TREATMENT 2015

UNAIDS

EMBARGOED UNTIL SATURDAY 13 JULY 2013 AT 12:00 GMT

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PREFACE

For the first time since the beginning of the AIDS epidemic, we have an historic opportunity to lay the groundwork to achieve zero new infections, zero discrimination, and zero AIDS-related deaths. One of the clearest lessons in global health is that victory can only be achieved through active partnership. For us to win, it is essential that we move together to support countries to achieve their goals. Getting to zero requires commitment, innovation, sound science, and community-centered strategies. A determination to embrace and respect human rights is critical if we are to reach those most vulnerable to HIV infection.

As we now have the tools to achieve universal access to HIV testing and treatment, we must unite around the principle that every person who needs HIV treatment should receive it. By strategically focusing HIV treatment and other proven prevention tools on the key geographic settings and populations where rates of transmission and unmet need for HIV services are high, we can significantly bend downward the rate of new infections.

Treatment 2015 provides a results-driven framework to expedite and greatly expand coverage. With less than 1000 days before the end of 2015, much work remains to be done. The WHO's new 2013 guidelines on *The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection* recommend a CD4 threshold of 500 for initiation of HIV treatment. As an important step towards getting to zero AIDS-related deaths, countries should be encouraged to prioritize immediate efforts to ensure that all people eligible for HIV treatment have access to it.

The rapidly evolving evidence base for HIV testing and HIV treatment raise a number of technical issues. Yet the most important factor of all is the commitment we each bring to the AIDS response. To end the AIDS epidemic, we must work together. Only through partnership, beginning with leadership of the countries burdened by HIV and supported by the collective determination of all stakeholders, can we reach our common goal.

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INTRODUCTION

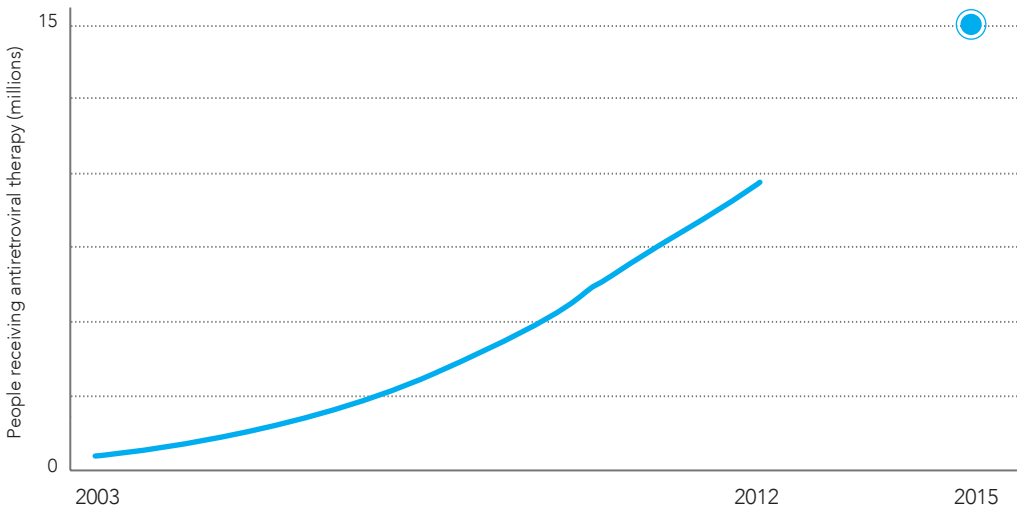
Pivotal moments are points when a decision must be made, a clear path chosen. These pivotal moments have profound, long-term consequences. Today, as the 2015 deadline draws near for global targets set forth in the United Nations 2011 Political Declaration on HIV/AIDS, the world faces such a pivotal moment. Making the right choice at this historic crossroads will help determine the future course of the HIV pandemic.

A critical 1000 days

Roughly 1000 days remain to reach the global target of 15 million people on antiretroviral therapy by 2015. In a growing number of countries, the foundations for ending the AIDS epidemic are being established by scaling up HIV treatment combined with expanding access to other essential programmatic activities. At the end of 2012, 9.7 million people accessed antiretroviral therapy in resource-limited settings (Figure 1). Today, more than 4 million people are alive because the global community opted more than a decade ago, against considerable odds, to commit to introducing treatment worldwide.

Figure 1

ACCESS TO TREATMENT CONTINUES TO EXPAND BUT THE 2015 TARGET REMAINS AMBITIOUS



Source: UNAIDS 2011 estimates

Following through to zero AIDS-related deaths and zero new infections

As one component of a comprehensive response to AIDS, scaling up HIV treatment is essential if we are to end the AIDS epidemic. A recent review of prevention intervention trials noted that among the biomedical prevention tools evaluated to date, effective antiretroviral therapy provides the greatest prevention effect *(1)*. Given its dual

benefits – saving the lives of people living with HIV and sharply restricting the spread of HIV – antiretroviral therapy constitutes a cornerstone of an effective response.

The 2015 target is only a stepping-stone towards the ultimate goal of ending the HIV epidemic. At the same time that efforts are redoubled to meet the 2015 target, longer-term plans should be made to continue and expedite scale-up towards universal access to treatment for the 25.9 million people worldwide who need antiretroviral therapy. (For the purposes of this framework, universal access as defined as at least 80% coverage.)

A framework for scaling up HIV treatment

Although current trends are encouraging, it would be unwise to rely on existing momentum to achieve the 2015 target. The people who have not yet been linked to HIV testing and treatment services are the most difficult to reach, suggesting that new approaches will be need to sustain and accelerate recent trends.

This report outlines an accountable and results-driven framework, using proven tools and lessons learned-, to achieve the 2015 target and accelerate further progress towards universal access.

Demand, invest, and deliver

Treatment 2015 has three fundamental pillars: demand, invest and deliver.

- ***Demand.*** Creating demand for HIV treatment – led by people living with HIV, as well as by key populations heavily affected by HIV, and sustained by civil society and the international community.
- ***Invest.*** Mobilizing sustained investment, giving priority to innovation and using the available resources as strategically as possible.
- ***Deliver.*** Ensuring that health and community systems, infrastructure, enabling laws and policies as well as community systems are in place to deliver treatment to all people living with HIV who are eligible.

The ***Treatment 2015*** framework leverages existing international and national guidelines to generate new ways of thinking about HIV testing and treatment. Rather than expecting people to adapt themselves to complicated service systems, ***Treatment 2015*** calls for systems to be adapted to the needs and circumstances of the people who use them. Community-led initiatives are vital to expanding and sustaining access to life-saving treatment services. As the evidence base continues to evolve and new challenges and opportunities emerge, new mechanisms for translating evidence into action will be needed. Efforts to scale up treatment will need to respond more swiftly to information on epidemiological trends and service coverage using a data-driven strategic approach that focuses programming on the populations and settings in which HIV is spreading most rapidly and the unmet need for HIV treatment is most acute.

The key elements of the ***Treatment 2015*** framework are already being implemented in many countries. As disparities between countries in which major progress has been achieved and those where progress lags become increasingly apparent, what is needed now is renewed global determination to apply the lessons learned worldwide.

The first three sections of this report make the case for the ***Treatment 2015*** framework, describing the potential impact of expedited scale-up and identifying the key elements of success. The second half of the report sets forth a framework for action, identifying priority action steps under each of the three pillars. A closing section on "making it happen" outlines the strategic, institutional and partnership approaches needed to promote accountability in the quest to reach 15 million people with HIV treatment by 2015.

Increasing strategic focus on key settings and populations to expedite scale-up

National figures on epidemiological trends and service coverage are essential resources for sound decision-making. Within every country, however, some populations and geographical settings are more severely affected by the epidemic or experience greater unmet need for HIV treatment services. Understanding where these key settings and populations exist and developing tailored and intensified efforts to close service gaps will play a vital role in meeting the 2015 treatment target and advancing towards universal access to treatment.

THIS REPORT AT A GLANCE

THE STAKES

A description of the health, economic and development benefits of rapidly scaling up HIV treatment.

PROOF OF CONCEPT

A review of the growing number of countries that are laying the groundwork for an end to the AIDS epidemic by scaling up HIV treatment.

AN EXPANDED UNDERSTANDING OF HIV TESTING AND TREATMENT

The ways in which HIV testing and treatment need to change to achieve the ***Treatment 2015*** target.

THE TREATMENT 2015 FRAMEWORK

- **Pillar 1 – Demand.**
  Strategic actions to enhance the demand for HIV testing and treatment services.
- **Pillar 2 – Invest.**
  Strategic actions to mobilize sufficient resources for expediting the scaling up of treatment and to enhance the effectiveness and efficiency of spending.
- **Pillar 3 – Deliver.**
  Strategic actions to close gaps in the HIV treatment continuum.
- **Making it happen.**
  Ensuring national preparedness to rapidly bring HIV treatment to scale and strategically focusing resources on key settings and populations with high HIV prevalence and unmet need for HIV treatment.

THE STAKES

Overwhelming evidence indicates that rapidly scaling up quality-assured HIV treatment will prevent millions of people from dying, prevent millions of people from acquiring HIV infection, save money and lay the foundation for the end of the AIDS epidemic. The time to act is now, since speed is essential to success.

Expediting the comprehensive scale-up of HIV treatment will have a transformative effect on humankind, making our world healthier, more just and more prosperous. Accelerating the scale up of antiretroviral therapy will drive progress across the broader AIDS response. It will reduce HIV-related illness and death, prevent people from acquiring HIV infection, address the needs of women and girls, reduce stigma and social exclusion and promote service integration.

Public health effects of rapidly scaling up antiretroviral therapy

HIV treatment is already profoundly affecting the epidemic in countries where it has been brought to scale. In South Africa, where HIV treatment coverage reached 83% in 2012 under WHO's 2010 treatment guidelines *(2,3)* (initiating treatment at a CD4 cell count of 350 cells/mm^3), scaling up treatment is estimated to have reduced the number of people newly infected with HIV by 17–32% in 2011 *(4)*. In KwaZulu-Natal, South Africa, life expectancy in 2011 was 11.3 years greater than in 2003, when HIV treatment in the province began to be scaled up *(5)*. In parts of KwaZulu-Natal where a substantial level of HIV treatment coverage (30–40%) had been achieved, the odds of acquiring HIV were 38% lower than in communities in which fewer than 10% of treatment-eligible individuals were receiving therapy *(6)*.

