

# Towards HIV Treatment on Demand for All

Closing the gap between science and policy: Analysis of the current state of practice regarding the initiation of HIV treatment

## Summary

The world faces an important window of opportunity in the trajectory of the global AIDS response. New scientific evidence shows that starting HIV treatment immediately upon diagnosis enables people to live longer, healthier lives and is among the most effective ways to prevent HIV transmission. Several years ago, in response to this evidence, some countries began providing all people living with HIV access to immediate treatment. Since results from the START trial were released in July 2015, there is widespread global consensus that immediate treatment is the best medical standard. Yet, the vast majority of people living with HIV live in countries that do not provide the opportunity for immediate access to treatment for all (or ‘treatment on demand’) as a matter of policy and practice, typically because of insufficient resources and rationed health services.

The global goal to end the AIDS epidemic by 2030 is both ambitious and achievable. A key step in achieving this goal is the UNAIDS target for 2020, ensuring that 90% of all people living with HIV know their HIV status, 90% of all people with diagnosed HIV receive antiretroviral treatment and 90% of all people receiving antiretroviral therapy are virally suppressed. These goals will only be met if the human right to access to treatment immediately upon diagnosis is realized. This is particularly true for key affected populations, including men who have sex with men, people who use drugs, sex workers, transgender persons and others who are systematically discriminated against, criminalized and underserved.

This report, assembled by activists, clinical providers, people living with HIV, and public health practitioners, provides a global overview of the key advances in science, the current state of practice regarding the initiation of HIV treatment around the world, and the policy barriers to ensuring universal access to treatment on demand for all people living with HIV, everywhere. Most importantly, it includes a set of demands—clear actions that donors, country governments, policy makers and implementers should take, between now and June 2016, when

activists, experts and world leaders convene in New York for the United Nations (UN) High Level Meeting on HIV/AIDS. Our goal, is substantial progress on realizing treatment on demand for all, by the time activists convene for the International AIDS Conference in Durban, South Africa in July 2016, where we will again report on the global state of play.



*No person living with HIV should be told to wait until they become sicker to receive treatment. We envision a world where everyone has access to effective, high-quality care from the moment they are diagnosed.*

# Key points

Our analysis, detailed in this report, shows that:

**1** Fewer than 1 out of 10 people living with HIV worldwide live in a country where the science of immediate antiretroviral therapy or “treatment on demand” is currently policy for all people. Instead, many are sent home from clinics after diagnosis, to come back only once they are sick enough to be eligible for treatment.

**2** Of the 114 countries with published guidelines, 101 countries will need to move quickly to adopt the current global consensus to provide ART for all irrespective of CD4 count. Fifty-five countries are severely out of compliance (even with the previous WHO guidelines), and only provide for treatment initiation at either <350, <250 or <200 CD4 counts.

