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Executive summary

The massive global expansion of access to HIV treatment has transformed not only the HIV epidemic but the entire public health landscape, demonstrating that the right to health can be realized even in the most trying of circumstances.

This publication reports on the progress being made in the global scale-up in the use of antiretroviral (ARV) medicines in low- and middle-income countries, the challenges that are being overcome or that await solutions and the opportunities for building on the achievements of the past decade.1

Promising results

The remarkable increase in access to life-saving ART continued in 2012. Fully 1.6 million more people were receiving ART in low- and middle-income countries at the end of 2012, compared with a year earlier – the largest annual increase ever – with the greatest contribution coming from the WHO African Region. The 300 000 people who were receiving ART in low- and middle-income countries in 2002 increased to 9.7 million in 2012.

In the WHO African Region, which continues to bear the brunt of the HIV epidemic, more than 7.5 million people were receiving treatment at the end of 2012 compared to 50 000 a decade earlier. There has been progress in every region, including ones that have been lagging behind. The pace of this global scale-up of treatment is being maintained even in the midst of economic crisis.

These accomplishments reflect the political commitment, community mobilization, technical innovation, domestic and international funding, and other forms of support that have catalysed the global scaling up of ART.

Nevertheless, substantial additional effort is needed to enable 15 million people to access ART in 2015, the target agreed to by United Nations Member States in June 2011 at the General Assembly High-Level Meeting on AIDS in New York (2). The 9.7 million people receiving ART in 2012 represented 65% of that 15 million target, up from 54% at the end of 2011 (Fig. 1).

The overall progress, however, masks some important disparities in access to ART. In most regions, including the WHO African Region, men eligible for ART appear to be less likely to be receiving it than women. Further, the treatment gains are not reaching enough children, adolescents and key populations who face high risk of HIV infection (including sex workers, people who inject drugs, men who have sex with men and transgender people).

The number of children younger than 15 years receiving ART in low- and middle-income countries increased from 566 000 in 2011 to 630 000 in 2012, but the increase was substantially less than for adults. In 2012, over 900 000 pregnant women living with HIV received ARV prophylaxis or treatment for PMTCT (excluding single-dose nevirapine, which WHO no longer recommends) – one third more than in 2009. However, many women living with HIV who need ART are missing opportunities to start treatment

Chapter 1 provides new data on the latest developments in the global treatment effort, highlighting positive trends as well as aspects that require improvement. It also discusses the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection (1), which are designed to take maximum advantage of the multiple benefits of antiretroviral therapy (ART) for treating and preventing HIV infection. Chapter 2 summarizes the impact of the scale-up in reducing AIDS-related mortality and new HIV infections. Chapter 3 examines in detail the sequence of steps that constitutes successful provision of ART services and surveys some of the ample opportunities for innovation. Finally, Chapter 4 discusses the implications and anticipated impact of the new 2013 WHO antiretroviral (ARV) guidelines.

1 At the time this report was prepared (June 2013), country-level HIV programme data for 2012 were available for most but not all countries, and estimates of the number of people eligible for ART were available only for the 22 countries prioritized in the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. The report therefore focuses on presenting and analysing data on expanding services that are based on programme reports from countries that have submitted data and limits the discussion of service coverage at the end of 2012 to the 22 priority countries in the Global Plan. References to global and regional coverage estimates are limited to 2011, using 2011 eligibility estimates generated by country Spectrum models from 2012.
during pregnancy, including in some countries that have a high burden of HIV infection.

Based on current trends in the scaling up of ART programmes, countries can be grouped into three broad categories. In the first group are countries – including some with a high burden of HIV infection – that already are providing treatment to at least 80% of the people who are eligible for it along with several other countries that are poised to emulate them. A second group includes countries that have made considerable progress in scaling up treatment but that need to boost the pace and scope of their efforts significantly if they are to reach the 80% coverage target in 2015. Finally, a third group of countries is far short of the global target and is struggling with serious structural weaknesses in health and governance systems. These countries need major support to boost their treatment efforts.

Regardless of the status of countries in scaling up ART, renewed efforts are needed everywhere in order to achieve the maximum treatment and prevention benefits.

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2 The categorization is based on a linear projection of changes in the number of people receiving and eligible for ART until the end of 2015, based on the most recent year with available data for both ART provision and eligibility, i.e. the year 2012 for the 22 countries included in the Global Plan.