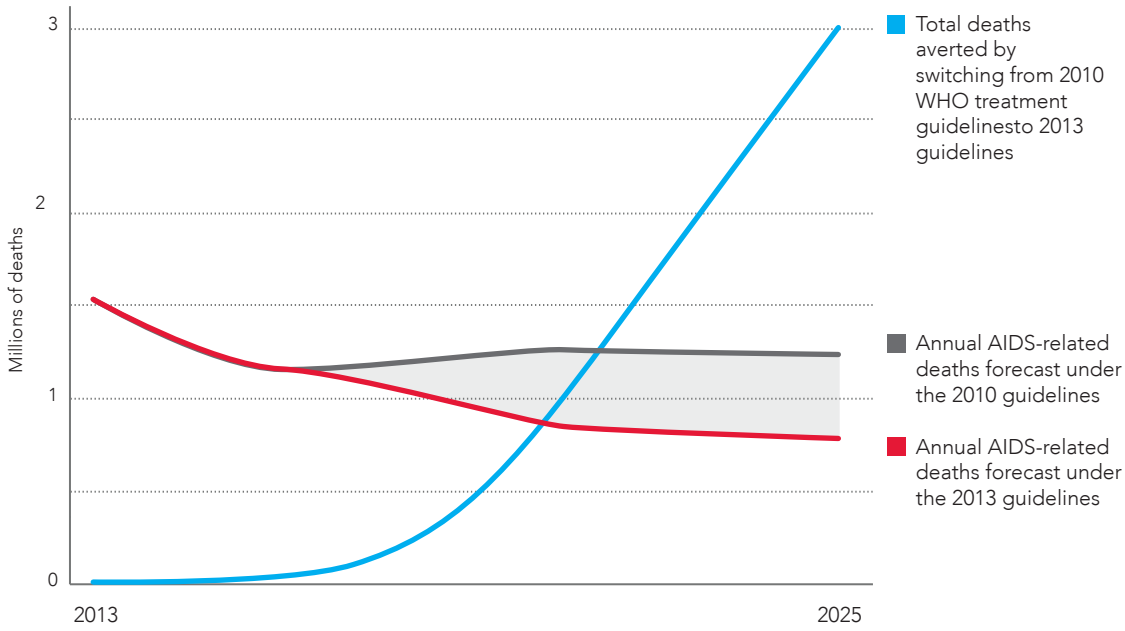
Even greater health benefits will accrue with full implementation of WHO's 2013 guidelines *(7)*, which recommend initiating antiretroviral therapy earlier. Achieving and maintaining 80% global coverage under the 2013 guidelines would prevent more than 3 million additional AIDS related deaths and prevent an additional 3.5 million people from acquiring HIV infection through 2025, in comparison with the 2010 guidelines *(3)* (Figure 2).

Laying the groundwork for an end to the AIDS epidemic in British Columbia, Canada

Through concerted action to scale up HIV testing and treatment services, the Canadian province of British Columbia increased the use of antiretroviral therapy 6.5-fold from 1996 to 2012. During this time, the incidence of AIDS fell by 90%, the incidence of HIV infection dropped by 42% and the number of people newly diagnosed with HIV declined by 66%.

Figure 2

NEW TREATMENT GUIDELINES CAN AVERT MILLIONS OF AIDS-RELATED DEATHS



Source: Global Update on HIV Treatment: Results, Impact and Opportunities and the new Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (WHO), Geneva, 2013

Economic and development benefits of rapidly scaling up antiretroviral therapy

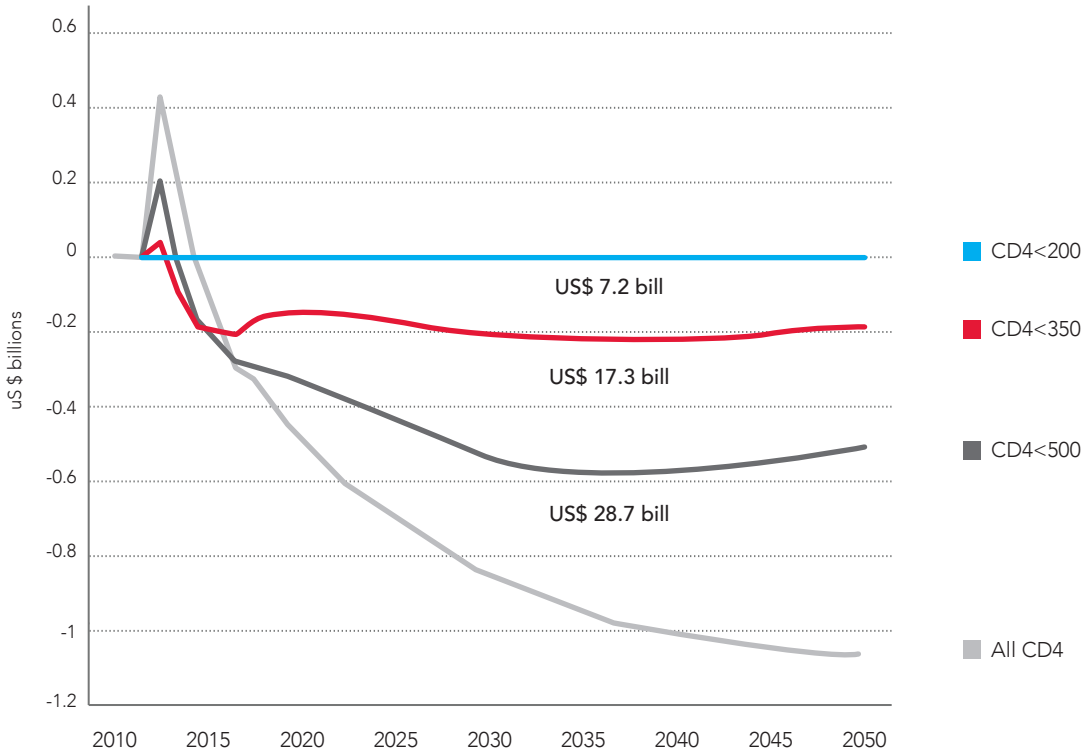
In the rapidly developing countries most heavily affected by HIV, scaling up antiretroviral therapy preserves and strengthens the health and well-being of the adolescents and working-age adults on which future economic growth depends. Investing in HIV treatment generates economic returns up to three times the investment, increasing productivity, preventing children from becoming orphaned and deferring the health care costs associated with advanced HIV-related illnesses *(8)*.

Achieving 80% coverage of HIV treatment under the 2013 WHO guidelines *(7)* will require a modest increase in HIV spending, amounting to a 10% increase, at most *(3)*. In 2015, reaching 80% coverage using the new WHO 2013 treatment guidelines criteria would require an additional US$ 2.2-2.4 billion on top of the treatment costs estimated using the 2010 Guidelines. This expenditure will be money well spent as previous analyses have demonstrated that treatment is both cost effective and potentially cost saving over time.

As indicated by modelling exercises examining the projected outcomes in South Africa with rapid scaling up of HIV treatment, swiftly implementing the 2013 guidelines will substantially lower future treatment costs by preventing a much larger number of people from becoming newly infected with HIV (Figure 3).

Figure 3

EXPANDING ACCESS TO HIV TREATMENT IS A SMART INVESTMENT



Source: Expanding ART for Treatment and Prevention of HIV in South Africa: Estimated Cost and Cost-Effectiveness 2011-2050. PLoS ONE 7*(2)*: e30216.

Towards a more just and equitable world

Rapidly scaling up HIV treatment could significantly contribute to the global goal of reducing global health inequities. Although the results attained to date, as measured by increased life expectancy, are genuine, some populations are benefiting much less than others. For example, treatment-eligible children are significantly less likely to receive antiretroviral therapy than treatment-eligible adults, and men have notably lower HIV treatment coverage than women in many settings with generalized epidemics. People who are living with HIV among the world's 42.5 million refugees and internally displaced people experience particular challenges in accessing health care.

HIV testing and treatment programmes often fail to reach sex workers, men who have sex with men, people who inject drugs and other marginalized groups. According to surveys through the People Living with HIV Stigma Index, many members of key populations who are diagnosed with HIV experience hostility, service denial or other forms of discrimination when they seek to access treatment services. In the quest to bring HIV treatment to everyone who needs it, no one should be left behind.

Persistent inequities for children living with HIV

In 2011, 28% of children eligible for treatment in accordance with WHO guidelines received HIV treatment versus 58% of treatment-eligible adults. Although practical and logistical difficulties had accounted for this inequity in earlier years, these current inequities stem from failure to use the proven tools that are available. Children born to women living with HIV should be swiftly linked to follow-up health care services, the use of innovative methods to ensure affordable early infant diagnosis should be optimized, and redoubled efforts are required to ensure the availability and effective use of affordable antiretroviral formulations for children. Efforts to reduce mother-to-child transmission should be more closely linked with HIV treatment and care, which is life-saving for children living with HIV, their mothers and their mothers' partners. Option B+ (lifelong treatment for pregnant women living with HIV, irrespective of CD4 cell count) has significant potential to enhance the health of the mother and prevent transmission to their children and partners.

Key populations and the HIV epidemic

Although considerations of equity demand concerted efforts to increase access to HIV testing and treatment services for key marginalized populations, promoting equity in national responses also has practical public health benefits, as key populations (specifically, men who have sex with men, people who inject drugs, sex workers and transgender people) represent a sizable share of national epidemics throughout the world. According to HIV modes-of-transmission studies, key populations and their sex partners account for a substantial share of the people newly infected with HIV in widely diverse countries, including Nigeria (51%) *(9)*, Kenya (about 33%) *(10)*, Mozambique (more than 25%) *(11)*, Morocco (80%) *(12)*, Dominican Republic (47%) *(13)* and Peru (65%) *(14)*.

PROOF OF CONCEPT

Achieving an end to the AIDS epidemic is not a dream. In more and more countries, the groundwork for an end to the AIDS epidemic is being laid, as HIV treatment and other high-impact strategies have been rapidly brought to scale, resulting in sharp declines in AIDS-related deaths and new HIV infections. These success stories exemplify the critical ingredients for success – ingredients that now need to be applied worldwide.

As a growing number of countries have rapidly expanded access to HIV treatment and other critical HIV prevention and treatment services, it has become increasingly plain that an AIDS-free generation is entirely feasible.

Towards getting to zero

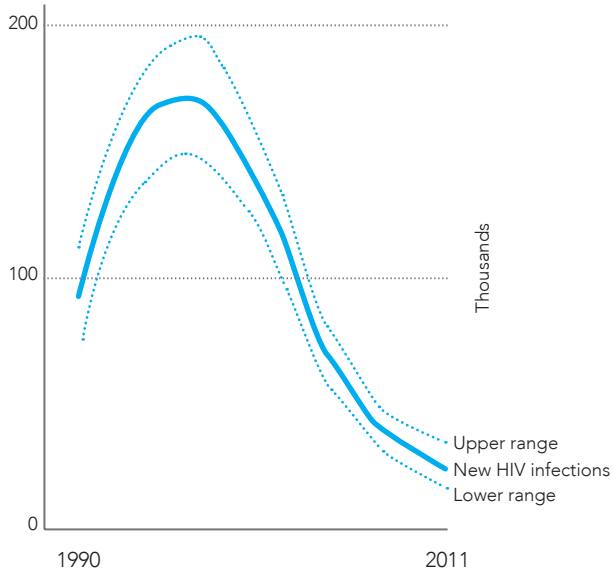
In an expanding array of countries, from diverse regions, important gains have been recorded following the implementation of sound, evidence- and human rights-based approaches. In Ethiopia, where major investments in HIV testing programmes and community-centred treatment delivery led to sharp increases in HIV treatment coverage (reaching 56% by 2011), the estimated HIV incidence rate fell by 90% from 2001 to 2011, in part due to HIV treatment (Figure 4).

