



# THE ROLE OF PEOPLE LIVING WITH HIV IN NEW PREVENTION TECHNOLOGIES

OUR ADVOCACY AGENDA

# CONTENT

<b>INTRODUCTION</b>	03
<b>1. MEANINGFUL ENGAGEMENT</b>	04
<b>2. A COMMON UNDERSTANDING</b>	06
<b>3. TREATMENT FIRST</b>	08
<b>4. RESPECT OUR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS</b>	10
<b>5. SHARED RESPONSIBILITY</b>	12
<b>6. UNIVERSAL ACCESS</b>	14
<b>POSITIVE HEALTH, DIGNITY AND PREVENTION</b>	16
<b>REFERENCES</b>	17

# INTRODUCTION

In 2009, the Global Network of People Living with HIV (GNP+) began working with networks of people living with HIV in order to explore the role of HIV-positive people in shaping research and development of biomedical HIV prevention, also known as new prevention technologies (NPTs).

Specifically, GNP+ convened a working group comprising members of six regional networks of people living with HIV as well as partner networks. The working group held four teleconferences throughout 2009 supplemented by an online discussion forum. The outcomes of the working group were presented at AIDS 2010 in Vienna<sup>i</sup> and included a discussion paper<sup>ii</sup> and a toolkit.<sup>iii</sup>

In July 2010, GNP+ convened a two day consultation in Amsterdam on the implications of NPT research and development for people living with HIV. The objectives of the consultation were as follows:

- To provide networks of people living with HIV with an update of current HIV prevention trials;
- To foster open and constructive dialogue

between different stakeholders (networks of people living with HIV, NPT advocacy organisations, product developers and normative agencies) on the role of people living with HIV in the research and development of biomedical HIV prevention; and

- To develop an advocacy agenda driven by people living with HIV.

This advocacy agenda is a tool for people living with HIV to advocate with other stakeholders in NPTs. It features six key points and is the outcome of the presentations and discussions at the consultation, as well as the working group's recommendations. It is envisaged that this agenda is a work in progress that will evolve in response to the results of NPT clinical trials currently in progress as well as broader developments in HIV policy as it relates to HIV prevention and people living with HIV.

# 1. MEANINGFUL ENGAGEMENT

PEOPLE LIVING WITH HIV MUST BE MEANINGFULLY ENGAGED, INVOLVED AND REPRESENTED IN THE ETHICS, DESIGN AND IMPLEMENTATION OF NPT CLINICAL TRIALS.

## RATIONALE

People living with HIV have a critically important role to play in HIV prevention, both in advocating for improved access to existing prevention options and for the development of NPTs. As community members with a great deal of insight into the realities of living with HIV and with professional, as well as personal, expertise in many areas of HIV we must be able to contribute on an equal footing as representatives of people living with HIV when we engage in NPT clinical trials development, and with normative agencies.

Biomedical HIV prevention clinical trials for products that are aimed at HIV-negative individuals—preventative vaccines, PrEP, and antiretroviral (ARV)-containing vaginal and rectal microbicides—may involve people living with HIV in the following ways: potential participants who discover their HIV-positive status during recruitment and screening; participants who test HIV-positive during the study; and HIV-positive partners of HIV-negative participants enrolled in a trial as part of a sero-discordant couple. People living with HIV may also be part of the trial

staff (for example, doing outreach, working in labs, or providing counselling); be members of Community Advisory Boards (CABs) and other community outreach initiatives; and, may sit on clinical trials' Institutional Review Boards (IRBs).

Including people living with HIV in the design and implementation of NPT clinical trials will not only help ensure that the experience, rights and interests of HIV-positive people are recognised and addressed, but will also improve the trial's outcome due to their unique perspectives on translating international clinical trial ethical standards<sup>iv</sup> and good participatory practice<sup>v</sup> to local community settings.

People living with HIV can inform the design and implementation of NPT clinical trials in various ways including: the research protocol; study populations; recruitment and retention of participants; informed consent regarding the potential harms and benefits; confidentiality; risk-reduction counselling; and the inclusion of key populations.<sup>1</sup>

Furthermore, understanding the broader context of living with HIV in the local

community is critical to a range of ethical and practical issues, including designing appropriate referral and follow-up approaches that link HIV-positive people involved in HIV prevention trials to treatment, care and support services. In particular, people living with HIV can provide guidance on how to mitigate the harm of HIV-related stigma, which may be a barrier to trial participation, HIV testing, disclosure of HIV-positive status and ability/willingness to follow-up linkages to treatment, care and support.

