

Executive summary

1. Scaling up access to HIV treatment

The “3 by 5” strategy was announced by the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) in December 2003 and unanimously endorsed in May 2004 by all 192 WHO Member States at the Fifty-seventh World Health Assembly.

From a baseline of approximately 400 000 people receiving antiretroviral therapy in low- and middle-income countries in December 2003, more than 1.3 million people were receiving treatment by December 2005. Antiretroviral therapy coverage in low- and middle-income countries increased from 7% at the end of 2003 to 12% by the end of 2004 and 20% at the end of 2005. Over the past year, the number of people receiving treatment increased by about 300 000 every six months. Scale-up in sub-Saharan Africa was most dramatic, from 100 000 at the end of 2003 to 310 000 at the end of 2004 and 810 000 at the end of 2005. More than half of all people receiving treatment in low- and middle-income countries are now living in this region compared with one quarter two years earlier.

By the end of 2005, data reported from 18 countries¹ indicate that they had met the “3 by 5” target of providing treatment to at least half of those who need it.

In sub-Saharan Africa, the number of people receiving treatment increased more than eight-fold over the two-year reporting period (from 100 000 to 810 000) and more than doubled in the past year. Coverage increased from 2% in 2003 to 17% at the end of 2005. About 1 in 6 of the 4.7 million people in need of antiretroviral therapy in this region now receive it. However, progress is uneven, with coverage reaching 50% or higher in countries such as Botswana and Uganda but remaining below 10% in others. With over 200 000 people now receiving treatment, South Africa accounts for one quarter of those receiving antiretroviral therapy in the region.

The number of people receiving antiretroviral therapy in East, South and South-East Asia increased from 70 000 in 2003 to 180 000 (estimated coverage 16%) at the end of 2005. Thailand has been a major driver of this increase. With more than 70% of the region’s total treatment need, India’s antiretroviral therapy coverage still remains well below 10%.

In Latin America and the Caribbean, the number of people receiving treatment has increased gradually to 315 000 (estimated coverage 68%), up from 210 000 at the end of 2003. In this region, 13 countries with over 1000 people who need antiretroviral therapy are treating at least half of those in need.

Progress has been less dramatic in low- and middle-income countries in Europe, central Asia, North Africa and the Middle East, with 21 000 people in Europe and central Asia and 4000 in North Africa and the Middle East now receiving treatment as compared to 15 000 and 1000 respectively at the end of 2003.

At the end of 2005, funding provided by the United States President’s Emergency Plan for AIDS Relief was supporting programmes treating 471 000 people. Programmes funded by the Global Fund to Fight AIDS, Tuberculosis and Malaria were providing treatment to 384 000 people. However, according to the methods developed by the Emergency Plan and the Global Fund, approximately 214 000 people were receiving treatment through programmes jointly financed by the two initiatives. Together, the two initiatives were therefore supporting 641 000 individual people receiving treatment.

Estimates based on drug disbursements show that 716 000 people in low- and middle-income countries were receiving treatment with at least one antiretroviral drug provided by the research-based pharmaceutical industry through the Accelerating Access Initiative.

¹ Countries with at least 1000 people needing antiretroviral therapy that are treating at least half of those in need. These are Argentina, Botswana, Brazil, Chile, Costa Rica, Cuba, El Salvador, Guyana, Jamaica, Mexico, Namibia, Panama, Peru, Poland, Thailand, Uganda, Uruguay and Venezuela.

Immune and viral responses were good, and mortality reductions in low-income settings were similar to those achieved in high-income countries. Expanded antiretroviral therapy access averted between 250 000 and 350 000 deaths in 2005. The full effects of scale-up, especially during 2005, will only be seen in 2006 and subsequent years.

There is currently no evidence of systematic gender bias in access to antiretroviral therapy. However, some studies indicate that women experience particular barriers to adhering to antiretroviral therapy, including fear of disclosure and domestic violence.

An estimated 660 000 children younger than 15 years needed treatment in 2005, representing slightly more than 10% of the total number of people in need. The vast majority of the 570 000 children younger than 15 years who die from AIDS-related illnesses every year contract the disease through mother-to-child transmission. Less than 10% of pregnant women living with HIV/AIDS are estimated to be receiving antiretroviral prophylaxis, resulting in 1800 infants becoming infected with HIV every day. In October 2005, the United Nations Children's Fund (UNICEF) and UNAIDS launched a campaign that seeks to provide 80% of women in need with access to services to prevent HIV from being transmitted to their babies by 2010.

An estimated 36 000 injecting drug users were receiving antiretroviral therapy by the end of 2004, of which 30 000 were in Brazil and the remaining 6000 were distributed among 45 other countries. In eastern Europe and central Asia, injecting drug users account for more than 70% of HIV cases but represent only about 24% of the people receiving antiretroviral therapy.

Treatment sites grew from about 500 sites providing antiretroviral therapy in low- and middle-income countries in June 2004, not including private outlets, to more than 5100 antiretroviral therapy service delivery sites by the end of 2005. The average client volume per site is at least twice as high in sub-Saharan Africa (399 people per site) than in most other parts of the world.