Sharp gains against HIV, as measured by estimates of HIV incidence, have been reported in numerous other countries in which HIV treatment has reached over 60 percent, including Botswana (70% reduction in HIV incidence from 2001 to 2011), Malawi (more than 70% incidence decline), Namibia (more than 50% reduction in incidence), and Rwanda (more than two-thirds decline in deaths and more than 50% reduction in incidence).

Speed matters, as rapid scale-up of quality-assured HIV treatment services is associated with greater gains against the epidemic *(15)*. Countries where HIV treatment has been rapidly scaled up in combination with other core prevention strategies have reported declines in the estimated HIV incidence rate of at least 50% between 2001 and 2011. In contrast, among countries with relatively slow scale-up, declines in HIV incidence from 2001 to 2011 were far more limited.

Figure 4

TOWARDS ZERO NEW HIV INFECTIONS IN ETHIOPIA



Source: UNAIDS 2011 estimates

Reaching the programmatic tipping point: a critical step towards realizing the promise of HIV treatment

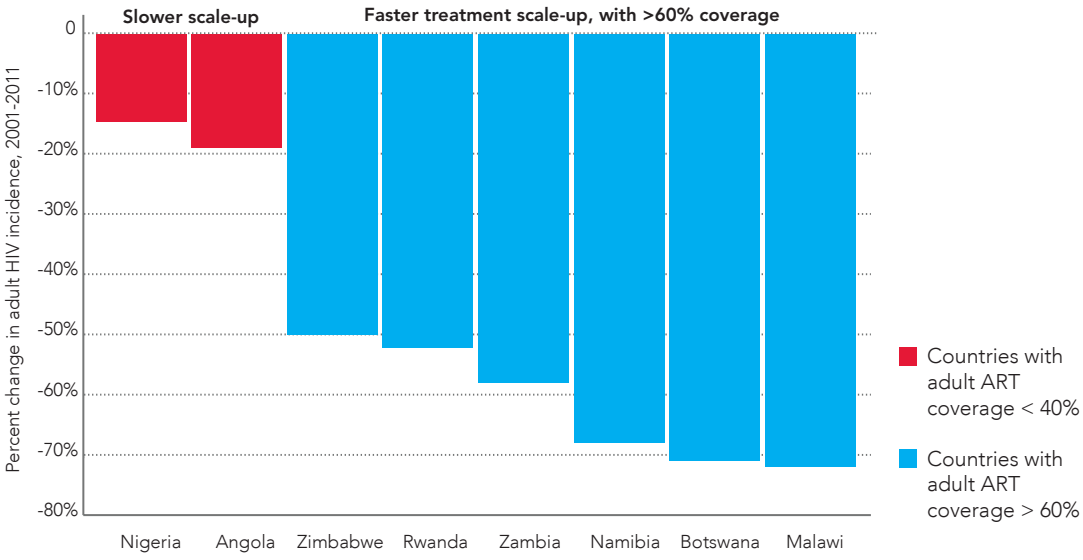
In achieving universal access to HIV treatment, an important milestone is passed when the annual increase in the number of adults receiving HIV treatment exceeds the number of adults becoming newly infected with HIV. This transition, first conceptualized and promoted by the United States President's Emergency Plan for AIDS Relief in its 2012 *Blueprint for Creating an AIDS-free Generation*, is referred to as programmatic tipping point when the response begins to outpace the epidemic itself *(16)*.

As of December 2011, several countries had passed this tipping point. However, globally, the world has yet to reach the point where the scaling up of HIV treatment is outpacing the epidemic. In 2011, 2.5 million people were newly infected, while the number of people taking antiretroviral therapy increased by 1.6 million.

Epidemics continue to expand in countries and regions where HIV testing and treatment have yet to be brought to scale. In 2011, the two regions with the lowest HIV treatment coverage were eastern Europe and central Asia (24%) and the Middle East and North Africa (15%). These regions are also the only ones in which the number of people becoming newly infected with HIV is clearly rising.

Figure 5

COUNTRIES THAT SCALED-UP TREATMENT FASTER, HAVE REDUCED INCIDENCE MORE SIGNIFICANTLY OVER THE PAST DECADE



Source: UNAIDS 2011 Estimates

Distilling lessons from the growing number of success stories

To extend worldwide the transformative gains seen in many countries, key features that have characterized effective scale-up should be applied in settings where progress has been less pronounced.

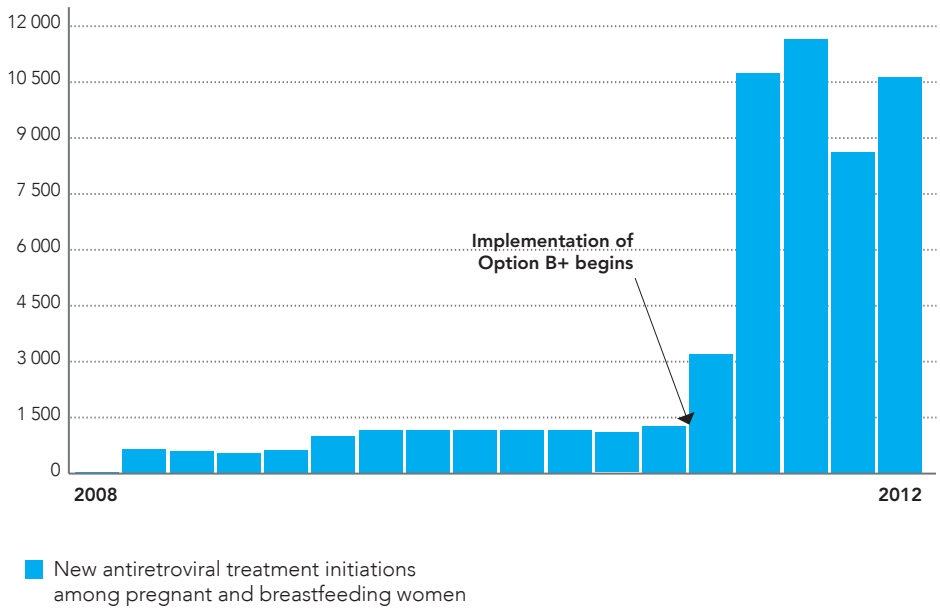
- **Leadership and commitment.** Where rapid scale-up has occurred, senior national leaders have led national efforts. For example, in Botswana, where low testing rates were impeding efforts to bring HIV treatment to scale, national leaders sparked the development and roll-out of effective new testing approaches, such as provider-initiated HIV testing and counselling.
- **Accountability.** Countries that have had the greatest success have established ambitious targets for scaling up, with diverse national stakeholders holding each other accountable for the results. Civil society has the right to act as watchdogs to hold governments accountable for their AIDS commitments.
- **Following the evidence.** Countries that have been most successful have taken proactive steps to translate emerging evidence into new policies, programmes and practices. For example, as evidence pointed decisively towards the benefit of initiating HIV treatment earlier, South Africa moved decisively to increase the CD4 cell count threshold for initiating antiretroviral therapy from 200 to 350 cells/mm^3. Zambia made early moves to initiate antiretroviral therapy among serodiscordant couples, and Rwanda and other countries pioneered the scaling up of HIV testing and treatment for people with tuberculosis (TB).
- **Innovation.** Where success has been most marked, countries have implemented programme management strategies, including ongoing monitoring and evaluation, that provide continual feedback on outcomes, permitting policy-makers and programme implementers to identify challenges and develop innovative strategies to overcome them. This approach enabled Malawi to pioneer the initiation of lifelong antiretroviral therapy for pregnant or lactating women living with HIV, accelerating uptake and improving health outcomes. In Cambodia, innovative community models have been used to bring HIV treatment and other services to key populations.
- **A commitment to rights-based and other best-practice approaches.** Countries where scale-up has been sharpest have generally endeavoured to implement policy frameworks that prohibit discrimination against people living with HIV, reduce or eliminate out-of-pocket costs for HIV testing and treatment services and address the epidemic's gender dimensions. In Kenya, for example, national legislation prohibits mandatory HIV testing, prohibits discrimination based on HIV status and prevents insurers from excluding people living with HIV from coverage. Kenya has also established an HIV equity tribunal to enable individuals who have experienced discrimination to obtain redress.
- **Participatory and inclusive approaches.** In countries where the foundation is being put in place to end the AIDS epidemic, people living with HIV and civil society play visible roles in the national response, delivering services, participating in national planning bodies and functioning as watchdogs to ensure accountability.

Rapidly scaling up HIV treatment for pregnant women in Malawi

Systematically implementing option B+ (initiating lifelong treatment for all pregnant or lactating women living with HIV) in Malawi resulted in a 748% increase in the number of such women receiving antiretroviral therapy over a 15-month period in 2011–2012.

Figure 6

OPTION B+ HAS DRAMATICALLY INCREASED THE NUMBERS OF PREGNANT AND BREASTFEEDING WOMEN ON TREATMENT IN MALAWI



Source: Chimbwandira F. et al, Impact of an Innovative Approach to Prevent Mother-to-Child Transmission of HIV — Malawi, July 2011–September 2012, United States Centers for Disease Control and Prevention (2013), 62(08);148-151

AN EXPANDED UNDERSTANDING OF HIV TESTING AND TREATMENT

The HIV care and treatment continuum begins on the day an individual is diagnosed with HIV. Effective HIV treatment involves more than just medicines but also includes access to the complementary services that promote health and ensure that individuals are retained across the treatment cascade and achieve durable viral suppression.

Individuals living with HIV need to be diagnosed as early as possible after infection. And while initiation of antiretroviral therapy will for many people depend on their immunological status, the HIV care and treatment imperative is triggered on "day 1" of the HIV diagnosis.

Understanding and addressing the HIV treatment cascade

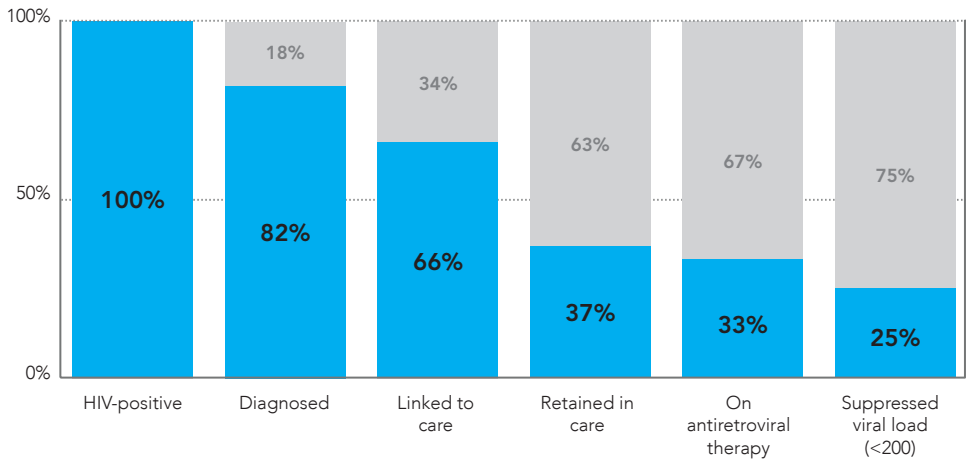
Accessing HIV treatment is only part of the HIV care and treatment continuum, which is a long-term process that moves individuals through a set of stages that begin with HIV diagnosis. The aim of HIV care and treatment is to achieve durable viral suppression.