## ACTION

- People living with HIV networks, and advocates working on behalf of HIV-positive people, should advocate for the full and meaningful participation of HIV-positive people in all aspects of NPT clinical trials.
- This requires increasing discussion among and between regional and national networks and between networks and NPT researchers, advocates and other stakeholders in order to improve the participation of the community in the dialogue on NPTs.

<sup>1</sup> Key populations at higher risk of living with HIV due to their social or legal status and/or behaviour include: indigenous peoples, men who have sex with men, migrants, people who use drugs, prisoners, refugees, sexual minorities (including intersex and transgender people), sex workers, women, and young people.

## 2. A COMMON UNDERSTANDING

WE REQUIRE A COMMON UNDERSTANDING BETWEEN PREVENTION ADVOCATES AND TREATMENT ACTIVISTS IN ORDER TO ADVOCATE FOR NEW PREVENTION TECHNOLOGIES TO FIT WITHIN THE BROADER UNIVERSAL ACCESS AGENDA.

### RATIONALE

Despite unprecedented progress over the past decade in the move towards universal access to antiretroviral therapy (ART), it is estimated that only 36% of the 14.6 million people in low- and middle-income countries eligible for treatment based on the latest WHO treatment guidelines<sup>2</sup> were receiving ART at the end of 2009. Recent reports from Africa<sup>vii</sup> and Eastern Europe<sup>viii</sup>,<sup>3</sup> highlight that governments are beginning to cap the number of people living with HIV enrolled in treatment programmes and that drug stockouts are becoming increasingly more frequent.

The rollout of ARV-based prevention methods may lead to competition for resources in terms of ARV supply, as well as on health systems generally. Notably, experimental PrEP regimens in most current and planned clinical trials include two of the most commonly prescribed ARVs, both produced by Gilead: tenofovir, and tenofovir plus emtricitabine (FTC), packaged in one pill under the trade name *Truvada*.

Networks of people living with HIV in low- and middle-income countries are already hearing concerns about the impact of resource limitations should PrEP be made available in settings where access to ART is less than universal. The consultation heard that some women and other vulnerable people living with HIV already worry that their ARVs may be taken away from them and given to another family member who is viewed as “needing them more” for PrEP. Might people living with HIV sell their ARVs to be used as PrEP in order to obtain basic essentials of daily life?

Voluntary counselling and testing, followed by prescription, will likely become the gateway to obtaining ARV-containing NPTs. Regular follow-up will be required due to concerns over toxicity, adherence, and resistance should the individual become HIV-positive whilst using ARV-containing NPTs.<sup>ix</sup> Such increased testing will also likely greatly expand the number of diagnosed people living with HIV who require ART for their own health, as well as for ART’s additive prevention benefit (see 3). If resources are limited, however, such individuals may compete not only for ARVs, but also for

ongoing care and support with individuals who require ARV-based NPTs for prevention purposes.

For the first time, the consultation brought together networks of people living with HIV, prevention advocates and treatment activists to create a common understanding of NPTs that helped to remove the false dichotomy between prevention and treatment. Rather, it was agreed that advocacy for NPTs should be placed within with the broader universal access movement. However, such advocacy requires further collaboration between prevention advocates and treatment activists as well as broader community engagement.

### ACTION

- A common understanding requires capacity building between prevention advocates and treatment activists of the NPT research agenda as it relates to people living with HIV.
- Treatment activists and prevention advocates must further engage in dialogue regarding the challenges and opportunities for linkages between ARV-based prevention, other NPTs, and universal access to existing prevention, testing, treatment, care and support.

<sup>2</sup> In November 2009, WHO produced new guidance recommending ART before CD4 counts fall below 350 cells/mm<sup>3</sup>; prior guidance recommended treatment for people with advanced symptoms of HIV disease, or a CD4 count below 200 without symptoms. See [www.who.int/hiv/pub/arv/advice/en/index.html](http://www.who.int/hiv/pub/arv/advice/en/index.html)

<sup>3</sup> The website [www.pereboi.ru](http://www.pereboi.ru) from the International Treatment Preparedness Coalition in Eastern Europe and Central Asia (ITPCru) reports stockouts in Ulyanovsk, Samara, Arkhangelsk, the Moscow Oblast, Vladimir, Kaliningrad, Saratov and other regions.

