

UNAIDS 2015

# **IMPLICATIONS OF THE START STUDY DATA**

**QUESTIONS AND ANSWERS**

*“Every person living with HIV should have immediate access to life-saving antiretroviral therapy. Delaying access to HIV treatment under any pretext is denying the right to health.”*

Michel Sidibé, Executive Director of UNAIDS

*“The results show unequivocally what has been advocated for by advocates for people living with HIV for years—that universal access to treatment for all people living with HIV at diagnosis is a right to health. There is no ethical reason now to not make treatment accessible to all.”*

Suzette Moses-Burton, Executive Director of GNP+

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## IMPLICATIONS OF THE START STUDY DATA

### QUESTIONS AND ANSWERS

UNAIDS welcomes additional evidence released in May 2015 that early initiation of antiretroviral therapy has a positive effect on the health and well-being of people living with HIV. The United States National Institutes of Health-funded international randomized clinical trial START (Strategic Timing of Antiretroviral Treatment) has found compelling evidence that the benefits of starting antiretroviral therapy as soon as someone is diagnosed outweigh the risks of delaying until their CD4 count has fallen to 350 cells/mm<sup>3</sup>.<sup>1</sup>

These findings reaffirm the goal of making quality HIV treatment available to all people living with HIV.

Earlier provision of HIV treatment can mean both better health outcomes for people living with HIV and simplification of treatment services. Availability of earlier treatment can encourage more people to learn their HIV status, offering opportunities to provide expanded access to HIV prevention services along with treatment. Scale-up of earlier HIV treatment also implies increased global resource needs and additional strains on already overburdened public and community health systems.

Realizing the promise of the START results will require governments, donors, civil society and other stakeholders to systematically address the implementation, financing and other challenges ahead.

### WHAT ARE THE FINDINGS OF THE START TRIAL?

The START results suggest that all people who test positive for HIV should be offered HIV treatment and receive information to make an informed choice about treatment initiation. In many settings, people testing HIV-positive have been told they cannot access treatment until their CD4 count falls below the national standard for antiretroviral therapy initiation. The START data suggest this practice does not benefit the health of the individual patient.

The study has found that earlier treatment reduced the risk of a combination of serious AIDS-related illness, serious non-AIDS-related illness and death by more than half compared to deferring treatment. Previous research has established that HIV treatment also has a prevention benefit, making it less likely that HIV will be passed on to sexual partners.

Data from the START study showed that the risk of progression to AIDS diagnosis, other serious illnesses or death was reduced by 53% among people who initiated treatment when their CD4 levels were 500 cells/mm<sup>3</sup> or above, compared to the group whose treatment was deferred until after their CD4 levels dropped to 350 cells/mm<sup>3</sup>. Given that people in the earlier treatment arm of the trial had a relatively high CD4 count, it is not surprising that clinical events were not common in this group. The START results

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<sup>1</sup> <http://www.niaid.nih.gov/news/newsreleases/2015/Pages/START.aspx>.

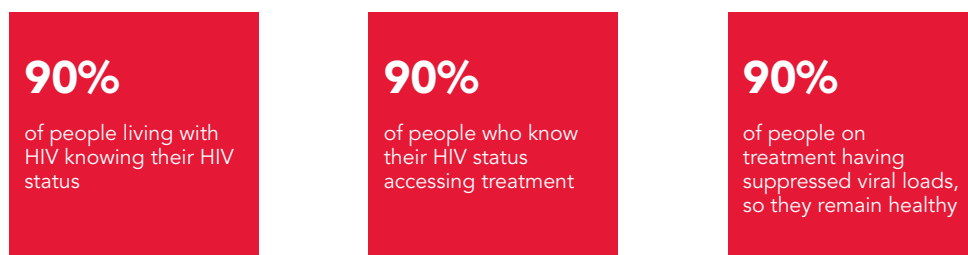
demonstrate, however, that the benefits of earlier treatment clearly outweigh the risks of toxicity or other adverse events during the three-year follow-up period.

The World Health Organization is currently undertaking the revision of its consolidated guidelines on the use of antiretroviral medicines for treating and preventing HIV infection. Data from the START trial will directly impact future World Health Organization guidance.

