DIAGNOSTICS ACCESS INITIATIVE

to achieve the 90-90-90 treatment target

UNAIDS, the World Health Organization (WHO), the Clinton Health Access Initiative (CHAI), the United States President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS,Tuberculosis and Malaria, the US Centers for Disease Control and Prevention (CDC), the African Society for Laboratory Medicine, USAID, UNITAID and UNICEF have joined together to launch a global Diagnostics Access Initiative. The aim of the new initiative is to leverage improved, accessible, affordable and optimally used diagnostic technologies and strategies to ensure achievement of a bold new HIV treatment target for 2020.

BACKGROUND

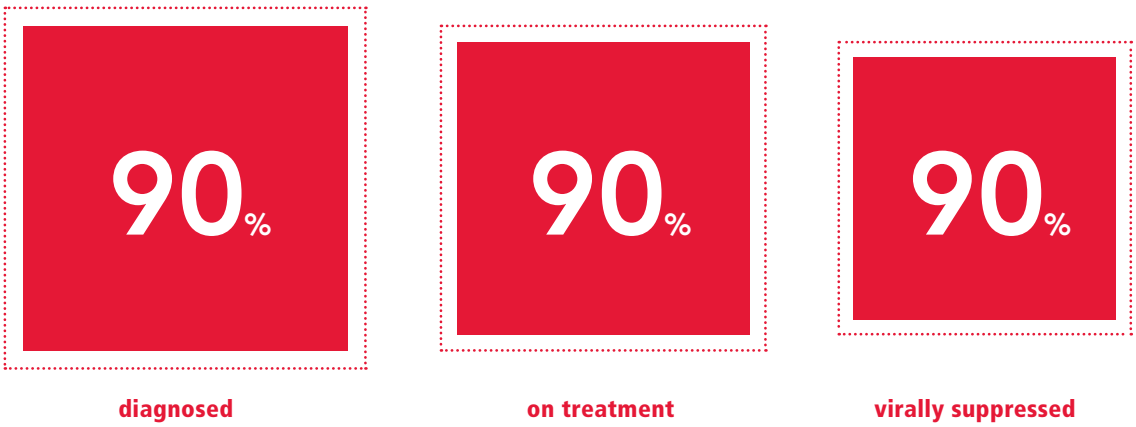
A new target for HIV treatment scale-up

The world is uniting around an ambitious HIV treatment target to lay the groundwork to end the AIDS epidemic as a public health threat by 2030. Through national, regional and global-level consultations, diverse stakeholders are pledging to ensure that by 2020:

- 90% of people living with HIV know their HIV status;
- 90% of people who know their status receive treatment;
- 90% of people on HIV treatment have a suppressed viral load.

Optimizing the use of diagnostics will be critical to achieve this target. In particular, it will be necessary to maximize innovative and effective use of available tools and to develop and scale up new tools and strategies to achieve the first and third parts of the target, ensuring the earliest possible diagnosis of HIV infection and promoting and measuring viral suppression for people receiving HIV treatment.

THE TREATMENT TARGET



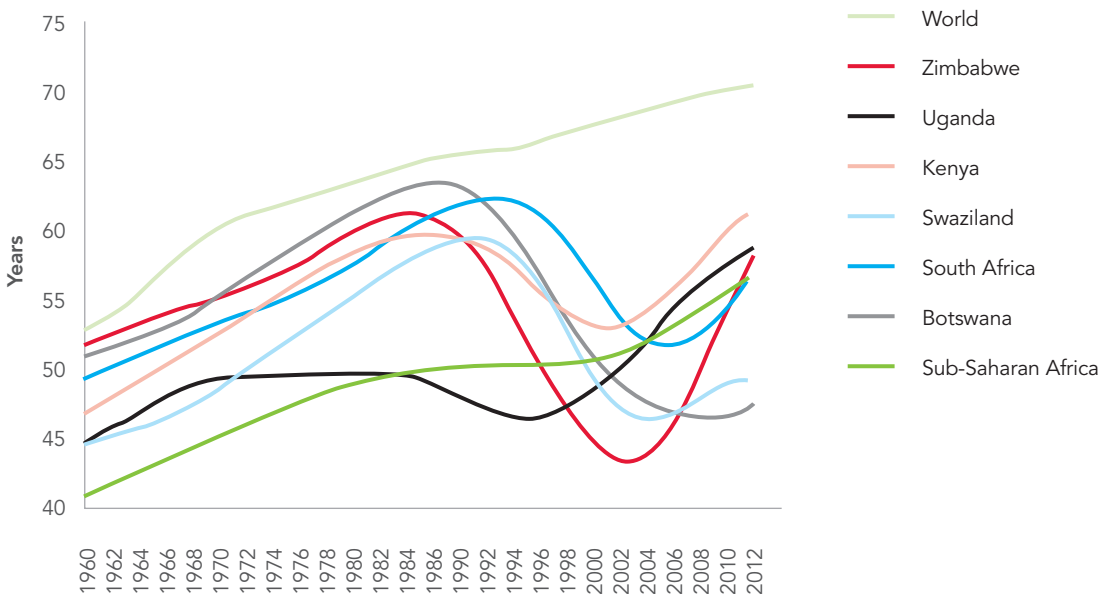
The critical importance of expedited HIV treatment scale-up