3 Based on the 2010 WHO treatment eligibility criteria: CD4 count ≤350 cells/mm³.
An increasingly powerful impact

Expanding access to ART is changing the global HIV epidemic in momentous ways. AIDS-related mortality rates are declining rapidly. The scaling up of ART averted an estimated 4.2 million deaths in low- and middle-income countries in 2002–2012 (Fig. 2). Joint TB and HIV interventions saved the lives of more than 400 000 people in 2011 alone (eight times more than in 2005) (4).

Improved access to ART is resulting in major increases in life expectancy. In South Africa, for example, data from ART programmes in three provinces show that the life expectancy of adults receiving ART is about 80% of the normal life expectancy, provided they do not start treatment late (5).

The preventive impact of ART is increasingly evident (6–10), including in concentrated HIV epidemics (11) and especially when ART is combined with classical prevention efforts. A recent study in rural South Africa, for example, found that the incidence of HIV infection fell by 17% for every 10% increase in the number of people receiving ART (12).

The scaling up of ART is contributing significantly to the ongoing drop in annual new HIV infections around the world, including among children. Expanding programmes for PMTCT and using more effective ARV regimens helped prevent more than 800 000 children from becoming newly infected between 2005 and the end of 2012. In the 21 African priority countries in the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (13), which account for about 90% of all pregnant women living with HIV and new infections among children globally, mother-to-child transmission rates declined overall from an estimated 26% [24-30%] in 2009 to 17% [15-20%] in 2012.

Fig. 2. Annual number of people dying from AIDS-related causes in low- and middle-income countries globally compared with a scenario of no antiretroviral therapy, 1996–2012

<table>
<thead>
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<th>Year</th>
<th>AIDS-related deaths without ART</th>
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<td>2012*</td>
<td>8 500 000</td>
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*The data points for 2012 are projected based on the scaling up of programmes in 2009–2011 and do not represent official estimates of the number of annual AIDS-related deaths.
Maximizing the benefits of antiretroviral therapy

Programme coverage is improving in all regions, but significant numbers of adults and children still drop out of care at various points along the treatment cascade, from HIV diagnosis to long-term retention in care. Maximizing the multiple benefits of ART requires improving the uptake of HIV testing and counselling, linking people to care, enabling them to initiate ART early and supporting adherence and retention in care.

In many countries surveyed in sub-Saharan Africa more than half the people estimated to be living with HIV are not aware of their HIV status (14). In some countries, significant proportions of pregnant women living with HIV either remain undiagnosed or, if diagnosed, do not start on ARV medicines for their own health and to prevent the mother-to-child transmission of HIV. Other studies in sub-Saharan Africa show that close to half the people who test HIV-positive are lost between testing and being assessed for eligibility, and 32% of the people considered eligible for ART are lost between being assessed for eligibility and initiating ART (15). Numerous efforts are underway to reduce such attrition.

Expanding HIV testing and counselling

HIV testing is the critical first step in linking people living with HIV to the treatment cascade, and it also provides an important opportunity to reinforce HIV prevention. Testing uptake increased impressively in every region, with more than 118 million people in 124 low- and middle-income countries receiving HIV testing and counselling in 2012.

High coverage of provider-initiated testing and counselling has been achieved in antenatal care and TB clinics (but not in other clinical services), especially in countries with a high burden of HIV infection (16). Community-based HIV testing and counselling services, including for key populations, and integrating HIV testing with other disease campaigns are proving effective in increasing testing uptake.

However, large proportions of people are not aware of their serostatus. In all regions, men are less likely than women to take an HIV test. Coverage of HIV testing and counselling...
is especially low among adolescents and key populations. Structural, operational, logistical and social barriers—including stigma, discrimination, and punitive laws and policies—continue to hinder access to testing for key populations. Although the early diagnosis of HIV in infants is improving in many countries, in 2011 only 35% (29–41%) of infants born to mothers living with HIV received an HIV test within the first two months of life.

As a consequence, in all regions, large numbers of people test and present late for HIV treatment, usually once their health is failing, which diminishes the benefits of ART.

**Linking patients from testing to care**

Too many patients are being “lost” between taking an HIV test and starting ART. Several approaches for overcoming this challenge are showing promise, including counselling, providing co-trimoxazole prophylaxis free of charge, ensuring shorter waiting times at clinics and using point-of-care CD4 testing (17).

**Antiretroviral therapy initiation, retention and adherence**

Initiating ART early is vital for successful treatment. The median CD4 count when ART is initiated is rising in all regions but is still too low, and about 1 in 4 people in low-income settings initiate ART late, with CD4 counts <100 cells/mm³.