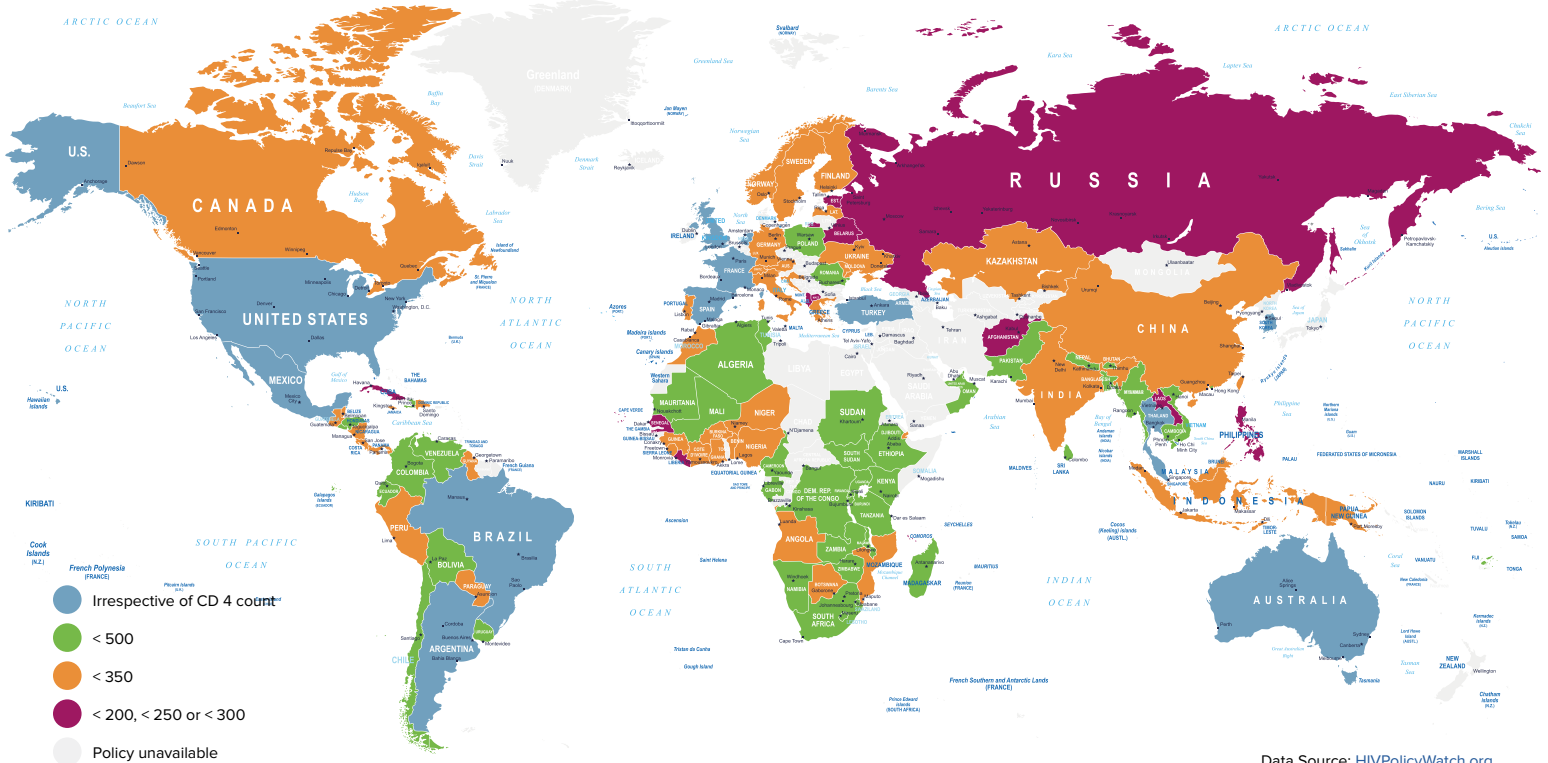
**3** The 13 countries that offer immediate treatment to all people with HIV represent just 4.4% of the estimated global burden of 1.2 million AIDS-related deaths in 2014.<sup>3</sup>

**4** The majority of the global burden of HIV is among low and middle-income countries, while all 13 countries that extend HIV treatment for all are either high-income (62%) or upper middle-income (38%).<sup>4</sup>

**5** The average GNI per capita among the 13 countries adhering to WHO-recommended standards of care is \$29,388, whereas for the 20 countries accounting for approximately 80% of global disease burden, the average GNI per capita is only \$9,003.<sup>5</sup>

**6** Across all countries, people living with HIV experience other routine barriers to quality treatment, including outmoded models of clinical care, poor quality of treatment effectiveness monitoring, intellectual property barriers that prevent affordable access to the most effective medicines with the least side-effects, and stigma, discrimination and criminalization that undermine access to quality, non-judgmental services.

## There is a stark global divide between people who do and do not have access to HIV treatment upon diagnosis



Data Source: [HIVPolicyWatch.org](http://HIVPolicyWatch.org)

# A new standard of care to help end the epidemic

In September 2015, world leaders convened at the United Nations to launch a new set of global development goals, and pledged their commitment to ending the AIDS epidemic as a public health threat by 2030. This is achievable. The scientific evidence is clear—extending access to HIV treatment for all people with HIV, regardless of disease stage, enables a longer, healthier lifespan and is among the most effective ways to prevent HIV transmission as one part of a comprehensive HIV response.

In the face of overwhelming evidence, the World Health Organization (WHO) brought its recommendations in line with the best science and released new global guidelines on HIV in September 2015, recommending that all people living with HIV be started on HIV treatment regardless of disease stage. Additionally, the new WHO guidelines call for expanded availability of pre-exposure prophylaxis (PrEP) to groups at “substantial risk” of contracting HIV.