Although stigma and lack of perceived benefits of treatment may slow the uptake of antiretroviral therapy, demand does not appear to have been the limiting factor in scale-up. Rather, the rate of increase is determined primarily by supply-side factors such as drug supply, funding, identifying people's HIV status and human resource capacity. Providing treatment free of charge in low-income settings has been found to be associated with improved adherence and treatment outcomes.

Drug procurement and prices

Health systems must provide an uninterrupted supply of antiretroviral drugs to maximize the chances of good treatment outcomes and prevent the emergence of drug-resistance. At the end of 2005, about half of the US\$ 3.5 billion allocated by the Global Fund, for example, had been designated for procuring drugs and health care commodities for HIV/AIDS, tuberculosis and malaria. In many countries, however, the systems for procuring and distributing essential medicines of any kind to the district and facility levels have been chronically weak and in some cases, virtually nonexistent. WHO established the AIDS Medicines and Diagnostics Service (AMDS) – a network of agencies involved in procurement and supply chain management – to help countries obtain the most competitive prices for essential medicines and other supplies and to make sound choices in purchasing drugs and diagnostics. AMDS has helped ensure that investment in systems for procuring and distributing antiretroviral drugs also builds local capacity to procure and supply other essential medicines.

Between 2003 and 2005, the price of first-line medication decreased between 37% and 53%, depending on the regimen. Nevertheless, prices remain unacceptably high in some countries, especially for second-line regimens. In 2005, the average price per person per year paid for WHO-prequalified first-line treatment in low-income countries ranged from US\$ 148 (for the most widely used combination of stavudine + lamivudine + nevirapine) to US\$ 549 (for zidovudine + lamivudine + efavirenz). The average price of these two combinations was US\$ 268 per person per year in 2005. The fall in drug prices has been fuelled by the ongoing scaling up of antiretroviral therapy, competition among a growing number of WHO-prequalified products and negotiations between the William J. Clinton Foundation and generic manufacturers. In middle-income countries, the price of first-line treatment was considerably higher and remained almost stable between 2004 and 2005.

Second-line treatment is significantly more expensive. In 2005, a regimen of tenofovir + abacavir + lopinavir or ritonavir cost an average of US\$ 1888 per person per year in low-income countries and US\$ 4126 in middle-income countries. The prices paid for second-line regimens varied significantly between countries. For example, Côte d'Ivoire pays on average US\$ 1700 for this regimen per person per year, whereas El Salvador pays US\$ 6788.

The prices of diagnostics and laboratory supplies need to be further reduced.

Health systems strengthening

WHO defines health systems strengthening as building capacity in critical components of health systems (policy, funding, human resources, service management and information and monitoring systems) in order to achieve more equitable and sustained improvements across health services and improved health outcomes. "3 by 5" has contributed to governments, donors and technical agencies giving higher priority to strengthening health systems, with encouraging implications for the realization of all the health-related Millennium Development Goals. "3 by 5" has also challenged the belief that antiretroviral therapy cannot be provided where only basic health systems exist.

Strategies to maximize human resource capacity and to train health workers in delivering antiretroviral therapy are essential to scaling up access to antiretroviral therapy in low-income countries. These include innovative training techniques and approaches to expand the range of people who can deliver HIV/AIDS services, such as the Integrated Management of Adult and Adolescent Illness (IMAI) training approach developed by WHO and its partners, which has been adopted in some 29 countries.

"3 by 5" has also highlighted the importance of using existing health infrastructure and services (often referred to as entry points) in the areas of tuberculosis, sexual and reproductive health, and preventing mother-to-child transmission to deliver antiretroviral therapy and scale up HIV prevention. Links between HIV and malaria are also now receiving more attention.

Integrated services addressing the needs of injecting drug users are also being scaled up. Harm reduction programmes such as needle and syringe exchange sites and drug dependence treatment services provide valuable entry points for HIV testing and counselling, referral to treatment and care and the delivery and monitoring of antiretroviral therapy. Methadone and buprenorphine, the most effective forms of drug dependence treatment for heroin and other opioid users, were included on the WHO Model List of Essential Medicines in 2005.

Political and financial commitment

Building on years of advocacy by treatment activists and civil society groups, the "3 by 5" target has contributed to the significant increase in commitment to scaling up antiretroviral therapy at both the global and national levels over the past two years. The number of the 49 "3 by 5" focus countries with national plans in place or in development for antiretroviral therapy access jumped from three in December 2003 to 46 by December 2005.

Countries are demonstrating their commitment to ensuring that treatment programmes are not only started but also sustainable over the long term. The Russian Federation increased its federal AIDS budget for 2006 18-fold to nearly US\$ 107 million and has doubled its contribution to the Global Fund. China's central government continued to increase its prevention and care investment, increasing the HIV/AIDS budget from about US\$ 49 million in 2003 to US\$ 100 million in 2005.