Once people start ART, the retention rates are initially high and then gradually decline. Data reported in 2013 for 18 countries with cohorts of at least 2000 people on ART indicate that the average retention rates decrease from about 86% at 12 months to 82% at 24 months and 72% at 60 months. Studies confirm that decentralizing ART services improves retention in care (18–20), including for children (21), and various forms of adherence support are also proving effective, including treatment support networks and adherence clubs, using mobile-phone text reminders, diary cards and food rations (22).

The goal of ART is to achieve and sustain viral suppression among the people receiving ART. Recent studies show very good outcomes can be achieved, even in poorly resourced settings (23). In a large study in Rwanda, for example, 86% of the people receiving ART had viral suppression 18 months after starting ART (24); in Senegal, about 80% of the people receiving ART were achieving viral suppression after five years (25). Sustaining such achievements will take special efforts, particularly as there are indications that, as ART continues to be scaled up, the rates of drug resistance may increase (26). Systems for monitoring early warning indicators and conducting surveillance of HIV drug resistance must be in place to detect these patterns in a timely manner.

**Implications of the 2013 WHO antiretroviral guidelines**

Current trends in the global scaling up of ART give great cause for optimism. Nevertheless, further improvements are both necessary and possible. To take full advantage of the enormous impact of providing ART for preventing people from dying and from becoming newly infected with HIV, WHO has revised its ARV guidelines to recommend earlier initiation of ART—at CD4 count ≥500 cells/mm³—and immediately initiating ART for serodiscordant couples, pregnant women living with HIV, people with TB and HIV, people with HIV and hepatitis B, and children living with HIV who are younger than five years, irrespective of CD cell count (1).

If fully implemented, the 2013 WHO ARV guidelines could avert at least an additional 3.0 million deaths and prevent close to an additional 3.5 million new infections between 2012 and 2025 in low- and middle-income countries, compared with continuing with the 2010 treatment guidelines (Fig. 4 and 5).

Realizing these benefits could require a 10% increase in total annual investment in the global HIV response in the coming years, which is “very cost effective” according to global criteria. These resource needs are projected to level off over time before declining after 2025, a trend that reflects the accumulated prevention benefits of expanding the provision of ART. Greater access to ART will reduce new HIV infections and thereby eventually reduce the number of people eligible for ART.

The demonstrated benefits of ART in terms of averted deaths and prevented infections exceed many of the
expectations that helped launch the global scaling up of ART a decade ago. The 2013 WHO ARV guidelines (1) are designed to extend these benefits more widely and will increase the potential number of people eligible for ART to an estimated 25.9 million in 2013 (9.2 million more people than were eligible under the previous 2010 WHO treatment guidelines). These changes underscore the need to intensify efforts globally to expand access to ART.

**Fig. 4.** Projected annual number of people dying from AIDS-related causes in low- and middle-income countries based on the 2010 WHO treatment guidelines and the 2013 WHO ARV guidelines and cumulative deaths averted by switching from 2010 to 2013 guidelines, 2011–2025

**Fig. 5.** Projected annual number of adults acquiring HIV infection in low- and middle-income countries based on the 2010 WHO treatment guidelines and on the 2013 WHO ARV guidelines and additional cumulative number of people avoiding HIV infection by switching from 2010 to 2013 guidelines, 2011–2025

Maintaining 80% coverage under the WHO 2010 treatment guidelines involves initiating ART at CD4 ≤ 350 cells/mm³ or clinical stages III or IV, maintaining 80% coverage under the WHO 2013 ARV guidelines involves initiating ART at CD4 ≤ 500 cells/mm³, and for serodiscordant couples, pregnant women living with HIV and children living with HIV younger than five years, irrespective of CD4 count.

Source: special analysis conducted by Futures Institute, 2013.
Chapter 1: Progress towards global targets

KEY POINTS

More people than ever received life-saving antiretroviral medicines in 2012

The number of people accessing ART globally continues to climb rapidly, and the target of reaching 15 million people with this life-saving treatment is within grasp.

• The number of people receiving HIV treatment has tripled in five years – and reached 9.7 million in low- and middle-income countries in 2012. That total represents 65% of the global target of 15 million people set for 2015, up from 54% at the end of 2011.

• There were about 1.6 million more people on ART at the end of 2012 compared to end-2011, the largest-ever increase in a single year. The remarkable pace of scaling up ART is continuing despite the ongoing global economic crisis.