However, at each key stage, individuals may fall out of the HIV care continuum. This results in a "cascade", reducing the number of people living with HIV who remain healthy and well. In the United States of America, for example, only one in four people living with HIV have suppressed viral load because of gaps in the HIV treatment continuum (Figure 7).

Some people do not join the treatment continuum because they have not been diagnosed with HIV. Many people do not continue to access care following their diagnosis and are "lost to follow up" because of the absence of proactive interventions and support services.

Figure 7

UNITED STATES TREATMENT CASCADE, FROM HIV DIAGNOSIS TO VIRAL SUPPRESSION



Source: Hall et al. Continuum of HIV care: differences in care and treatment by sex and race/ethnicity in the United States. 2012 International AIDS Conference.

Also, many individuals who test positive for HIV (almost half in sub-Saharan Africa), according to some studies *(17)*) are not effectively linked to care, and many who are linked to care do not receive antiretroviral therapy once they are eligible according to WHO criteria. Finally many who start HIV treatment are not retained in care. If such individuals return to care, it is often at an extremely late stage, when the effectiveness of antiretroviral therapy is often compromised. These gaps undermine the public health impact of scaling up HIV treatment, reducing the proportion of people living with HIV with viral suppression *(3)*.

Having built and expanded HIV treatment services, programme planners and implementers must now devote as much attention to closing key gaps within the HIV treatment continuum. Timely and accurate data for each stage of the treatment cascade need to be collected and analysed, with the results used to influence programme management and the development of targeted interventions to prevent the loss to follow-up across the cascade.

Community engagement in service planning and delivery is essential if gaps in the treatment cascade are to be closed. As non-clinical issues are often the most significant barriers to effective navigation of the HIV treatment continuum, communities are often best placed to provide leadership and support to address these issues. This is especially true for key populations, who often face especially acute challenges in accessing services through mainstream health systems. Including paid community workers in HIV treatment programmes offers an especially useful strategy to complement public health services and minimize patient loss throughout the HIV treatment process.

Reconceptualizing HIV testing

Although much has been accomplished in promoting knowledge of HIV status, much more must be done to fully leverage HIV testing as a gateway to HIV treatment. Even though it is becoming increasingly clear that annual testing is critical to timely initiation of treatment and rapid scale-up in countries or populations with elevated HIV prevalence, HIV testing services reach only a small fraction of the population annually in many countries.

Many people living with HIV first learn they are infected late in the course of infection, undermining the effectiveness of HIV treatment and facilitating the continued spread of HIV. In nine sub-Saharan African countries, the median CD4 cell count when HIV treatment was initiated in 2010 was below the critical life-threatening threshold of 200 cells/mm3 – substantially lower than recommended standards for the optimal start of treatment *(19)*.

In many countries, investment in HIV testing services remains concentrated in stand-alone testing sites that require individuals to recognize their risk and voluntarily seek to learn their serostatus. Several countries, however, have shown the way towards more proactive and more effective approaches, using multiple low-threshold strategies to extend the reach and impact of testing services. In Kenya, for example, the number of tests administered rose seven-fold from 2008 to 2010 after the country implemented provider-initiated testing and counselling in health care settings and began supporting energetic community testing campaigns *(20)*. Community campaigns, including those that provide screening or prevention services for multiple diseases, have proven effective in Kenya, Malawi, South Africa, Uganda, the United Republic of Tanzania and Zambia. Further efforts are required to normalize HIV testing in health care settings. Pilot projects in both concentrated and generalized epidemic settings suggest that home-based testing is highly acceptable, in part because it protects confidentiality, as a complement to, rather than a replacement for, provider-initiated or facility-based HIV testing and counselling services.

Substantially increasing the demand for HIV testing is essential. This requires robust and sustained investment in community-based HIV literacy programmes. Enhanced support for strengthening community systems is also needed, to broaden awareness of the availability of simple, easily tolerated regimens, increase access to

user-friendly testing options and alleviate stigmatizing attitudes that deter many from seeking testing services. Focused, community-centred testing outreach can help reach marginalized populations at elevated risk.

Broadening understanding of HIV care and treatment

For people diagnosed early in the course of infection, clinical settings have typically adopted a wait-and-treat approach that offers few services or interventions until the individual's immune system is damaged to such an extent that antiretroviral therapy is medically indicated. By offering minimal intervention during the interim between diagnosis and eligibility for therapy, programmes fail to prepare individuals to take antiretroviral therapy or proactively address factors (such as mental health issues, transportation barriers, social isolation or housing instability) that may ultimately affect retention or adherence. Waiting years before meaningful services are provided also increases the risk that individuals will be lost to follow-up, reducing the likelihood that they will receive treatment when they need it. By recommending that HIV treatment be initiated earlier, the 2013 WHO guidelines *(7)* will alleviate but not eliminate the challenge of engaging HIV-diagnosed individuals who are not yet eligible for antiretroviral therapy. Service systems will need to take a more holistic approach, effectively partnering with lay and community workers and lower-level health staff to leverage the pre-treatment period to provide HIV care and treatment not only involves administering antiretroviral therapy but also encompasses medical, psychosocial, legal and community support services that, together, address the broad range of needs that people living with HIV experience across their lifetime. Ensuring a comprehensive array of health and support services for people living with HIV will enable providers to provide holistic patient-centred care, increasing its effectiveness and addressing other medical and psychosocial issues. Many of these health and support services are applicable in the pre-antiretroviral and antiretroviral phases of HIV care and may improve clinical outcomes and support retention and adherence both before and after antiretroviral therapy is initiatedw(Figure 8).

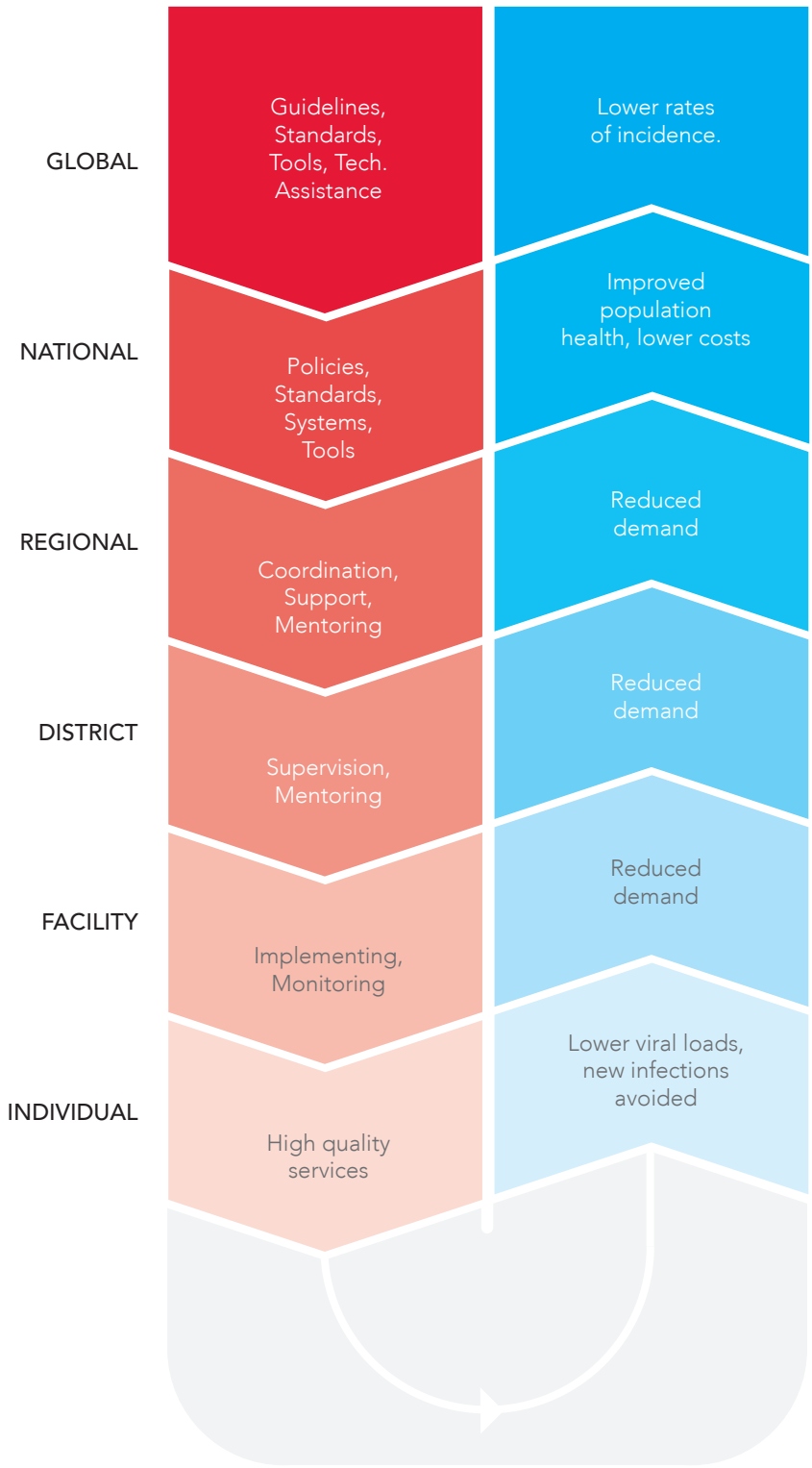
Countries are encouraged to consider interventions including: early HIV diagnosis and linkage to care, CD4 testing, pre–antiretroviral therapy care, TB interventions (intensified case-finding, isoniazid preventive treatment and TB infection control), co-trimoxazole prophylaxis, treatment preparedness, early initiation of antiretroviral therapy, and positive health, dignity and prevention activities. Depending on the country and community context, additional services may include preventing and managing coinfections; malaria prevention; nutritional interventions; sanitation and hygiene services; reproductive health services; diverse mental health services; pain and symptom management and end-of-life care; and social services. Countries should consider defining country-specific packages of care services, based on need, public health impact and country priorities, with particular attention to the needs of priority populations, such as women, adolescents and key populations. At all stages, communities should be involved in defining and promoting comprehensive care packages.