Currently 15.8 million people worldwide have access to HIV treatment.<sup>6</sup> Earlier WHO treatment

guidelines recommended that health care providers wait until people with HIV are immunocompromised before starting treatment.<sup>7</sup> The new WHO guidelines mean an additional 21.2 million people need urgent access—countries must accelerate scale up by doubling the pace of treatment enrollment in order to reach the 90-90-90 targets by 2020 and to defeat AIDS by 2030. The new guidelines herald a new, game-changing global standard of HIV treatment, the implementation of which will determine success or failure in the struggle to end the AIDS epidemic within the next 15 years.

## SNAPSHOT

# The Science to End the Pandemic

### HPTN 052:

In 2011, this randomized controlled trial showed that ARV treatment was 96% effective in preventing HIV transmission. People living with HIV receiving ART are more than 20 times less likely to transmit HIV. When a person’s viral load is undetectable, the chances of transmitting HIV are virtually zero.

### START

In May 2015, The Strategic Timing of Antiretroviral Treatment study conducted in 215 sites in 35 countries showed that rather than waiting for immune deterioration (CD4 cell count counts to fall below a set level), immediate ARV treatment more than doubles an individual’s prospects of staying healthy and surviving.

### TEMPRANO

This trial, conducted among 2076 people in Cote d’Ivoire, showed in 2015 that starting treatment at CD4 cell count >500 reduced the risk of death and serious illness by 44% compared with waiting to start treatment according to the WHO guidelines at the time.

# A stark global divide

In some of the wealthiest countries in the world, treatment upon diagnosis, has been the standard of care for at least 3 years. However, only an estimated 9% of people living with HIV live in a country where this standard of care is national policy. The vast majority of people living with HIV in the world live in countries where at least some people must wait to start treatment—sometimes until they are gravely ill—as a matter of policy and practice.

The result is disease progression, premature death and avoidable HIV transmission. Ending AIDS and realizing the human right to health requires that all people with HIV have the opportunity to choose to start quality life-saving treatment immediately upon diagnosis instead of being turned away or told to come back after their immune system is further compromised.

## Eliminating preventable delays in bridging the gap between policy and science

People with HIV in high burden countries have experienced major delays between the time of scientific innovation and implementation. Prior experience with WHO-recommendations have shown unacceptable time lags in the adoption and implementation of global guidelines on a country-level. There have been time lags of 2 years and counting before national guidelines have been changed to reflect global consensus; and of up to 5 years before country-level implementation, when actual clinical practice shifts to reflect policy.<sup>8</sup>

**Eliminating these delays as quickly as possible—through increased government and donor funding, better investment of existing resources, and greater accountability to those living with and affected by HIV—has never been more important in the struggle to end AIDS by 2030.**



*Fewer than 1 in 10 people with HIV live in a country where they can access HIV treatment immediately on diagnosis.*

## Moving from Catch-up to Scale-up

Today at least 101 countries are yet to adopt the current WHO guidance, which recommends provision of ART irrespective of CD4 count. Of these, 55 are severely out of compliance and have not yet caught up to the 2013 WHO guidelines, and are instead recommending initiation of ART at <350, <250 or <200 CD4 counts.

In addition to the 13 countries recommending test and treat for all PLHIV, 12 countries have prioritized ART for key populations.

**13**

Countries providing ART irrespective of CD4.

(WHO 2015 GUIDELINES)

**12**

Countries providing ART for key populations only irrespective of CD4 count

Including: Tanzania, Uganda, Rwanda, Cameroon, Indonesia, Myanmar and Viet Nam.

(WHO 2013 GUIDELINES)

**46**

Countries providing ART at <500.

(WHO 2013 GUIDELINES)

**43**

Countries providing ART at <350 CD4 count.

(WHO 2010 GUIDELINES)

**12**

Countries providing ART at <200, <250 or <300 CD4 Count.

Including: Afghanistan, Belarus, Cape Verde, Comoros, Cuba, Estonia, Lao People's Democratic Republic, Liberia, Macedonia, Philippines, Russia, Senegal.