• If this substantial effort is sustained, the world can reach the global target of 15 million people receiving ART by the end of 2015.

• Most countries with a high burden of HIV infection are potentially on track to achieve universal access (defined as 80% ART coverage, based on the 2010 WHO criteria for treatment eligibility). However, some countries urgently need major support to boost their scaling up of treatment.

• Access to ART has increased in every region. The WHO African Region is leading the scale-up effort and is home to 4 of 5 people who started ART in 2012. The WHO European Region and Eastern Mediterranean Region have seen substantial rates of increase but remain the regions with the lowest treatment coverage among low- and middle-income countries.

• Based on current trends, one of the core targets of the Global Plan – providing ARV medicines to 90% of pregnant women living with HIV globally by the end of 2015 – appears to be within reach.

HIV treatment is still not reaching enough children and key populations.

• The number of children younger than 15 years receiving ART rose from 566,000 in 2011 to 630,000 in 2012, but the percentage increase was smaller than for adults (10% versus 20%).

• A huge effort is needed to reach the goal of providing ART to all children eligible for treatment by 2015.

• Certain populations at higher risk of HIV infection are not benefiting equitably from ART, including people who inject drugs, men who have sex with men, transgender people and sex workers.

• Stigma, discrimination and punitive laws are denying these key populations the multiple benefits of ART.

• In some regions, including the WHO African Region, men eligible for ART are less likely than women to receive it.

New WHO global guidelines on using ARV medicines for treatment and prevention aim to boost the impact of ART by broadening the criteria for eligibility for ART.

• The new guidelines reflect evidence indicating the multiple benefits of initiating ART earlier for both prevention and treatment.

• The CD4 threshold for treatment of adults living with HIV is being raised to 500 cells/mm3, and treatment regardless of CD4 count is recommended for all children living with HIV younger than 5 years, all pregnant women living with HIV, people living with HIV and coinfected with TB or hepatitis B and HIV-positive partners in serodiscordant relationships.

• Applied to the current reality, the new 2013 guidelines would increase the total number of people eligible for ART in low- and middle-income countries globally from 16.7 million to 25.8 million people. However, the additional prevention benefit of ART means that the total number of people eligible for ART will peak in 2021 and will then decline significantly.
Chapter 2: Making impact: the strategic use of antiretroviral drugs to treat and prevent HIV

KEY POINTS

Expanding access to antiretroviral therapy is changing the global HIV epidemic in momentous ways

AIDS-related mortality rates are declining rapidly, including in countries with a very high burden of HIV infection.

- The global scale-up of treatment has saved 4.2 million lives in 2002–2012 in low- and middle-income countries.
- The annual number of people dying from AIDS-related causes globally fell from a peak of 2.3 million in 2005 to 1.7 million in 2011.
- In eastern and southern Africa, AIDS claimed 38% fewer lives in 2011 than in 2005, when ART began to be scaled up in that region.
- The life expectancy for people receiving ART now approaches normal life expectancy, including in countries with a high burden of HIV infection.

Scaling up ART is a major factor in recent HIV prevention successes and is driving down the incidence and mortality of TB.

- The number of people acquiring HIV infection globally declined by 20% between 2001 and 2011.
- The scaling up of PMTCT services has prevented more than 800 000 children from acquiring HIV infection between 2005 and the end of 2012.
- Joint TB and HIV interventions saved more than 400 000 lives in 2011 alone (8 times more than in 2005).
Chapter 3: Challenges and opportunities in strengthening the treatment cascade

KEY POINTS

- The main steps in the treatment cascade involve diagnosing HIV infection, linking people who take an HIV test to treatment and prevention services, enrolling and retaining people in pre-ART care, initiating ART, ensuring long-term adherence and ultimately achieving and maintaining viral load suppression.

- Programme coverage is improving in all regions, but significant proportions of people still drop out of care at each step of the treatment cascade.

- Programmes are identifying new opportunities to improve uptake of testing, reduce the time elapsing before eligibility is assessed and treatment is initiated, and support adherence and retention in care.

- The Treatment 2.0 framework provides a lens for identifying opportunities for improvement at every step, with a focus on adapting service delivery, optimizing treatment regimens and diagnostics, reducing costs and mobilizing communities.

