to discuss it. In November 2013 a substantially revised version, incorporating revisions from the September 2013 meeting, was sent out to the meeting attendees and other HIV organizations and campaigners within and outside Europe for final revisions and preendorsement.

The consensus statement was launched publicly on 27 February 2014, when the www.hivt4p.org website was published. It will be the subject of symposia in several international HIV conferences throughout the year.

The consensus statement covers the issues enumerated in this article in 24 paragraphs, placing the issues within the broader HIV and human rights context and referring to already existing policy frameworks on prevention drawn up by the community of people living with HIV, such as the 2011 Global Network of People Living With HIV/United Nations Joint Programme on HIV/AIDS' Positive Health, Dignity, and Prevention policy framework [33].

The specific issues covered in the consensus statement include:

- the evidence for the efficacy of treatment as prevention;
- advantages: relief from guilt and anxiety;
- disadvantages: implications for risk behavior;
- misuses: coercion and pressure;
- the importance of adherence;
- the importance of patient choice, readiness, and agency;
- the influence of discrimination, social disadvantage, stigma, and criminalization on patient and physician choice;
- challenges to previously accepted norms and targets in HIV prevention;
- the integration of ART as prevention with current HIV prevention and sexual health programs; and
- the support and education needs of HIV-infected and uninfected people.

The full version of the consensus statement also includes 2 appendices: a summary of unanswered questions and research needs, and a review of the efficacy of ART in preventing HIV transmission in different populations and via different transmission routes.

The consensus statement was also introduced at a presentation in the main body of the September 2013 IAPAC evidence summit and was the subject of discussion by a community panel. This included community activists from Europe, Africa, and United States who in their everyday work focus on access to treatment and care for key affected populations and the general population.

Following is greater specificity regarding the topics addressed:

Equity

Access to quality treatment and care is an equity issue. Many parts of the world are far away from universal access [34], but it is vital that no country, and none of the communities that often have the lowest access to treatment despite the greatest need (including people who use drugs, sex workers, migrants, prisoners, and MSM), are left behind. Although the costs of treating all persons in need will be high, the cost argument should not be used to slow down the scale-up of treatment or to withhold treatment from hard-to-reach or stigmatized groups.

Communication of Research Results

The results about the meaning of the HPTN 052 study need to be communicated without bias to patients, medical personnel, and decision makers. To make proper treatment decisions, there is a need both to understand and communicate the study's possible limitations and its unquestionable benefits.

The data from the study may impact on people who live with HIV, especially on their relationships and sexual relations, in

unpredictable ways. Prevention messaging should not be over-medicalized; it is healthcare workers' responsibility to communicate to patients at a level that suits their knowledge.

Ethical Standards of Research and Implementation

Research needs to be based on ethics and standards of prevention and care. The Bangkok Tenofovir Study in people who use drugs is an example of a study that faced challenges by local statutes to provide best evidenced-based preventions, in this case needle and syringe programs (NSPs) [35]. The same holds true of implementation of ART as prevention among key affected populations. Harmful policies and laws that restrict access to NSPs and opioid substitution therapy, or condoms and lube for sex workers and MSM, which are either illegal or seen as evidence of illegal activities, must not shape the way health programs are implemented.

Process of Science

Scientists, the HIV community, and policymakers have been discussing and recognizing research gaps. These need to be methodically followed to avoid research duplications, reduce costs and, ultimately, serve the patients in need.

Additionally, the regions that have been excluded from the treatment as prevention discourse, such as Eastern Europe and Central Asia, need to have implementation researchers address the questions about coverage of NSPs, opioid substitution therapy, ART, and their impact on reduction of HIV and HIV-related conditions, tuberculosis, and multidrug-resistant tuberculosis-related mortality.

Implementation

In a reality where universal healthcare is not guaranteed, where gender-based violence and violence toward key affected populations is prevalent, where physicians' responsibility and patients' choice do not always go hand-in-hand, and where a patient-centered approach needs much improvement, a discussion about implementation of treatment as prevention can be academic. Late diagnosis and late initiation of treatment are still an issue, and linkage to care, case management of patients, adherence, and retention need to be improved if the treatment cascade is to end up with more people on ART, healthy, and with controlled viremia.

Community involvement in the treatment cascade does exist, and community members are key in performing outreach, counseling, case management, and peer support, but community involvement is not a sufficient condition for patients to have self-determination about how HIV testing, treatment, and care are delivered. New areas to be explored include the implications of new technologies such as home-based testing, and how much of HIV testing and care can be done by nonmedical professionals in nonmedical settings.

CONCLUSIONS

In short, what initially may have seemed like a straightforward issue—the expansion of the use of ART so as best to realize its potential in helping curb the HIV epidemic—has a number of different implications, some of which are opportunities for the global population of people with or at risk of HIV, and some of which, if applied without regard to their human rights and human dignity, could be threats.

Serving the communities in need is at the core of community-based interventions. Community-based prevention and testing workers are dedicated to providing a service but often have to work in gray areas of the law. Civil society needs support and bold thinking from medical professionals about how criminalized communities can be effectively and meaningfully involved in healthcare delivery.

“Test, treat, and retain” programs will only work if they have a human face. Noncoerced testing, access to care for everyone in need, affordable medicines, and a focus on interventions that work for key affected populations are all needed to secure patient retention and to bring about the preventive potential of ART. For all these to happen, the involvement of communities, clinicians, and politicians are all crucial.

It is hoped that the consensus statement (available at www.t4p.org) can form a broad set of principles that can be referred to when devising HIV prevention and sexual health programs that truly have the interests and rights of target populations at their heart.

Notes

Disclaimer. No funder had any influence on the writing of the Community Consensus Statement or its process of development. The content of EATG’s work is not influenced by the funders. NAM publications as a charity is supported by numerous funders, including 9 pharmaceutical companies; a full list of supporters can be viewed at <http://www.aidsmap.com/our-funders>. Gilead Sciences provided in-kind resources to NAM Publications to assist in the statement’s press launch but had no control over press releases, speakers, or any other content of the launch.

Financial support. The development of the Community Consensus Statement was supported by Gilead Sciences, ViiV Healthcare, and Merck.

Supplement sponsorship. This article is published as part of a supplement entitled “Controlling the HIV Epidemic With Antiretrovirals,” sponsored by the International Association of Providers of AIDS Care.

Potential conflicts of interest. G. C. works for NAM publications. NAM received grants from Gilead Sciences, ViiV Healthcare, and Merck toward setting up a European prevention advocacy program, of which the Community Consensus Statement that is the subject of the article was part. B. W. is chair of the European AIDS Treatment Group, which is funded partially by funding from ViiV, MSD, Gilead AbbVie, and Janssen. A. C. B. works for the health development nonprofit organization FHI 360, where he is project director for the National Institute of Allergy and Infectious Diseases (NIAID)–funded Be the Generation Project to educate and build support among community for HIV biomedical prevention research. FHI 360 receives additional funding from NIAID and other partners to conduct research of biomedical prevention strategies.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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