# Key Roadblocks to Scaling up Treatment on Demand

There is no longer a debate about when to start treatment, so what is causing this deadly inequity? Four main policy barriers have created a vicious cycle that has prevented people from accessing quality treatment upon diagnosis:

1

## **Insufficient funding, and ineffective resource allocation, from both donor and key affected countries:**

Leaving no one behind in the effort to ensure universal access to HIV treatment on demand will require clear targets, greater efficiencies, and increased investments over the short-term. However, turning people away from life-saving treatment will cost us more in the long run, and the additional resources required for universal access to treatment on demand will result in substantial benefits for individuals, families and communities. Many low and middle-income countries have taken great strides to increase spending on their HIV responses over recent years, but governments can and should do more to improve their national response. At the same time, over the past 5 years, some donors have flat-lined or reduced resources for global AIDS programs and others, while increasing their funding overall, have significantly reduced funding to middle-income countries. These reductions, coupled with poor priority setting in some cases, have led many national programs to ration life-saving care rather than acting on scientific evidence. Donors must take immediate action to reverse these trends by increasing global funding for the response and ensuring middle income countries can and will scale up their domestic responses before donors pull out. Funding cuts by donors have also impacted funding for the civil society organizations (CSOs), who played an essential role in mobilizing political will in response to the AIDS epidemic throughout the 2000s. Civil society will again have to play this role if the AIDS response is to break out of the current inertia and flat-lining. It is therefore essential

that donors invest in civil society organizations that are willing to once again politicize the AIDS response. Yet today some of the most important CSOs in the AIDS response face financial crisis as donors change priorities.

2

## **High price of newer, improved medicines:**

While the price of many antiretroviral medicines has decreased significantly over the past 15 years, trade and intellectual property rights barriers inhibit affordable access to newer, more effective medicines. Side effects of many antiretroviral medicines can be a hindrance in adhering to treatment and starting treatment early may exacerbate this challenge. Combination regimens containing the least toxic and most effective medicines are unavailable in many countries due to their higher cost. This problem is especially acute in middle-income countries, which are excluded from voluntary licenses and price discounts. Overcoming patent and other IP monopolies and driving down the cost of medicines through robust generic competition is urgently needed.

3

## **Models of care that contradict evidence of what works best:**

Many HIV programs are using less-effective models of care that are particularly ill-suited to scaling up treatment access for asymptomatic people. These programs may offer ineffective testing and outreach programs, provide first line treatment regimens that use medicines with multiple side effects, lack routine viral load monitoring, use frequently costly

CD4 cell counts and chemistries that are unnecessary for treatment management, or do not include community-based programming to help ensure that people stay in care and remain virally suppressed. Models that include community testing, treatment education, reduction in the number of clinic visits for stable patients and multi-month refills have all been shown to decrease burden on patients and health systems, without compromising care and, in many cases, improve patient outcomes. Treatment programs need a radical overhaul to respond to the new imperative of extending HIV treatment to all people with HIV and communities need to be at the center of these models of care.<sup>9</sup>

4

## **Stigma, discrimination and legal barriers:**

In many countries key affected populations, such as men who have sex with men, people who use drugs, sex workers, and transgender persons, are criminalized and systematically excluded from health services. In these cases, institutionalized discrimination and punishment result in their exclusion. Moreover, in middle-income countries (where governments often have a greater ability to pay), lack of political will or inexperience in delivering effective key population programming results in the exclusion of the people most in need. In some cases, laws meant to protect vulnerable populations, such as children, end up preventing them from getting access to HIV testing and being enrolled into care. These barriers deny the fundamental human right to health to millions of people and therefore must be systematically overcome.

# No time to lose

This new global standard is meaningless if governments do not adopt, fund, and implement WHO's recommendation that all people with HIV be offered treatment upon diagnosis. The world cannot afford the costs of inaction - without accelerated access to quality treatment and health services, HIV deaths and new infections will continue at an unacceptable rate.

## The Benefits of Action



### Worldwide<sup>10</sup>

According to UNAIDS, scale-up of ART to achieve 90-90-90 targets in 2020 could:

- Avert 21 million AIDS-related deaths by 2030
- Avert 28 million HIV infections by 2030
- Allow for a 17-fold return on HIV investments, based on total economic benefits of improved health from increased access to ART and from infections averted (using a full income approach)



### Uganda<sup>11</sup>

Uganda's HIV 'investment case' suggests that increasing treatment coverage to 80% by 2025 will:

- Avert 2,160,000 new infections
- Reduce new infections in children by 72%
- Prevent 570,000 deaths among adults, and 42,620 AIDS-related deaths among children



### South Africa and Nigeria<sup>12</sup>

Between 2014-2020, scale-up of ART to achieve 90-90-90 targets in 2020 will avert an estimated 840,000 and 760,000 AIDS-related deaths in South Africa and Nigeria, respectively.