# 3. TREATMENT FIRST

PROVIDING ART TO PEOPLE LIVING WITH HIV SHOULD ALWAYS PRIORITISE AND RESPECT OUR HEALTH AND DIGNITY, WITH PREVENTION AN IMPORTANT, BUT SECONDARY, BENEFIT.

## RATIONALE

Antiretroviral therapy may be one of the single most effective prevention methods currently available.<sup>x</sup> A number of studies have shown that where ART is widely available and accessible it has the potential to greatly reduce HIV transmission risk between couples of different HIV status<sup>xi xii xiii</sup> and also have an impact on new infections at a population level.<sup>xiv xv xvi</sup> These results have been found in both high income and low income countries.

The use of ART in combination with existing prevention methods in order to reduce new infections on a population level is currently being studied around the world using four different models:

- Increased treatment uptake, also known as 'seek and treat' (pilot study, Vancouver, Canada)
- Increased testing with linkage to care, plus treatment based on clinical need, also known as TLC+ (pilot study, Bronx and Washington DC, United States)
- Early versus deferred treatment, to understand the optimal CD4 count to initiate treatment and appropriately balance the

health needs of the individual with the additive preventative benefit of ART (clinical trial HPTN052 in eight low-and middle-income countries and Boston, US)

- Universal voluntary testing and treatment at any CD4 count, to 'test and treat' entire communities and begin ART immediately (two feasibility studies in preparation: Pop ART in Uganda and Zambia and TasP in South Africa.)
- In addition, a population-based 'treatment as prevention' approach is currently being implemented in San Francisco, although it is not being labelled as such by its implementers.<sup>xvii xviii</sup>

Consultation participants agreed that the primary purpose of ART for someone who is HIV-positive is to benefit their own health, and that any preventative benefits are important, but secondary, considerations. Clinical trials, as well as any 'treatment as prevention' policies and programmes must therefore occur within a human rights framework that respects and supports the health and dignity of people living with HIV.

Potential human rights violations such as forced or uninformed testing, or coerced initiation of ART primarily for the benefit of public health rather than of the individual are likely to lead to loss of follow-up, poor adherence and an increase in the prevalence and transmission of drug resistant strains of HIV, all of which will undermine the potential of treatment's prevention benefits, as well as the rights of people living with HIV.

Individuals living with HIV must have the right to choose *if* and *when* to start (or stop) treatment after receiving appropriate risk-benefit counselling. Adherence counselling both before and after initiation of ART is essential to support the individual living with HIV to make informed decisions about whether and when to initiate treatment and to adhere to a treatment programme once started. The individual benefits of treatment on health versus reducing the risk of new HIV infections and of reinfection must inform this discussion. It is also essential that there is uninterrupted access to ART once treatment commences.

However, consultation participants were also clear that impact of treatment on

preventing new HIV infections is an important opportunity for widespread HIV-related stigma reduction (where fear, discrimination and/or prosecution is based on infectiousness of the HIV-positive individual) and to further advocate for scaling-up universal access to testing, treatment, and care, including access to viral load testing and regular screening for sexually transmitted infections (STIs).

## ACTION

- People living with HIV networks, and individual advocates working on behalf of HIV-positive people, should take ownership of the 'treatment as prevention' agenda to ensure that ART is primarily for the health needs of HIV-positive people and that the prevention benefits are seen as an important secondary goal.
- Scaling-up 'treatment as prevention' literacy for people living with HIV to understand the various 'treatment as prevention' models, and focusing on human rights as it relates to testing and treatment must be part of this advocacy.

# 4. RESPECT OUR SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS

DEVELOPMENT AND IMPLEMENTATION OF NEW HIV PREVENTION TECHNOLOGIES MUST ENSURE THAT THE SEXUAL AND REPRODUCTIVE HEALTH AND RIGHTS (SRHR) OF PEOPLE LIVING WITH HIV ARE AFFIRMED AND RESPECTED.