At all times, scale-up needs to be accompanied by a commitment to improving quality focusing on implementing interventions to ensure that programmes are effective and that desired outcomes are achieved. Factors that influence the quality of HIV treatment services include how services are organized, leadership at the policy and programmatic levels, the strength and comprehensiveness of monitoring systems, the adequacy of infrastructure and the available human, material and financial resources *(21)*. High-quality care is client- and family-centred, addressing the needs and preferences of service users and the cultures of their communities. Continuous quality improvement must occur at all levels of the HIV and health system, documenting systems and outcomes and their adherence to standards and using quality management systems as a continual feedback system to enhance quality.

At the same time that HIV treatment strategies are revised to improve their reach and effectiveness, consistent, ongoing efforts are needed to maximize the efficiency of treatment delivery. Efforts should build on the considerable efficiency gains that have already been achieved; prices for regimens to prevent mother-to-child transmission declined by 88% from 2011 and 2013, and integration of HIV services with other service delivery systems (e.g., tuberculosis, sexual and reproductive health) has accelerated scale-up and improved efficiency. The United States President's Emergency Plan for AIDS Relief (PEPFAR) estimates that it has more than halved the average per-patient cost of PEPFAR-supported treatment delivery by leveraging efficiencies.

Figure 8

CONTINUOUS QUALITY IMPROVEMENTS RESULT IN MORE EFFECTIVE PROGRAMMES



Source: adapted from Porter L. United States Centers for Disease Control and Prevention, Division of Global HIV/AIDS, Program Quality Assurance Workshop, 2013.

Overcoming obstacles to HIV treatment utilization

Accelerating scale-up and enhancing treatment success requires that countries address key social and systemic obstacles including:

Punitive laws and policies
In recent years, more than 100 countries have used criminal law to prosecute people who fail to disclose their HIV status or have transmitted the virus to others. Some 600 individuals have been convicted of such offences. Although this number may appear small in the context of an epidemic in which 34 million people are currently living with HIV, such laws reinforce the stigma associated with HIV, driving people away from HIV testing and counselling and from HIV services. Key populations at higher risk of HIV are further deterred by other punitive laws, such as compulsory rehabilitation centres for people suspected of drug use or criminalization of sex work or sexual relations between people of the same sex. Such punitive laws create a climate of fear and concealment and exacerbate the social marginalization that keeps many people from seeking the HIV services they need.

Stigma and discrimination
Surveys through the People Living with HIV Stigma Index reveal that substantial percentages of people living with HIV have experienced violence or the threat of violence, ostracism, loss of employment or housing or denial of essential health or social services as a result of their HIV status. People who report belonging to key populations report higher levels of stigma and discrimination. In an era when HIV treatment holds the promise of accelerating progress towards an end to the AIDS epidemic, especially concerning is the high frequency of stigma regarding people living with HIV and key populations in the very health care facilities designed to deliver HIV treatment services.

Health workforce challenges
Public health systems in low- and middle-income countries are generally understaffed, especially outside large cities and towns. Low-income countries with high HIV prevalence often experience an acute shortage of health workers – a pattern that stems from insufficient national fiscal capacity to invest in training health workers or adequately remunerating or retaining skilled health professionals. Although community systems have the potential to assume critical roles in HIV care and treatment, they often struggle with limited capacity as a result of inadequate support.

Other health system challenges
In addition to inadequate human resources, health systems experience other challenges that hinder efforts to expedite the scaling up of HIV treatment. HIV information systems are weak in many countries, a challenge compounded by limited analytical capacity to make optimal use of strategic information. Laboratory capacity remains inadequate; for example, in a WHO survey of 47 countries in 2012, each CD4 machine on average performed four tests a day, well shy of the cost-effective goal of 20–100 samples per day for each machine.

National procurement and supply management systems must be robust, efficient and scaled-up. Effective systems have the capacity to forecast needs; to procure, warehouse and distribute key commodities; and to collect and disseminate strategic information among national programmes and partners.

Task shifting to extend limited human resources for health

Task shifting enables stretched health care systems to extend limited human resources further, reaching more people with life-preserving HIV treatment. Task shifting redistributes tasks within health workforce teams, shifting elements of care from the limited number of highly qualified health workers to the more plentiful number of health workers with shorter training and fewer qualifications. The models and types of task shifting vary in differing contexts, although clearly defined roles, appropriate training and sufficient support and referral systems are crucial in all settings.

Roles of various providers

Non-physician clinicians can carry out most clinical tests when they are appropriately trained and supervised and have access to well-functioning referral systems.

Nurses and midwives are able to undertake a range of HIV clinical services formerly considered the responsibility of physicians or non-physician clinicians, including initiating antiretroviral therapy. Nurse-centred antiretroviral delivery has been shown to reduce waiting lists for treatment, minimize congestion at treatment centres, avert unnecessary travel by service users and localize the support provided for adherence and education. Nurse-centred delivery of antiretroviral therapy is especially useful for people who enter care early in the course of HIV infection, as they are less likely to be ill and require complicated health care interventions.

Community health workers may provide HIV services that were previously the responsibility of nurses, such as self-care, adherence support and interventions to address stigma and discrimination. Community workers can undertake clinical monitoring of weight and vital signs, determine functional status, identify symptoms of coinfection and monitor and support adherence. Like other workers engaged in the delivery of HIV treatment, community health workers (including peer workers) deserve appropriate compensation for their services.

People living with HIV who have no health training may be trained to become patient experts and provide support services to others in such areas as self-care, treatment and rights literacy, adherence support and efforts to overcome stigma and discrimination.

Pharmacists, pharmacy technicians, laboratory technicians, records managers and administrators should also be taken into account in developing task-shifting strategies. Several studies indicate that pharmacists may safely and effectively assume a range of clinical tasks.

15 MILLION ON ANTIRETROVIRAL TREATMENT BY 2015: THE TREATMENT 2015 FRAMEWORK FOR STRATEGIC ACTION

Acknowledging the pivotal moment we now face, the world must ensure that 15 million people receive HIV treatment by 2015 and use this achievement as a springboard to further accelerate progress globally towards universal access to treatment. In particular, focused efforts are needed to:

- generate demand for testing and treatment,
- invest adequately and strategically in evidence-informed, quality-assured programmes and innovative approaches; and
- implement new ways of promoting and delivering services to reach people who have yet to access life-saving treatment, including often-marginalized populations most affected by the epidemic.

Countries should identify key settings and populations in need of intensified efforts and tailor the ***Treatment 2015*** to local needs.

Treatment 2015 and the right of all people, including people living with HIV, to the highest attainable level of health

In the 2011 Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV and AIDS, United Nations Member States recognized that "access to safe, effective, affordable, good quality medicines and commodities in the context of epidemics such as HIV is fundamental to the full realization of the right of everyone to enjoy the highest attainable standard of physical and mental health."

To obtain the highest attainable level of health for people living with HIV, this framework seeks to catalyse strategic action across three pillars to ensure that all people living with HIV are able:

to know their HIV status

to obtain the care and treatment they need

to prevent HIV transmission

to be protected from harm.

TREATMENT 2015
PILLAR 1: DEMAND

Although 25.9 million people worldwide are now eligible for antiretroviral therapy, actual demand for HIV treatment services is substantially lower. Demand will be increased by reconceptualizing HIV testing, engaging communities in the promotion of HIV services, and intensifying educational and marketing efforts to increase awareness of the benefits of early therapy to individuals and secondarily to society at large.

Treatment 2015 principles

Access to HIV testing and treatment is essential to realizing the highest attainable level of health for people living with HIV.

Treatment delivery is simplified and decentralized.

Treatment, including associated costs, is affordable to all.

Zero discrimination or coercion is allowed.

Access to HIV testing and treatment is equitable, and social or legal impediments to access for vulnerable and key populations are eliminated.

Treatment scale-up is optimally effective and efficient.

Treatment scale-up is based on the best available evidence.

Treatment scale-up leverages the lessons learned to strengthen health and community systems.

Strategic partnerships are central to success, and community leadership is an essential component of effective partnerships for HIV treatment.

All stakeholders must be accountable for the results.

Under ***Treatment 2015***, concerted efforts will focus attention on the importance of demand creation. Generating robust demand for HIV testing and treatment cannot be achieved by health ministries or clinicians alone but will require community engagement and leadership.

A more active approach to HIV testing

Early knowledge of HIV status enables people living with HIV to obtain timely HIV care and treatment, and protect their health and well-being while secondarily minimizing the risk of HIV transmission. Passive, partial approaches to HIV testing should be developed into more active, more comprehensive strategies, taking care at all times to avoid coercion or discrimination, protect confidentiality, and ensure at all times that testing is voluntary and accompanied by counselling. Consistent with WHO guidance, countries should choose a strategic mix of service delivery models to increase access to voluntary HIV testing and counselling. Communities are essential partners in efforts to promote and deliver HIV testing services.

Key actions

- **Build and support community demand for HIV testing.** Countries should implement proven models to increase knowledge of HIV serostatus, including multi-disease health screening campaigns and integration of voluntary HIV testing and counselling into wider health screening *(22)*. Widespread information and mobilization campaigns should be undertaken in, and in partnership with, highly affected communities, emphasizing the therapeutic and secondary prevention benefits of HIV treatment and addressing misperceptions about HIV testing and available HIV treatment and care options. Communication initiatives should educate communities about their right to be free of coercion with respect to HIV testing.

- **Normalize HIV testing in health care settings.** Health authorities should collaborate with professional medical and nursing societies and other partners to ensure that no opportunity for HIV testing in health care settings is overlooked *(23)*. Professional training and education, enhanced supervision in clinical settings and integration of HIV testing in diverse health service settings are needed.

- **Leverage community-led efforts to promote HIV testing.** Communities, especially people living with HIV, are best positioned to address misconceptions about HIV testing and treatment. Community-led initiatives should educate communities about the importance of early diagnosis and the availability of simple, well-tolerated treatment regimens.

- **Scale up couples counselling and testing services.** Scale-up should draw from the lessons learned in implementing couples services in various settings *(24)*.

- **Consider integrating HIV testing and counselling, including couples counselling, into community based multi-disease prevention efforts.** HIV screening should be promoted and provided alongside other health interventions (such as long-lasting insecticide-treated nets, safe drinking-water and/or screening for noncommunicable diseases).

- **Support community leadership to partner in delivery of HIV testing services.** Community systems are often better equipped to reach individuals who need HIV testing services and to deliver services in an effective, rights-based, culturally competent manner.

- **Explore the potential of home-based testing.** Home-based HIV testing and counselling – offering HIV testing and counselling in the home using trained providers – may help in overcoming uptake barriers and expanding access to testing. Several countries now have considerable experience with this approach. Home-based testing and counselling, which has been successfully implemented in numerous countries, may facilitate early HIV diagnosis, decrease stigma and increase access to testing for couples and families, including increasing follow-up for HIV-exposed infants *(22)*.

- **Continue research to examine the potential of self-testing.** Although self-testing offers potential to expedite testing uptake, there is limited experience with self-testing in low- and middle-income countries. Concerns about self-testing have been expressed, including the lack of quality assurance systems, availability of pre- and post-test counselling, potential for adverse consequences and challenges associated with ensuring linkage to care for people who test positive. WHO has advised that further research is needed before self-testing can be recommended *(22)*, and pilot programmes are underway to evaluate this approach.