It is estimated that as of December 2013, almost 12.9 million people worldwide were receiving antiretroviral therapy. Although this represents an extraordinary global achievement, the world has yet to fully leverage the profound therapeutic and preventive benefits of HIV treatment. Despite historic gains, the majority of people living with HIV still do not receive treatment.

Failure to bring HIV treatment to people who need it represents a profound missed opportunity in the global efforts to end the AIDS epidemic:

- **HIV treatment saves lives and prevents illness.** As a result of advances in the science of HIV treatment, a young person who contracts HIV today has the potential to live a normal lifespan. In the most heavily affected countries, scale-up of HIV treatment has resulted in sharp increases in life expectancy and major reductions in HIV morbidity.

TRENDS IN LIFE EXPECTANCY DURING THE AIDS EPIDEMIC

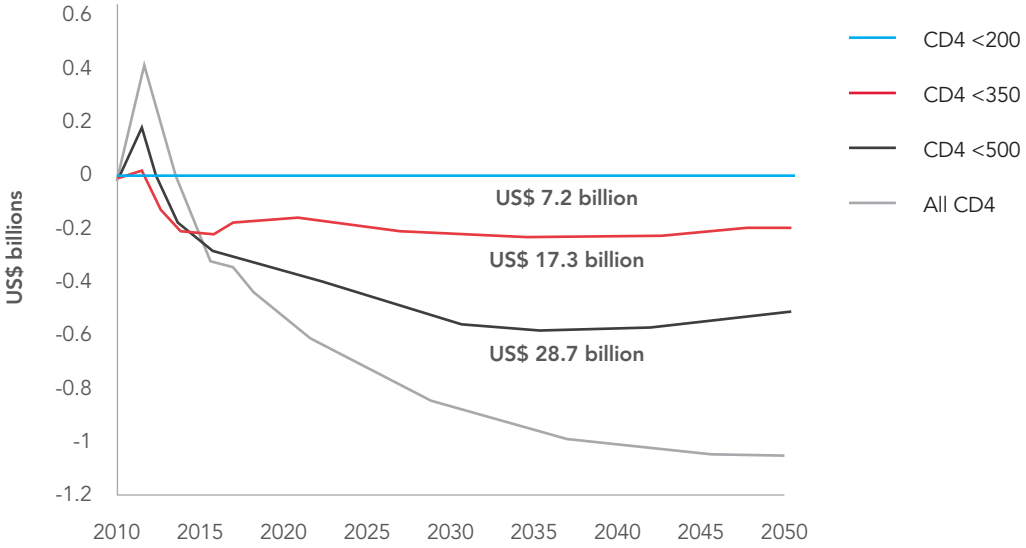


Source: World Population Prospects, 2012 revision.

- **HIV treatment prevents new infections.** Of all HIV prevention strategies rigorously evaluated in randomized controlled trials, HIV treatment is the *most* effective, reducing the odds of HIV transmission by 96%[1]. According to several studies every 1% increase in HIV treatment coverage translates into at least a 1% decline in new HIV infections.[2-3]

- **HIV treatment saves money.** HIV treatment represents a sound investment, yielding economic returns more than double the cost of treatment services due to averted future medical costs and increased labour productivity. In South Africa, home to the world's largest HIV epidemic, early investments to bring HIV treatment to all people living with HIV, regardless of their immunological status, would save tens of billions of dollars.[4]

EXPANDING ACCESS TO ANTIRETROVIRAL TREATMENT (ART) IS A SMART INVESTMENT: CASE OF SOUTH AFRICA



Source: Granich R, Kahn JG, Bennett R, Holmes CB, Garg N, Serenata C, et al. Expanding ART for treatment and prevention of HIV in South Africa: estimated cost and cost-effectiveness 2011-2050. PLoS One. 2012;7(2):e30216.