## RATIONALE

Although there are efforts to develop non-ARV-based microbicides as an important option both for people who are HIV-positive and HIV-negative, most NPTs—including preventative vaccines, PrEP, and anti-retroviral-containing microbicides—are being designed for the exclusive use of HIV-negative individuals.

In addition, current high-level policy discussions regarding one of the sole NPTs aimed at people living with HIV—ART's preventative effects—are not focusing on how individuals living with HIV are to be informed regarding ART's effects on their individualised HIV transmission risk.<sup>xx</sup> This is primarily due to the following concerns:

- Lack of randomised controlled studies to show a direct correlation between reduced viral load due to ART and a reduction in new infections
- Unknown threshold of viral load below which transmission cannot occur
- Residual risks due to differences in viral load between the blood and sexual fluids

- Residual risks due to variations in viral load between clinic visits
- Incomplete data for anal sex
- Unknown impact on sexual behaviour

Following diagnosis, people living with HIV continue to have the same needs and desires for intimacy, family and community as before. However, the consultation heard that some healthcare providers do not respect the sexual and reproductive rights of people living with HIV. In Kenya, for example, HIV-positive women face negative attitudes from healthcare providers when they seek prevention commodities.<sup>xx</sup> In Chile<sup>xxi</sup> and Namibia<sup>xxii</sup> HIV-positive women have been sterilised against their will. Consultation participants also noted the gap in research and current discourse on non-barrier HIV prevention methods for the purposes of intimacy and pleasure, not only for reproduction.

People living with HIV and their partners need to be able to make informed choices regarding whether, and how, to be sexually active and fulfilled, and whether, and how, to conceive and enjoy a family. To this

end, consultation participants agreed that people living with HIV urgently require the development of NPTs—in particular non-barrier prevention methods, such as non-ARV-containing vaginal and rectal microbicides—that are safe, affordable, accessible and responsive to the needs of people living with HIV. Such options are especially important since they could also help reduce the risk of STI acquisition and transmission.

Further research regarding the impact of ART on individual infectiousness is necessary to better understand the exact circumstances when ART might be used by an individual living with HIV as their sole HIV prevention method. Both strands of research would provide new options, new benefits, and new motivations for people living with HIV to be involved in HIV prevention research and advocacy.

## ACTION

- There should be continued advocacy for the rights of people living with HIV to have sex and to have children. This includes community sensitisation to accept HIV-positive parents, and the desire by

people living with HIV for non-barrier sex for intimacy and pleasure. In particular, grass roots-led engagement with public health officials who will roll-out NPTs is required to emphasise the particular needs, desires and rights of people living with HIV.

- People living with HIV networks, and individual advocates working on behalf of HIV-positive people, must continue to advocate for non-ARV-containing microbicides and other NPTs, to ensure a robust pipeline of approved and experimental compounds that are safe, affordable, accessible and responsive to the needs of people living with HIV.

# 5. SHARED RESPONSIBILITY

RESPONSIBILITY FOR HIV PREVENTION SHOULD BE SHARED REGARDLESS OF KNOWN OR PERCEIVED HIV STATUS.

## RATIONALE

One of the key principles of Positive Health, Dignity and Prevention—the new framework that uses a holistic, human rights-framed approach to prevention for people living with HIV (see page 16)—is that preventing new HIV infections is the shared responsibility of everyone irrespective of HIV status. Consequently, the framework rejects the criminalisation of HIV-positive status non-disclosure, or non-intentional HIV transmission, as well as policies and programmes that focus exclusively on ‘preventing onward transmission’—both of which can create the perception of one-sided responsibility for HIV prevention and suggest that people with HIV are scapegoats to blame when new HIV infections occur. It suggests that ‘shared responsibility’ for HIV prevention is about recognising the role that broader social determinants of health play in human and sexual behaviour, and creating an environment for HIV prevention beyond the individual to include everyone regardless of their HIV status or proximity to the HIV epidemic.

Consultation participants welcomed the promise of NPTs—particularly PrEP and microbicides—for their potential to assert increased personal responsibility for HIV-negative partners to protect themselves. However, since no individual NPT is ever likely to be 100% effective (i.e. reducing HIV transmission risk to zero) even if NPTs are shown to have high efficacy when used as prescribed, there still may be occurrences of new infections for HIV-negative partners who elect to use NPTs as their primary or sole means of HIV prevention. Unlike condoms, which are usually visible to both partners, NPTs—including vaccines, PrEP, microbicides and using ART for its preventative effects—could be used invisibly, allowing for independent decision-making for HIV prevention that may or may not be disclosed to a sexual partner.