## WHAT ARE THE IMPLICATIONS OF THE START STUDY FOR COUNTRY TREATMENT TARGETS?

The findings from the START clinical trial are consistent with the Fast-Track approach to ending the AIDS epidemic and the ambitious 90–90–90 treatment targets. The START results offer a new opportunity to engage countries in setting ambitious HIV targets and addressing challenges around early treatment initiation. (Several countries have already adopted the 90–90–90 treatment targets, and several also suggest treatment initiation at HIV diagnosis.)

### 90–90–90 treatment targets by 2020



*90–90–90 envisions that by 2020 73% of people living with HIV will have achieved sustained suppression of HIV.*

## WHY ARE HUMAN RIGHTS CRITICAL TO EFFORTS TO EXPAND EARLIER TREATMENT?

Protection of human rights is critical to effective health responses. In the context of HIV, access to antiretroviral therapy is a fundamental aspect of the right to health and to life. Recognition of this right calls for redoubling efforts to ensure early access to antiretroviral therapy for everyone, everywhere. The implementation of expanded access to antiretroviral therapy should uphold key human rights principles such as informed consent, privacy, confidentiality and non-discrimination. Under no circumstance should efforts to expand HIV testing or treatment involve coercion or mandatory approaches. It is critical that individuals be provided information to allow them to make informed decisions about treatment initiation.

Programmes to address HIV-related stigma, discrimination and other human rights violations must be scaled up alongside HIV treatment and prevention services. This is necessary to ensure that everyone, particularly groups at higher risk of HIV, can protect themselves and receive the care and treatment they need.

It is important to pay specific attention to equality and non-discrimination in access as earlier treatment is implemented. This is particularly true for rural populations, poor communities and key populations, including gay men and other men who have sex with men, people who inject drugs, sex workers and transgender people. Barriers to access to services, including punitive laws, violence and harassment against these populations, must be addressed.

### WHY IS HIV TESTING SO IMPORTANT?

It is estimated that in 2013, 54% of people living with HIV globally did not know their HIV status, and only 42% of infants born to women living with HIV were tested and diagnosed. Expanding access to early treatment requires greatly increased access to testing and improved linkage to care.

There is an urgent need to expand public health and community-based testing models, such as mobile and multidisease testing campaigns, home-based testing and self-testing, and new technologies, such as point-of-care testing for early infant diagnosis. It is also important to increase demand for HIV testing and treatment using community outreach and innovative communications strategies, such as mobile phone applications and social networks.

Good retention in care and adequate viral load suppression will be key to preventing the development of drug resistance in people accessing antiretroviral therapy. Expanded public and community-based systems to support adherence to treatment and retention in care are needed, as is more research to better understand how to help people access treatment and remain in care.

With adoption of earlier HIV treatment, the value of routine CD4 monitoring drops significantly as the emphasis moves to assessing viral suppression through viral load testing. Scaling up access to viral load testing will be an essential step to achievement of the 90–90–90 treatment targets.

### WHAT IS THE ROLE OF COMMUNITIES IN EARLIER TREATMENT DELIVERY?

An increased role for community-based services is central to expanded HIV testing and early treatment and retention in care. Communities play an important role in supporting public health systems, linking people to services, reaching people not accessing public health services, providing testing and supporting people in adhering to treatment.

Communities should also be supported in building demand for prevention, testing, treatment and viral load suppression, in particular for key populations, who have too often been left behind in the AIDS response.

*According to the most recent surveys, fewer than one in five adolescent girls (aged 15–19) in Africa know their HIV status.*

*The UNAIDS Fast-Track approach assumes that by 2020 community-based services should account for approximately 30% of antiretroviral therapy and testing services, compared to the current levels of approximately 5%.*

Community-based models have proven their efficiency for improving uptake of HIV and other health services.

Communities also play a central role in protecting the human rights of people living with HIV and key populations most affected by the epidemic. Civil society should be resourced to play critical roles in a human rights-based delivery of HIV services.

*One study found that with an increase of one community-based organization per 100 000 people there was a 64% increase in treatment access.<sup>2</sup>*

## **WHAT DOES START MEAN FOR HIV PREVENTION AND THE BROADER HEALTH SYSTEM?**

Access to a package of evidence-based HIV prevention services, tailored to the needs of people most at risk, remains essential, alongside wider and earlier access to HIV treatment. Increasingly, HIV services need to be integrated into strong and resilient health and community systems that deliver both quality care and effective prevention. Integrating the delivery of HIV and other health-care services can both optimize use of limited health infrastructure resources and remove barriers to multiple care and preventative services. Communities need strong systems for health, adaptive and responsive to the needs of people.