The treatment cascade

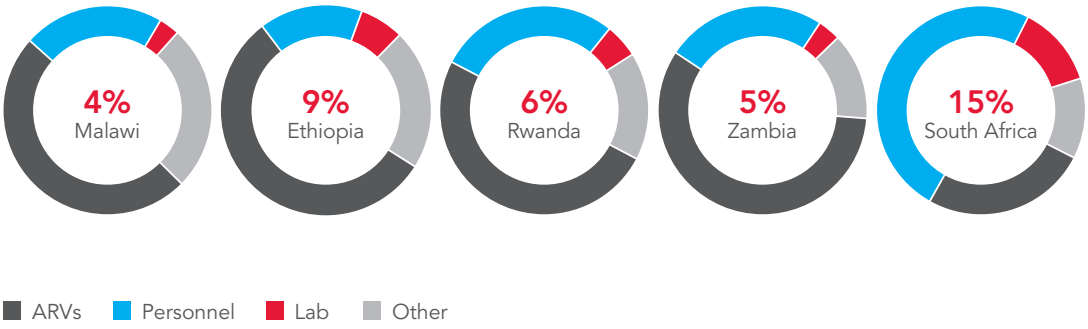
Gaps across the HIV continuum of care hinder efforts to optimize the health benefits of HIV treatment. UNAIDS estimates that more than half of all people living with HIV in sub-Saharan Africa do not know their status.[5] Although a growing body of evidence highlights the importance of the earliest possible initiation of HIV treatment, most people who enter HIV care do so at a very late stage of infection, generating sub-optimal health outcomes. In 2013, only 42% of children born to women living with HIV received a diagnostic test within the first two months of life – a potentially life-threatening gap, as half of these children will die by the age of two in the absence of treatment, with peak mortality occurring at 2-3 months.[6-7]

Among people diagnosed with HIV, a substantial proportion fail to access antiretroviral therapy or do not remain engaged in treatment services. Although measuring viral load is central to effective medical management of HIV as robust viral suppression is the ultimate goal of HIV treatment only 25% of people receiving HIV treatment, have access to viral load tests.[8] This gap worsens health outcomes and wastes scarce health resources; clinicians who cannot prescribe a viral load often switch patients whose CD4 count is rising to costly second- and third-line drugs when timely adherence support services might have preserved the more affordable first-line regimen.

THE NEED FOR A GLOBAL DIAGNOSTICS ACCESS INITIATIVE

Effective strategies either already exist or could be developed to close the gaps that diminish the effectiveness of antiretroviral therapy. In the case of HIV diagnosis, community-centred health campaigns that integrate HIV testing in multi-disease initiatives have demonstrated the capacity to achieve near 90% knowledge of HIV status in Kenya and Uganda.[9] Simple self-testing technologies have proven highly acceptable in diverse populations, and continued efforts are needed to mainstream routine HIV testing across diverse health care settings. In the case of HIV-exposed children who are missed by existing neonatal testing services, integration of HIV testing in diverse child-focused services has the potential to ensure HIV diagnosis and

THE SHARE OF LAB PORTFOLIO WITHIN HIV TREATMENT BUDGET VARIES BY COUNTRY



linkage to care for substantial numbers of children living with HIV. Further simplification of laboratory techniques, combined with programmatic innovations, will be needed to ensure that 90% of all people living with HIV are diagnosed by 2020.

For both viral load testing and early infant diagnosis, simple, affordable point-of-care technologies are being developed. These new tools have the potential to expand access to essential diagnostic services and enhance the ability of clinicians to offer people living with HIV the best possible and available medical care.

However, efforts to leverage available and emerging diagnostic technologies and strategies confront substantial obstacles. At the most elemental level, laboratory medicine enjoys little political support and is often underfunded. Although the therapeutic and preventive potential of HIV treatment cannot be realized without robust diagnostics, laboratory services account for a minimal share of HIV treatment expenditures (as low as 4%) in many countries.