- **Link recipients of HIV testing services with follow-up HIV services.** Appropriate referral mechanisms should be in place in all settings where HIV testing is delivered to ensure that service recipients being tested have ready access to needed HIV prevention and treatment services *(22)*. Where feasible, co-locating HIV testing and clinical services in the same setting helps facilitate immediate linkage and may reduce loss to follow-up at early stages of the HIV treatment continuum.

Building demand creation into a pioneering commitment to HIV treatment access: the case of Brazil

Although few people living with HIV in low- and middle-income countries had access to HIV treatment before 2001, Brazil represented an inspiring exception to this rule, blazing the trail for the global commitment to HIV treatment that would come to fruition after the 2011 United Nations General Assembly Special Session on HIV/AIDS. Since 1996, everyone living with HIV in Brazil has had the right to access to HIV treatment free of charge.

From the beginning of its national commitment, Brazil recognized the importance of proactive steps to generate demand for HIV treatment. The Ministry of Health has long promoted *Fique Sabendo* (know your status) in such places as shopping centres, festivals and gay pride events. In 2012, 3.8 million rapid tests were distributed, and antenatal testing of pregnant women rose from 63% in 2004 to 85% in 2010–2011. In addition to the many primary health care sites that offer rapid HIV tests, more than 517 voluntary counseling and testing centres operate across the country.

Although Brazil has comparatively lower HIV prevalence (0.4%), much higher levels of infection are apparent in certain populations, including gay men and other men who have sex with men, sex workers, transgender people and people who use drugs. Brazil supports innovative and community-centred approaches to engage the members of key populations, provide HIV testing and counseling services and link those who test HIV-positive to HIV primary care. After promising results from a pilot project, the Ministry of Health is scaling up the use of mobile clinics that bring testing into the communities of vulnerable populations.

Today, about 250 000 people living with HIV are receiving HIV treatment in Brazil. Public producers in Brazil currently manufacture 11 of the more than 20 antiretroviral medicines currently available in the country.

Further expand treatment access

Countries should address impediments to health care access and utilization, and communities must be empowered to demand essential HIV testing and treatment services.

Key actions

- **Create an enabling environment for accessing treatment.** Countries should immediately align national treatment guidelines with WHO's 2013 consolidated HIV treatment guidelines *(7)*.
- **Take steps to overcome the deterrent effects of stigma and discrimination.** Countries should use an expedited legal and policy review to eliminate impediments to HIV treatment uptake. The overly broad criminalization of HIV non-disclosure, exposure and transmission should be eliminated. Laws and law enforcement practices that penalize key populations, such as sodomy laws and mandatory testing and treatment of sex workers and people who use drugs, should be replaced with laws that protect against discrimination and support access to voluntary HIV testing, counselling and treatment. Anti-stigma programmes, including school-based initiatives, should be implemented and/or strengthened; and key stakeholders, such as religious leaders and organizations or networks of people living with HIV and key populations, should be engaged in broader efforts to fight stigma and discrimination. Countries should actively work to create programmes to reduce discrimination in health care settings, implement mechanisms

for civil society monitoring and reporting on discrimination and coercion and establish accessible and effective systems for support and redress in cases of health care–related discrimination *(25)*.

- **Increase community literacy with respect to HIV treatment and rights.** Treatment literacy programmes empower people living with HIV to understand the importance of early HIV diagnosis and the availability of simplified, safer and highly effective regimens that dramatically improve health and the quality of life. Treatment and rights literacy enables people to make informed decisions about their health and helps generate broad-based demand for HIV testing and treatment services *(26)*. Empowered individuals understand their rights, including the right to a fair and public hearing by an independent and impartial tribunal if rights are violated.

Emphasize the prevention benefits of HIV treatment

In scaling up antiretroviral therapy, educational and awareness efforts have primarily focused on the health benefits of HIV treatment and care to the patient. However, people living with HIV, like all other people, wish to avoid exposing others to harm. HIV treatment for individual benefit, as well as for prevention, expands prevention options for people living with HIV, providing additional motivation for early treatment, robust adherence and retention in care. HIV treatment also has the potential to reduce HIV-related stigma and discrimination, since it dramatically lowers the risk of HIV transmission.

Key actions

- **Actively disseminate information regarding the secondary prevention benefits of HIV treatment** *(27)*. Education and outreach should focus particular efforts on reaching HIV serodiscordant couples and all sexually active individuals living with HIV, focusing on the complementary benefits of treatment with respect to conception, protecting sexual and needle-sharing partners and protecting children during pregnancy and breastfeeding. Similar information should be disseminated among people who inject drugs to ensure their awareness of the impact of HIV treatment on transmission as a result of needle-sharing. Efforts to increase awareness of the secondary prevention benefits of HIV treatment should be complemented by enhanced dissemination and implementation of evidence-informed behavioural prevention and tools and practices for reducing risk.
- **Implement the Global Plan towards elimination of new HIV infections among children and keeping their mothers alive.** Full implementation of the Global Plan *(28)* will increase the number of women and children accessing HIV treatment, keep families intact, empower women to reach their full potential and virtually eliminate new infections among children.

TREATMENT 2015
PILLAR 2: INVEST

Reaching the target of enrolling 15 million people and retaining them on antiretroviral therapy by 2015 will require significant financial investment, not only for the purchase of commodities but also to strengthen health and community systems.

Domestic HIV spending: major strides, considerable room for improvement

In 2011, domestic HIV spending for the first time accounted for a majority of HIV expenditure in low- and middle-incomes worldwide. Domestic public and private spending on HIV activities more than doubled from 2005 to 2011.

However, substantial work remains to maximize domestic contributions to the response. In Africa, only six countries in the region have met the Abuja Declaration target of allocating 15% of national public sector spending on health. Among 33 countries in sub-Saharan Africa, 26 receive more than half of HIV funding from international sources, including 19 that depend on external sources for at least 75% of HIV-related spending. Domestic support for HIV programmes focusing on key populations is especially low, with international sources accounting for at least 90% of such spending in 2010–2011.

Touchstones for an investment approach to scaling up HIV treatment include emphasizing innovation and recognition of the shared responsibility for the HIV response. Up-front investments to achieve universal access to treatment will save millions of lives and help lower long-term resource needs for the response.

Achieve optimal levels of strategic investment

Reaching 15 million people with HIV treatment by 2015 and advancing rapidly towards universal access to treatment will require robust, sustained financing.

Key actions

- **Close the HIV resource gap by mobilizing resources through domestic and international sources, including innovative financing mechanisms.** A combination of multiple funding avenues will be needed to mobilize the level of resources required to "close the resource gap by 2015 and reach annual global investments of US$22-24 billion in low- and middle-income countries." Countries should increase their domestic investment, taking into account their economic status; as economies grow, "growth dollars" should be rapidly translated into "health dollars". International donors will need

to bridge gaps in investments through continued support for vital bilateral programmes and through robust funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria, and UNITAID. Domestic and international partners should identify innovative funding mechanisms, such as the financial transaction tax, AIDS levies or surcharges on mobile phone use.

- **Develop investment cases that demonstrate the return on investing in HIV treatment.** Country-specific investment cases should be used to mobilize resources, influencing both national finance ministries and international donors *(29)*. Investment cases should assume that HIV treatment is initiated early and take into account broader societal and productivity gains, as well as averted medical costs.
- **Increase efficiency and effectiveness *(30)*.** To reduce costs, the latest evidence and cutting-edge technology should be effectively deployed. Rapid integration and scaling up of point-of-care CD4 diagnostics is critical, countries must ensure use of simplified, once-daily regimens of optimal durability, capacity for viral load monitoring should be increased, and enhanced programme management and use of focused interventions should reduce loss to follow-up across the HIV treatment continuum *(31)*. Eligible countries should maximize appropriate use of TRIPS flexibilities to lower treatment costs, and all partners should play their part to preserve and expand affordable generic antiretroviral medicines.
- **Give priority to scaling up in key settings and populations with disproportionately high unmet need for HIV treatment.** Improvements in HIV information systems and analytic capacity will be required in many countries to ensure a more strategic, focused approach to scaling up HIV treatment.
- **Invest in critical enablers and development synergies to enhance the effectiveness of HIV testing and treatment programmes.** Investment in HIV testing and treatment services should be complemented by commensurate scaling up of HIV prevention and support interventions as well as investment in critical enablers and development synergies that reduce vulnerability and enhance the reach, efficiency and effectiveness of services *(32)*.

International HIV spending: flattening support

At a time when the world has the means to move towards the end game of the epidemic, international investment in HIV programmes has remained flat since 2008. Robust, reliable funding for the Global Fund to Fight AIDS, Tuberculosis and Malaria will play a vital role in expediting the scaling up of HIV treatment.

Promoting efficient use of resources in South Africa

Despite having the world's largest antiretroviral therapy programme, South Africa long paid substantially more for antiretroviral medicines than most other low- and middle-income countries, purchasing only one third of its antiretroviral medicines at internationally competitive prices as recently as 2010. Having embarked in 2009 on a landmark national effort to increase HIV case-finding and expand access to antiretroviral therapy, South Africa determined to enhance the competitiveness of its antiretroviral medicine purchases, starting with a major antiretroviral medicine tender in 2011–2012.

The 2011–2012 tender, undertaken with financial and technical support from the United States President's Emergency Plan for AIDS Relief and the William J. Clinton Foundation, incorporated major new measures to lower antiretroviral medicine prices.

Benchmarking: To communicate price expectations to suppliers and incentivize competitive bidding, the Government of South Africa disseminated a list of reference prices for all products in the tender.

Price stability. The tender included provisions on mid-contract price adjustments to ensure that prices remain competitive throughout the contract period.

Reliability. The Government and its partners took steps to improve its antiretroviral medicine forecasting, increasing suppliers' confidence and enabling them to optimize production planning.

Transparency. Clear guidelines were established to ensure the transparency of the evaluation and adjudication processes.

South Africa's new approach yielded extraordinary results, resulting in a 53% overall reduction in the cost of antiretroviral medicines, with projected two-year savings of US$ 640 million.

Innovate for success

Although scaling up HIV treatment and other existing tools has the capacity to lay the foundation for an end to the AIDS epidemic, only innovation will produce the health tools needed to make new HIV infections a rare event.

Key actions

- **Invest in innovation.** Continued efforts are needed to identify new classes of HIV drugs, identify optimally simplified and durable regimens and find a cure for the disease and a preventive vaccine. Implementation science needs to be scaled up to expand the evidence base on strategies to reduce loss to follow-up across the HIV treatment continuum and improve treatment outcomes.
- **Give priority to translating evidence into effective programmes.** Norms and guidance should be rapidly produced at the global, regional and national levels, and country-level delays in adopting and rolling out international guidance must be eliminated. To ensure timely application of new knowledge, efforts should be made to increase countries' capacity to absorb innovation solutions quickly by strengthening health registration systems, promoting harmonized regional regulatory approaches and having nimble procurement and distribution processes in place.