## ACTION

- Advocates must work together to form a common understanding of shared responsibility for HIV prevention.
- Such understanding will also necessitate guidelines from normative agencies around HIV-related risk and NPT efficacy along

with community-relevant translation of such guidelines in order to improve literacy about risk and efficacy among people living with HIV, their partners, families and communities.

- Advocates must also work together to address the potential implications of NPTs for the HIV-positive partner in jurisdictions where legal frameworks currently hold an HIV-positive partner responsible for new infections under certain circumstances, including non-disclosure of known HIV-positive status.<sup>xxiii</sup>

# 6. UNIVERSAL ACCESS

UNIVERSAL ACCESS TO VOLUNTARY COUNSELLING AND TESTING, PREVENTION, TREATMENT, CARE AND SUPPORT MUST BE TRULY UNIVERSAL.

## RATIONALE

Globally, fewer than one person in five at risk of acquiring HIV has access to basic HIV prevention services.<sup>xxiv</sup> The consultation heard that in many settings around the world there remains inadequate access to male and female condoms, needle/syringe exchange, medical male circumcision, post-exposure prophylaxis (PEP), prevention of vertical transmission and voluntary counselling and testing. Consultation participants agreed that advocating for improved access to currently proven prevention methods sets the stage for the effective introduction of NPTs.

Doing this requires understanding and overcoming existing barriers to current HIV prevention methods, including HIV testing. Participants highlighted that truly universal access means focusing on structural and other barriers faced by marginalised communities and/or key populations. This will require the meaningful engagement of people living with HIV from key population groups in all aspects and at all levels.

Improving access also requires a better understanding of the end-user by manufacturers and marketers of NPTs. Participants agreed that limitations of existing and experimental prevention technologies are a 'product problem' and not a 'people problem'. In other words, an efficacious product must fit into the lives of those who use them, and not other the way round. To this end, participants agreed that a more helpful approach to NPTs would be to highlight a person-centred methodology and to promote linkages and synergies with other health needs, such as harm reduction or prevention of vertical transmission services.

## ACTION

- Advocates should work together to address concerns around the ethics of access and feasibility of NPT rollout, and understand the target audience for NPTs to prepare for NPT usage guidelines, programming and NPT communications strategies, including social marketing.
- The introduction of NPTs also presents a rare opportunity for advocates to be proactive and engage with agencies such as the World Trade Organization and the

International Monetary Fund to talk about trade-related aspects of intellectual property rights (TRIPS). Prevention advocates may benefit from the experience of treatment activists in this regard.



# POSITIVE HEALTH, DIGNITY AND PREVENTION

Positive Health, Dignity and Prevention is the new name for a revised concept of HIV prevention for and by people living with HIV, formerly known as 'positive prevention'. The Positive Health, Dignity and Prevention framework focuses on improving and maintaining the dignity of the individual living with HIV, which has a positive impact on that individual's physical, mental, emotional and sexual health, and which, in turn, creates an enabling environment that will reduce the likelihood of new HIV infections.

When it comes to HIV prevention, people living with HIV must be seen as part of the solution, and not as part of the problem. The public health goal of preventing new infections can only be achieved when the human, sexual and reproductive rights of people living with HIV are protected and supported; when the broader health and security needs of people living with HIV are met; and when access to timely and uninterrupted treatment and care encourages greater uptake of voluntary counselling and testing.

By linking together the social, health and prevention needs of the individual living with HIV within a human rights framework, Positive Health, Dignity and Prevention results in a more efficient use of resources with outcomes that are more responsive to the needs of people living with HIV, with additional benefits for their partners, families and communities.

A key principle of Positive Health, Dignity and Prevention is the assertion that policies and programmes for people living with HIV should be designed and implemented with the meaningful involvement of people living with HIV.

This NPT advocacy agenda for people living with HIV should not be used in isolation but as part of holistic work for all HIV prevention, health and dignity issues that affect people living with HIV. This will help ensure that opportunities presented by NPTs are fully realised and reflect the sexual and reproductive rights, holistic health and HIV prevention needs for people living with HIV, resulting in further community empowerment.

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NEW -----  
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