Where technologies are available, they are not always effectively used. The average viral load technology in low- and middle-income countries performs only 11 tests per day, substantially below the threshold needed to maximize cost-effectiveness.[10] In Malawi, Mozambique and South Africa, 51% of early infant diagnostic test results are never received by the child's mother.[11]

While the robust pipeline for viral load and early infant diagnostic services is encouraging, common impediments to the scale-up of new

laboratory tools (including cost, regulatory barriers, and the like) will need to be overcome. A mix of point-of-care and centralized laboratory services will be required for viral load testing in most settings, but national and sub-national decision-makers will require technical support to ensure the best configuration of laboratory services. As new tools emerge, laboratory personnel and other health care workers will require training to effectively use new diagnostic options. Quality assurance measures will be needed to ensure that available and future diagnostic technologies achieve their promise of improving care.

Focused funding will also be needed to rapidly scale up diagnostic tools, including new ones that become available in the next few years. Fortunately, evidence indicates that scale-up actually promotes efficient use of resources, reducing per-patient diagnostic spending.

THE DIAGNOSTICS ACCESS INITIATIVE: KEY PILLARS

Recognizing the urgent need to break through existing barriers to effective use of diagnostics to accelerate ending the AIDS epidemic, UNAIDS, WHO, CHAI, PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria, CDC, USAID, the African Society for Laboratory Medicine, UNITAID, UNICEF and other partners have joined forces to spearhead the Diagnostics Access Initiative.

Achieving the promise of expanded access to testing and treatment will require strong partnership and careful coordination among key stakeholders to collectively expand best practices and facilitate innovation. Under the Diagnostics Access Initiative, concerted efforts will be made to maximize the use of existing and new quality-assured HIV diagnostic tools to further accelerate and leverage ART scale-up and to improve individual and public health outcomes by reaching at least 15 million people on ART by 2015, achieve future treatment targets and to set the stage to end the global AIDS epidemic by 2030.

The Diagnostics Access Initiative will focus its work under seven different pillars:

- **Advocacy:** The Diagnostics Access Initiative will harness available evidence to help decision-makers understand the critical importance of investing in strategic diagnostic services. Advocacy efforts will be undertaken at national, regional and global levels.
- **Forecasting:** The initiative will leverage the comparative advantage of partners and work with external actors to facilitate the generation of sound forecasts of need and demand for diverse diagnostic tools. These forecasts will help national and sub-national decision-makers develop budgets and workplans, strengthen the ability of private companies to make manufacturing and marketing decisions regarding pipeline diagnostic tools and enable international technical agencies and donors to ensure timely availability of financial and technical support for diagnostics scale-up.
- **Financing:** Leveraging the resources of internal partners and identifying new funding options, the initiative will work to ensure the availability of robust, reliable funding to accelerate scale-up of essential diagnostics. Through analyses of available evidence and country context, the initiative will work to ensure that countries are able to identify the optimal mix of diagnostic tools and strategies and to effectively utilize diagnostic technologies that are put in place.
- **Pricing:** The initiative will work together to ensure optimal pricing for diagnostic technologies, using timely and state-of-the-art economic analyses, negotiating with manufacturers and working collaboratively with national partners, donors, and other key actors.

- **Delivery and systems strengthening:** The initiative will advocate for timely, well-funded, strategic training and capacity-building efforts to strengthen human resources and health systems, helping ensure that national AIDS responses are able to fully leverage diagnostic tools.
- **Normative guidance:** The initiative will work with partners to provide rapid, science driven guidance on the introduction of new technologies, as they become available and are field tested. As access to diagnostics are taken to scale (including HIV testing, CD4, viral load and early infant diagnosis platforms), this initiative will advocate for improved quality of both point of care and centralized laboratory tests to ensure reliability and accuracy of results. Furthermore, prequalification of diagnostics will be taken to scale to increase the number of WHO prequalified technologies, while at the same time strengthening certification and regulation of diagnostic activities. This will improve the effectiveness, efficiency and outcomes of HIV investments.
- **Coordination and partnership:** Partners will coordinate their activities on an ongoing basis, ensuring that the Diagnostics Access Initiative benefits from the comparative advantage and unique strengths of its respective partners. The initiative will work in close partnership with Ministries of Health, regional bodies, international agencies, non-government organizations, donors, the diagnostics and pharmaceutical industries, and other private and public sector entities with an interest in or role to play regarding health care.

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UNAIDS

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Organization

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