Strengthen health and community systems

Strong, accessible health facilities and well-trained health workers are pillars of effective HIV treatment.

Key actions

- **Increase the number of primary treatment delivery points *(31)*.** Every person living with HIV should have HIV treatment services within easy reach. Services should be client-friendly, with minimal waiting and transaction time for access to medicines and care.
- **Maximize service provision through integration *(31)*.** One proven strategy to increase treatment uptake is to deliver a range of integrated services at various points of entry into the health care system. Experience has proven that HIV may be effectively integrated with maternal and child health services, TB services, sexually transmitted infection clinics, drug treatment services (such as opioid substitution therapy) and other general health services. The capacity of primary health care centres to offer HIV treatment should be strengthened.
- **Build laboratory capacity.** Urgent efforts are needed to build the laboratory capacity that will be needed to sustain HIV treatment programmes. Focused work is especially required to ensure that people living with HIV and their clinical providers have ready access to high-quality, rapid-turnaround laboratory services for key diagnostic tools, such as CD4 and viral load tests.
- **Incorporate private and other health care providers.** Although public sector providers will and should play a central role in the delivery of HIV treatment, achieving universal access to HIV testing and treatment will require innovative models of partnership with private and other health and community care providers.
- **Strengthen community systems *(31)*.** Communities have the capacity to complement pressures on overstretched health systems. Countries should redouble efforts to train community health workers in providing HIV treatment and care, and community systems should be strengthened to offer peer support and assistance with treatment adherence as part of a broad package of community-led services. People accessing antiretroviral therapy and members of key populations at higher risk should be supported, where feasible, to be involved as paid community health workers and expert patients.
- **Increase investments in monitoring and evaluation systems.** Acting strategically requires having timely, reliable strategic information. Robust HIV information systems are required to identify and respond in a strategically focused manner to key geographic settings and populations that need intensified action. Monitoring and evaluation systems are also critical to ensuring a high level of quality for HIV testing and treatment services.

Produce generic antiretroviral drugs in Africa

With roughly 7 of every 10 people living with HIV residing in Africa, achievement of universal access to treatment will demand concerted efforts to ensure a long-term supply of affordable, high-quality antiretroviral drugs in the region. While external sources of generic medicines have served as a critical lifeline for the region, achieving and sustaining universal access to treatment in the region over the long term would be advanced by increasing Africa's local production capacity for pharmaceutical products.

Key actions

- **Promote technology transfer through South–South cooperation.** The BRICS countries (Brazil, Russian Federation, India, China and South Africa) should be

encouraged to share knowhow and expertise to strengthen manufacturing capacity in Africa.

- **Implement the African Union strategy on local production.** Shared procurement policies should be explored, and countries should take steps to remove tax and tariff barriers to lower prices and enable health goods to flow easily from country to country (see text box). Countries should create incentives for investment in local research and development, continue and strengthen relationships with major research and development funders and pharmaceutical and biotechnology companies and strengthen and harmonize regulatory systems to expedite the availability of medical innovations.
- **Support countries in using TRIPS flexibilities and in negotiating intellectual property issues and licensing.** South–South collaboration and international partners should help to build the capacity of eligible countries to make appropriate use of TRIPS flexibilities and to engage with industry on intellectual property and licensing issues *(31)*.

Leveraging viral load laboratory capacity to enhance the success and durability of HIV treatment

As of December 2010, there were nearly 40 000 people eligible for antiretroviral treatment in sub-Saharan Africa for every viral load laboratory. Urgent efforts are needed to build the capacity of health systems in low- and middle-income countries to monitor viral load. Viral load testing enables systems to assess medication adherence and the quality of care, and it alerts health care providers of the need to switch regimens.

TREATMENT 2015
PILLAR 3: DELIVER

With many delivery channels already stretched to their limit, innovation will be needed to achieve the 2015 target and advance further towards universal access to treatment globally. Countries should set and achieve annual national targets for scaling up treatment through 2015 and begin planning for annual targets post 2015, with the goal of achieving universal access to treatment in all settings and for all populations.

Innovation and worldwide application of lessons learnt will be needed to improve the reach, efficiency and effectiveness of HIV treatment delivery. To enhance treatment delivery, it will be essential not only to enhance public sector programmes but also to leverage the considerable share of HIV treatment and care services that are provided by civil society organizations and faith-based groups.

Implement innovative, effective delivery models

Service systems need to be specifically designed to respond to the needs and desires of the people who are to be served.

Key actions

- **Implement task shifting and empower communities to own their HIV treatment programmes.** Community health workers have the capacity to provide almost 40% of HIV service-related tasks *(34)*. Testing and treatment services need to be decentralized to promote early treatment and easier access. After a community support programme involving self-forming patient groups was rolled out to complement centralized clinical centres in Mozambique, two-year retention rates climbed to 98% *(35)*.
- **Redesign delivery systems.** Instead of centralized treatment delivery points that often require people to travel long distances to a health centre, delivery points should be redesigned around the needs – and convenience – of people living with HIV. Decentralizing treatment services is essential to meet scale-up targets and to sustain treatment gains *(31)*. For some services, remote consultation with physicians can be as effective as personal visits. Strategies exist for delivering antiretroviral medicines efficiently and inexpensively in place of travelling to often-distant dispensing centres. Face-to-face time should be concentrated where it is most needed, thereby improving the retention of people in treatment and saving the valuable time of health care workers.
- **Promote community partnerships.** Organizations such as the Red Cross and Red Crescent societies, medical associations, nursing associations, faith-based networks of health services and community outreach organizations have potentially valuable roles to play in extending health and social support networks. Innovative partnerships with such organizations should be promoted to leverage their community networks and their strengths in delivering services.
- **Give priority to programme management and innovation to close gaps in the HIV treatment cascade.** Individual clinical and service settings should immediately implement and strengthen quality improvement mechanisms, identifying and monitoring specific process and outcome indicators and using findings to enhance service quality and impact. Health ministries and other stakeholders charged with overseeing clinical and service settings should intensify quality monitoring through

such means as quarterly site visits by quality assurance teams. Service sites should be given incentives to use innovation to enhance linkage, retention and adherence, such as communication technology *(36)*.

Ensure equity

Equitable access is not only right; it is also essential to achieving universal access.

Key actions

- **Strengthen the capacity of key populations to access HIV treatment.** HIV treatment programmes for key populations should be integrated into other routine outreach services that are managed by members of the key populations themselves. In light of new data underscoring the prevention benefits of antiretrovirals for people who inject drugs, efforts are urgently need to enhance outreach and treatment delivery for this heavily affected population. Integrating HIV programmes in ongoing outreach services for key populations not only facilitates access for key populations into health services but also mitigates the deterrent effect of stigma and discrimination. At the same time that training, supervision and policy enforcement are mobilized to increase the responsiveness and sensitivity of mainstream health systems, consideration should be given, where indicated, to establishing specialized HIV treatment centres in settings where uptake is unlikely for key populations because of stigma and discrimination.
- **Increase children's access to HIV treatment.** Early diagnosis and treatment of children living with HIV is a critical priority in all settings. Immediate steps are needed to eliminate the gap in children's treatment access. Expanding access to early infant diagnosis, countries should commit to 100% active case-finding for all children testing positive for HIV. Countries should make HIV testing routine for children who are malnourished, have chronic acute respiratory infections or diarrhoea and are in non-emergent inpatient hospital paediatric wards. Additional efforts are needed to ensure universal access to paediatric antiretroviral formulations.
- **Take steps to encourage men to seek HIV testing and treatment services.** In countries with generalized epidemics, men are substantially less likely than women to get tested or to receive HIV treatment if they are living with HIV. In large measure, this appears to reflect differences in care-seeking behaviour among men and women. Focused efforts are needed to market the benefits of HIV testing and treatment for men.
- **Ensure meaningful access for women and girls.** By adopting formal laws and policies ensuring gender equity in access to services and adopting tailored service strategies, countries should work to ensure that women and girls have ready access to appropriate, high-quality HIV services.

Be accountable for results

All stakeholders in the response must assume their respective roles and responsibilities in the push for universal access to treatment.

Key actions

- **Measure to drive progress.** Countries should strengthen or establish systems to track people enrolling in and receiving HIV treatment in real time. Countries should use, where possible, modern communication technologies, including mobile phones, to gather information. Progress should be reviewed every quarter for the next 1000 days.
- **Systematically track outcomes across the HIV treatment cascade.** Indicators should be in place, along with corresponding data collection systems, to permit ongoing assessment of rates of linkage to care and retention in care. An international consensus should swiftly be forged on essential metrics to characterize and measure the treatment cascade.
- **Establish a rapid response system to monitor and avert stock-outs of medicines.** Such a system would help countries to anticipate stock-outs and move to bridge inventory stock-outs or address emergencies. Communities should be fully engaged in the process of developing the rapid response system and in monitoring the results and tracking commitments.

Ensuring a reliable, continuous supply of affordable high-quality medicines

Quality-assured generic medicines represent the backbone of HIV treatment in low- and middle-income countries, with Indian-manufactured generic medicines accounting for an estimated 80% of antiretroviral drugs used in Africa. Since an estimated 6% of the people receiving first-line antiretroviral therapy need to shift to second-line regimens per year, ensuring meaningful access to affordable second- and third-line drugs is critical to long-term success in the HIV response.

Flexibilities under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) allow countries to ensure that their public health needs are protected, The Doha Declaration on TRIPS and Public Health clarified the right of countries to take steps to advance national public health aims by ensuring the affordability of essential medicines. Least-developed countries have been granted an eight-year extension, until 1 July 2021, to protect intellectual property under the TRIPS agreement, in recognition of the economic, administrative and financial constraints that they continue to face, and their need for flexibility to create a viable technological base.

In recent years, Africa has taken important steps to preserve future access to affordable medicines. In 2007, the African Union adopted the Pharmaceutical Manufacturing Plan for Africa to boost the regional drug manufacturing capacity and to reduce Africa's dependence on external suppliers. Steps are also underway to harmonize regulatory systems across the region to avoid needless delays in access to medical products *(33)*. In 2012, the African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa extended these commitments by pledging to work towards developing drug manufacturing hubs in Africa and maximizing the use of appropriate TRIPS flexibilities.

Building regional capacity to manufacture and deliver essential medicines will not only enhance the reliability of drug supplies but also have other public health and economic benefits. All efforts should be made to combat the distribution and use of counterfeit or substandard medicines.

TREATMENT 2015: MAKING IT HAPPEN

In implementing the needed programmes and strategies to demand, invest and deliver HIV treatment, countries should take immediate steps to ensure their preparedness to rapidly scale up HIV testing and treatment services. Countries should immediately identify key geographical settings and populations in which the epidemic is concentrated and in which the scaling up of HIV treatment is lagging, using the findings to inform the setting of programme priorities and allocation of resources.

National readiness to accelerate progress towards the *Treatment 2015* goal

Countries should ensure that each of the following steps is implemented.