HIV TESTING AND LINKAGE TO CARE

HIV testing
Linkage to HIV care and prevention

Enrolment in care
Eligibility assessment
Pre-ART care
Retention

ART initiation
Lifelong ART:
Retention
Adherence
Supplies

Viral load suppression

KEY POINTS

Early HIV testing is the first step in the pathway to successful HIV care

- Globally, about 118 million people in 124 low- and middle-income countries received HIV testing and counselling in 2012.

- In most low- and middle-income countries surveyed, most men and women living with HIV have never been tested for HIV, and therefore are not in a position to know their status.

- In all regions, large numbers of people test and present late for HIV treatment, usually once their health is failing.

- Coverage of HIV testing and counselling is especially low among adolescents and key populations in most parts of the world.

- Globally, about 45% of pregnant women in low- and middle-income countries received HIV testing and counselling in 2012, up from 38% in 2011.

- Early infant diagnosis is being scaled up in many countries, but in 2011 only 35% [29–41%] of the infants born to mothers living with HIV received an HIV test within the first two months of life.

- The coverage of early infant diagnosis is less than 5% in five of the Global Plan priority countries.

- The number of people in HIV care globally who were screened for TB increased by 46% between 2010 and 2012, from 2.4 million to 3.5 million.
ENROLMENT IN CARE AND PRE-ANTIRETROVIRAL THERAPY

KEY POINTS

Substantial numbers of people are being “lost” between taking an HIV test and starting antiretroviral therapy

- Linking to treatment after diagnosis and eligibility assessment for children ranges between 40% and 99% in countries.
- Access to CD4 testing remains limited, with less than 20% of the people who test HIV-positive getting a CD4 count in some regions.
- Point-of-care CD4 testing can significantly speed up the initiation of ART and improve retention among people who are eligible for ART.
- Interventions that are improving outcomes for people receiving pre-ART HIV care include counselling, providing co-trimoxazole prophylaxis free of charge, regular assessment for eligibility for ART, shorter waiting times at clinics and methods that encourage regular clinic visits.
As of 2012, most countries globally allowed ART to be initiated at CD4 ≤350 cells/mm$^3$, and a few have already moved to the higher initiation threshold of CD4 ≤500 cells/mm$^3$.

Median CD4 when initiating ART is rising in all regions but is still too low, and about 1 in 4 people in low-income settings initiate ART late, with CD4 counts <100 cells/mm$^3$.

Option B+ for preventing the mother-to-child transmission of HIV is being rapidly adopted as a way to increase the coverage of ART for pregnant women living with HIV.

Decentralizing HIV care improves access and retention, and an increasing number of countries have piloted or are rolling out ART delivery at the community level.

Improving retention in ART care is a key challenge for programmes

- The latest data from 23 countries indicate that the average retention rates for people on ART decreases over time, from about 86% at 12 months to 82% at 24 months and 72% at 60 months, with considerable variation between countries.
Data from Rwanda showed that 86% of the people receiving ART had viral suppression 18 months after starting treatment. In Senegal, about 80% of the people receiving first-line therapy were achieving viral success after five years on treatment.

Access to viral load testing remains limited but is increasing rapidly in some countries. For example, Kenya has increased its viral load testing capacity 40-fold, from fewer than 10,000 tests in 2011 to a projected 400,000 tests in 2013.

Retaining people receiving antiretroviral therapy in care and ensuring good treatment adherence are critical determinants of successful long-term viral load suppression.
Chapter 4: **Looking forward: earlier antiretroviral treatment towards controlling the epidemic**

**KEY POINTS**

Implementing the 2013 WHO guidelines on the use of antiretroviral medicines for HIV treatment and prevention can prevent considerably more people from dying from AIDS-related causes and acquiring HIV infection.

- Fully implementing the 2013 WHO ARV guidelines could reduce the number of people dying annually from AIDS-related causes from 1.7 million in 2011 to about 800,000 in 2025, compared to an anticipated reduction to 1.3 million if the 2010 treatment guidelines were fully implemented.

- Between 2013 and 2025, the total number of AIDS-related deaths averted could increase from 9 to 12 million if the 2013 WHO ARV guidelines are fully implemented.

- Fully implementing the 2013 ARV guidelines could reduce the annual number of people newly acquiring HIV infection from 2.4 million in 2011 to close to 800,000 in 2025, compared to an anticipated decrease to 1.25 million if the 2010 treatment guidelines were fully implemented.

- Between 2013 and 2025, the total number of HIV infections averted could increase from 15.5 million if the 2013 ARV guidelines are fully implemented.
References


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