## The price of ending a pandemic

UNAIDS estimates treatment scale up toward reaching the remaining 21.2 million people will require an estimated additional \$5.32 billion annually by 2020. Also, a recent study by Dutta et al finds a total (6-year) gap of \$25 billion or \$4.16 billion annually. It is also possible that improved use of affordable drugs, service delivery focus, and community-based programming will result in lower costs even than those projected here. It is important to note that this is just one part of a comprehensive HIV response.

What we do know is that the benefits of action clearly outweigh the cost of inaction, and that a large portion of the funding gap is likely to be in East and Southern African countries, where action is most urgently needed.

### Note

While the results of models, detailed above, provide some guidance as to the benefits of action, and help to make the case for how resources should be allocated, we note that mathematical modelling is limited in its capacity to accurately predict the future. What is clear is that the cost in inaction clearly outweighs the cost of aggressive scale up in the near term.



# A call, a deadline and a reckoning

We call on countries to immediately implement HIV treatment science, in order to deliver quality treatment to all regardless of clinical stage. Key policies and funding commitments will need to be in place by the time of the UN High Level Meeting on HIV/AIDS in June 2016, and ahead of the International AIDS Conference in Durban, South Africa, when activists will gather to take stock of the world's progress. In particular, we call on:

**1**

**Every country, to adopt and implement access to HIV treatment for all**, regardless of CD4 count, and to take steps to increase domestic funding and adapt programming to do so.

**2**

**Country governments, international implementing agencies, and clinicians, to adopt community-based models of care** using improved combination therapies. Dramatic scale up of ART for all people, in particular for asymptomatic people, will require moving ART closer to communities and improving quality, treatment education and adherence support services, while ensuring access to viral load monitoring.

**3**

**Donors, to act to reverse the current trend of flat-lining and declining global donor funding for HIV**, by increasing multilateral and bilateral funding to ensure that the implementation of immediate access to ART is possible, as part of a broad and comprehensive response. We also call on donors and governments to ensure that existing resources are used to maximum effect to improve access to diagnosis and treatment, and to explore innovative sources of financing to sustain the response.

**4**

**Implementing governments, to fully use allowable intellectual property flexibilities** to ensure access to affordable generic versions of new HIV drugs, and donor countries desist from blocking or pressuring countries not to do so, including through expediting harmful free trade agreements.

**5**

**Governments and health providers everywhere, to work to combat stigma and discrimination** by dismantling laws and policies that criminalize and discriminate and by demanding that health providers adhere to minimum standards for non-judgmental service provision to ensure people's dignity and their right to access to life-saving treatment.

**6**

**All governments, to build human rights programs** into HIV treatment programs to ensure all people living with HIV can make informed, educated choices, free from overt or implied coercion.

**7**

**Civil society around the world, to mobilize in support of treatment on demand for all**, and to join the call for a reckoning of our leaders' progress towards this goal in July 2016 in Durban!



## Critical moments for reckoning

**June 2016**

**UN High Level Meeting on HIV/AIDS, New York**

Another opportunity for world leaders to publicly make commitments on how they will take action to end the pandemic

**July 18-22**

**21<sup>st</sup> International AIDS Conference, Durban, South Africa**

An important moment of reckoning and accountability for world leaders, to civil society (including PLHIV and their allies)

**2016 (Exact date TBD)**

**Global Fund Replenishment Pledging Conference**

Donors to announce new financial commitments to the Global Fund for the period 2017-2019

**2020**

**Target date for achieving 90-90-90**

**2030**

**Target date to end the global AIDS epidemic**



**We call on all governments to  
adopt, implement, and fund  
HIV treatment on demand for  
every person diagnosed.**



## Endorsing Organizations:

African Men for Sexual and Health Rights  
African Community Advisory Board (AFROCAB)  
Asia Pacific Network of People Living with HIV (APN+)  
Caribbean Regional Network of People Living with HIV/AIDS  
Caribbean Vulnerable Communities Coalition  
Center for the Development of People - Malawi  
Coalition Plus  
Delhi Network of Positive People  
\* Eurasian Harm Reduction Network  
Gays and Lesbians of Zimbabwe (GALZ)  
\* Health GAP (Global Access Project)  
\* International Association of Providers of AIDS Care  
International Civil Society Support  
International Community of Women living with HIV Eastern Africa (ICW-EA)  
International Treatment Preparedness Coalition  
International Treatment Preparedness Coalition - South Asia  
Malawi Network of People Living with HIV/AIDS  
Pangea Global AIDS  
\* Stop AIDS  
\* Treatment Action Campaign  
World AIDS Campaign

\* Report drafting team

## Footnotes:

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