## **CAN THE WORLD AFFORD TO OFFER TREATMENT TO ALL PEOPLE LIVING WITH HIV?**

Yes. UNAIDS projects that accelerated scale-up of HIV prevention and treatment will lead to significant economic benefits in low- and middle-income countries.

Achieving the Fast-Track Targets would reduce future direct treatment expenditures by 43% as a result of new infections averted. The gains in human terms are even more profound. In less than two generations (35 years), ending the AIDS epidemic will lead to 760 million life-years gained—75% of them in sub-Saharan Africa. It would mean that 7.9 million African children would avoid orphanhood.

Expenditures for HIV prevention, treatment and other services are strategic investments to save lives, avert new infections and achieve the end of the AIDS epidemic as a public health threat by 2030. With an increase in financing, international donors can help realize the end of the AIDS epidemic.

In addition, all countries will need to contribute resources to address their domestic HIV epidemics. Countries should increase their spending on health and, in particular, HIV services, based on their burden of disease and ability to pay.

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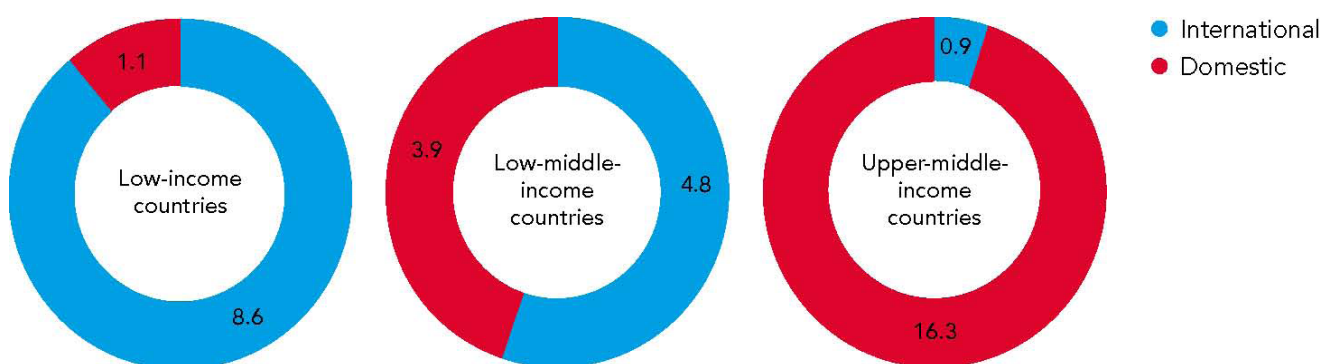
<sup>2</sup> Rodriguez-Garcia, Bonnel, Wilson & N'Jie, Investing in Communities Achieves Results, World Bank, 2013.

There is potential for increasing domestic funding within the existing fiscal space of many low- and middle-income countries. Options include integration of HIV into existing health financing systems, incorporation into universal health coverage initiatives, reprioritization and reallocation of existing funds, efficiency gains and innovative financing approaches, such as taxes on tobacco, alcohol, mobile phones, air travel or financial transactions.

*UNAIDS estimates that every US\$ 1 invested in HIV services will generate US\$ 17 in economic returns, as a global average.*

### Fast-Track financing: shared responsibility, global solidarity

2020 investments required (US\$ billion)



Source: UNAIDS, 2015.

### HOW CAN WE ENSURE COMMODITIES WILL BE AFFORDABLE?

Implementing early initiation of antiretroviral therapy will require efforts on all fronts to reduce its cost. Today there is a wide variation in HIV treatment costs for first-, second- and third-line medicines. Paediatric medicine costs are typically higher than for adults.

One priority is to ensure the use of flexibilities allowed under the current intellectual property regime to enable generic competition, which has proved to be an important driver of price reduction for first-line medicines in many low-income countries.

It is important to preserve the negotiation power of developing countries with pharmaceutical companies. For instance, TRIPS-plus provisions in free-trade agreements should be avoided since they reduce opportunities to access generic products. The least developed countries (LDCs) must continue to be exempted from complying with TRIPS requirements for pharmaceutical products while they remain LDCs, securing their opportunity to import generic products and fostering local production capacities.

In addition to public health oriented management of intellectual property rights, other mechanisms to lower medication prices include strengthening regulatory capacities, local production and bulk or pooled procurement.



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