- **Countries should establish and adhere to clear, ambitious national targets for scaling up.** In the push to expedite the scaling up of HIV treatment, countries should articulate clear, annual targets towards universal access to treatment, keeping in mind the importance of scaling up as rapidly as possible. Countries that already have targets in place should immediately review these to ensure that they are sufficiently ambitious and reflect the urgency of the ***Treatment 2015*** agenda. UNAIDS country teams will, where needed, assist countries in reviewing and revising their national targets.
    - **Each country should establish specific targets for populations in which the scaling up of HIV treatment is currently lagging, including: children; men; men who have sex with men; people who inject drugs; sex workers; transgender people and other sexual minorities; and prisoners.** These targets should provide for expedited progress towards equitable access for all populations.
    - **Countries are advised to undertake an expedited review that identifies and address bottlenecks to expediting scale-up.** These reviews should use existing institutional mechanisms, such as national AIDS coordinating bodies, and efforts should be made to include key partners who may not currently participate, such as the private sector or representatives of key populations.
- **Legal and policy frameworks should be reviewed and, where indicated, reformed to expedite progress.** Countries should undertake an expedited national assessment of legal and policy frameworks and, where indicated, initiate an evidence-informed national dialogue to reform measures that impede rapid scaling up towards universal access to treatment. In particular, countries should ensure that appropriate measures are in place to prohibit HIV-related discrimination, provide people living with HIV and key populations with meaningful access to legal services and eliminate legal or policy provisions that reflect or reinforce stigma or serve as deterrents to service utilization, such as unwarranted criminalization of HIV exposure. UNAIDS and UNDP will assist countries in making the case, based on sound public health evidence and reviews of legal frameworks, where reforms are needed.
- **Country-level partners should undertake a review of systems to identify and address bottlenecks.** Drawing on the best available evidence, including the input of programme implementers, people living with HIV and representatives of key

populations, national health ministries should identify factors that slow uptake and contribute to loss to follow-up at various stages of the HIV treatment continuum. This review should also geographically map capacity and utilization to identify settings where scaling up is slow and where focused efforts to expedite uptake are needed. Particular efforts should focus on closing the HIV treatment access gap for children. United Nations partners will work with other global partners (such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief, UNITAID, and international nongovernmental organizations) to inform and support these expedited national reviews.

- **Where they do not exist, countries should convene an inclusive, interdisciplinary advisory body to provide assistance and insight into efforts to achieve universal access to HIV testing and treatment.** This body should not have a formal mandate and should complement and support, rather than replace, existing institutional arrangements. The aim of this body is to ensure that national health authorities have ongoing access to diverse perspectives and expertise, enabling countries to anticipate and address challenges, seize emerging opportunities and make programmatic adjustments in a timely manner. It should include the widest possible array of partners, including national ministries, programme implementers, donors, international technical organizations, community-based organizations, people living with HIV, the private-sector, professional associations and representatives of key populations.

- **Countries should cultivate and support strategic partners to ensure the most effective, inclusive approach to scaling up HIV testing and treatment.** They should undertake a review of HIV-related partnerships to identify relationships that need to be forged and strengthened. Leveraging each partner's expertise and advantages, countries should develop multifaceted partnerships that unite diverse stakeholders in the common aim of expedited progress towards universal access to HIV testing and treatment.

Why HIV treatment targets for key populations are needed

Tracking the use of services by the general population often obscures the reality that many populations have difficulty accessing the services they need, in many cases because of the deterrent effects of stigma and discrimination. Population-specific tracking of treatment access is not a panacea; service coverage for children living with HIV has been tracked for years, but a marked disparity in treatment access for children persists. However, since strategic information is essential to formulating sound policies and programmes, population-specific tracking generates critical information that can inform resource allocation, drive the creation of tailored delivery models and support advocacy to close gaps in access.

TREATMENT PARTNERSHIPS

PARTNERS	ACTIONS CAN INCLUDE		
Governments Policy-makers Legislators Leaders Judges	Legal protection Enabling legal and policy environment	Investment and accountability	Critical enablers
Donors Bilateral and multilateral Global Fund to Fight AIDS, Tuberculosis and Malaria Private foundations UNITAID	Investments	Global solidarity	
People living with HIV	Leadership	Generating demand Informing strategy development Supporting service delivery	
Health care providers Physicians Nurses Counsellors Community health workers	Service delivery	High-quality services	Care with dignity, free of stigma
Social service providers Teachers Childcare institutions	Synergies		
Civil society Community-based organizations Faith-based organizations Nongovernmental organizations International NGOs	Advocacy and accountability	Service delivery	Community mobilization
Scientific community	Innovation	Evidence	Investment
Private sector Employers Pharmaceutical manufacturers	Medicines	Community support	Workplace policies
International organizations United Nations International nongovernmental organizations Regional bodies (European Union, African Union, ASEAN etc.)	Global standards	Accountability	Policy guidance

Intensifying scaling up in key settings and populations

Epidemics vary within each country. Among provinces in Kenya, the HIV prevalence varies 15-fold between the most severely affected province and the least severely affected one *(37)*. In all settings, some populations are more affected than others. The strength of local health systems also often varies within countries, which contributes to subnational differences in service coverage.

To build on previous gains, efforts should focus on accelerating progress in higher-prevalence areas where scaling up is insufficient. This will require the innovative use of HIV information systems to generate the strategic information needed to make informed decisions regarding the allocation of finite resources.

- **National HIV monitoring and evaluation systems should be reviewed and, where indicated, revised to drive progress, innovation and accountability in the scale-up of HIV treatment.** South–South cooperation and timely access to focused, high-quality international technical support should inform and support national efforts to build the HIV information systems that will be needed for scaling up.
- **Systems should be in place to permit the ongoing collection and timely reporting of focused, strategic information on the progress in closing gaps in the HIV treatment cascade.** Where needed, countries should have timely access to high-quality technical support to develop indicators and implement monitoring systems to gather needed information on the treatment cascade. The results from these cascade-focused monitoring and evaluation efforts should be available to national health ministries and the informal HIV treatment advisory body for regular quarterly reviews.
- **Countries should ensure that HIV information systems are able to identify the key settings and populations with the greatest unmet need for HIV treatment services.** Information systems need to be sufficiently flexible and nuanced to identify the populations and subnational geographical areas in which the epidemic is expanding the most and where HIV testing and treatment coverage is lower. Policy-makers should use this strategic information to inform the allocation of financial, technical and human resources for HIV testing, treatment and care services.

A focus on countries: international support to reach the Treatment 2015 target

In collaboration with countries, international technical organizations and donors should intensify and refocus technical support to accelerate progress towards universal access to HIV testing and treatment. Joint United Nations Teams on AIDS should spearhead efforts to link national stakeholders with intensified technical support in key areas such as reaching key populations with HIV testing and treatment services; reinventing HIV testing services; shifting to more durable and less toxic medicine regimens; closing gaps in the HIV treatment cascade; and revising national HIV monitoring and evaluation systems to collect, analyse and use strategic information on treatment gaps to improve health outcomes.

Although scaling up HIV treatment is a worldwide imperative, involving countries large and small, rich and resource-limited, in all regions, reaching the ***Treatment 2015*** target will demand focused action in areas in which the need and opportunities for scale-up are greatest. To expedite progress towards the 2015 goal and to show the way for other countries, UNAIDS will focus specific attention on 30 countries in which 9 in 10 people who lack access to HIV treatment live.

Reaching 80% of the people eligible for treatment in the 30 focus countries will account for 96% of the 15 million people who need to be reached by 2015. Twenty of these countries are in sub-Saharan Africa, six in Asia, two in eastern Europe and two in Latin America.

More than 90% of the people currently receiving antiretroviral therapy worldwide live in these 30 countries. However, the gap between current capacity and demand in these 30 priority countries requires substantial shifts in delivery strategies. In its broader assistance to all countries to expedite the scaling up of HIV treatment, UNAIDS will intensify its work in these 30 focus countries to ensure that the 2015 target is achieved.

The 30 countries can be grouped into three categories.

1. **Countries with concentrated HIV epidemics**
   Brazil, China, Colombia, India, Indonesia, Myanmar, Russian Federation, Thailand, Ukraine and Viet Nam
   A new focus is needed to expand services to populations at higher risk of HIV infection, including sex workers and their clients, people who inject drugs, men who have sex with men and transgender people. In addition, specific geographical areas (districts or counties) with a high prevalence of HIV should be given priority for scaling up HIV treatment access.

2. **Countries with generalized epidemics, low antiretroviral therapy coverage (less than 50%) and high gaps in treatment access**
   Angola, Cameroon, Central African Republic, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Mozambique, Nigeria, South Sudan and Togo
   In these countries, about 2.5 million people, do not have access to antiretroviral therapy. Special efforts are required to maintain and accelerate scale-up in these countries.

3. **Countries with generalized epidemics, medium to high antiretroviral therapy coverage (50–90%) but substantial unmet need**
   Kenya, Malawi, South Africa, Zambia and Zimbabwe have already achieved more than 70% coverage, with lower coverage in Ethiopia, Lesotho, Uganda and the United Republic of Tanzania.
   Although these countries have made important progress in expanding access to HIV treatment, each has significant unused capacity to reach those who have yet to obtain therapy. Current momentum needs to be continued and enhanced.

Enhanced, strategically focused efforts in these 30 countries will accelerate progress towards the 2015 target. The lessons learned in these focus countries will help to strengthen, inform and inspire efforts in other countries to expedite the expansion of HIV treatment access and maximize public health impact, especially in the post-2015 push to achieve worldwide universal access and lay the foundation for the continued response to the HIV epidemic.

Recognizing the unfinished AIDS agenda

Recognizing the ***Treatment 2015*** goal as an interim step towards the ultimate aim of laying the groundwork to end the AIDS epidemic, the international community should come together to ensure that the post-2015 development agenda prioritizes rapid achievement of universal access to HIV testing and treatment. The post-2015 agenda must recognize that AIDS is an unfinished Millennium Development Goal and that an historic opportunity exists to build a bridge to an end to the AIDS epidemic.

Treatment 2015: a worldwide imperative

To accelerate progress towards the 2015 target by enhancing strategic focus, ***Treatment 2015*** calls for particular efforts to expedite scale-up in 30 priority countries. The criteria used to select these countries include a large population of people living with HIV who are eligible for treatment, substantial unmet need for HIV treatment and an existing foundation on which to build in expanding treatment access.

However, the focus on these 30 countries is not intended to suggest that accelerating the scaling up of treatment is a lesser priority in other countries. On the contrary, every country, regardless of region, is urged to embrace the approach recommended here to ensure the fastest possible scale-up, and the international community should do everything possible to assist all countries in putting the needed policies and programmes in place.

All regions are encouraged to adopt a strategic approach to scaling up treatment. For example, in the Middle East and North Africa, regional efforts should focus on countries with the greatest treatment gaps, such as Djibouti, the Islamic Republic of Iran, Somalia and Sudan.

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