Countries in sub-Saharan Africa are also increasing domestic budget allocations. Between 2003 and 2004, Senegal increased its HIV/AIDS budget from US\$ 12 million to US\$ 19 million and Burkina Faso from US\$ 24 million to US\$ 35 million. South Africa has committed almost US\$ 1 billion of its own resources to HIV/AIDS over a three-year period.

The commitment of international donors has grown markedly in recent years, with global expenditure on HIV/AIDS in low- and middle-income countries increasing from US\$ 4.7 billion in 2003 to an estimated US\$ 8.3 billion in 2005. A significant proportion of funding is now being provided by the United States President's Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the World Bank's Multi-Country HIV/AIDS Program for Africa and Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Lending Program. However, UNAIDS estimates that up to US\$ 22 billion per year will be needed to fund a comprehensive response by 2008.

Partnerships

Between 2003 and 2005, more than 200 organizations indicated their intention to work with WHO or otherwise contribute to attaining the "3 by 5" target.

"3 by 5" has helped to foster new cooperation among trade unions, employers' associations and technical agencies addressing HIV/AIDS. It has also led to new ties between faith-based organizations, donors and technical agencies. It is estimated that faith-based organizations provide up to 40% of the medical infrastructure in sub-Saharan Africa.

The Collaborative Fund for HIV Treatment Preparedness, a joint venture of 20 international donors, WHO, the International Treatment Preparedness Coalition and the Tides Foundation provided technical and financial support to more than 200 community groups around the world to undertake treatment literacy activities in 2005. These resources are helping to train thousands of people living with HIV/AIDS in managing their care and to equip thousands of others with the knowledge needed to advocate for HIV treatment and prevention.

All UNAIDS Cosponsors have been involved in the effort to scale up treatment, and the UNAIDS Secretariat has played a leading role in all aspects of "3 by 5" policy development and implementation globally and at the country level. A Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors, established in 2005, recommended further measures the United Nations should take to assist countries in best utilizing their resources.

2. Towards universal access

In July 2005, leaders of the Group of Eight (G8) countries announced their intention to "work... with WHO, UNAIDS and other international bodies to develop and implement a package for HIV prevention, treatment and care, with the aim of as close as possible to universal access to treatment for all those who need it by 2010". All United Nations Member States subsequently endorsed this goal at the High-Level Plenary Meeting of the 60th Session of the United Nations General Assembly in September 2005.

"3 by 5" and the experience gained in these early years of delivering HIV treatment in low- and middle-income countries offer valuable lessons for future efforts to scale up treatment.

Treatment targets and policy reforms maximize programme effectiveness

By establishing a global benchmark, "3 by 5" encouraged countries to set ambitious national treatment targets, demonstrating that targets can play a vital role in encouraging national ownership and in mobilizing stakeholders, funds, technical agencies and donors.

"3 by 5" also encouraged countries to undertake a variety of policy reforms to expand access and improve the capacity of health systems. The critical shortage of health professionals in most low-income countries has required re-thinking service delivery models and led to the adoption of a public health approach to HIV treatment. A public health approach emphasizes simplified treatment guidelines, team-based approaches and delegating routine follow-up to trained nurses and community workers, community mobilization and education, public-sector procurement to ensure high quality and the rational use of drugs and commodities, standardized patient tracking, drug resistance surveillance, the expansion of voluntary testing and counselling and improved integration of prevention and treatment interventions.

Recent evidence indicates that user fees at the point of service delivery for HIV treatment, which are commonplace in low- and middle-income countries, inhibit access to treatment and undermine health

outcomes. Even if relatively small, user fees impose a significant financial burden on the people receiving antiretroviral therapy and their families and undermine adherence to medication, but generate little revenue at the national level, since collecting fees requires a larger government bureaucracy. Botswana, Brazil, Ethiopia, Senegal, Thailand, the United Republic of Tanzania and Zambia have all recently adjusted health financing policy to eliminate user fees for HIV treatment at the point of service.

Less than 10% of people in sub-Saharan Africa know their HIV status. Scaling up access to prevention, treatment and care will require that more people be tested for HIV and know their status. Since 2004, WHO and UNAIDS have recommended that an HIV test be routinely offered to everyone in clinical and community-based settings where HIV is prevalent and antiretroviral therapy is available. People must always retain the right to refuse the test, and the confidentiality of results must be maintained. A growing number of countries are adopting counselling and testing policies consistent with this model.

There is now broad consensus that focusing on treatment or prevention alone is not an effective option and that both must be scaled up together. Epidemiological modelling using different intervention scenarios consistently shows that more deaths can be averted with a comprehensive response including both treatment and prevention than with a response that focuses on treatment or prevention alone.

The challenges ahead

Despite progress to date, some persistent challenges continue to thwart the scaling up of antiretroviral therapy and HIV prevention. These include poorly harmonized partnerships, constraints in the procurement and supply of drugs, diagnostics and other commodities, strained human resource capacity and other critical weaknesses in health systems, difficulty in ensuring equitable access and lack of standardized systems for the management of programmes and for monitoring progress.

Although important steps have been taken to promote effective partnerships between technical agencies and to encourage harmonization in scaling up programmes, additional efforts must be made to eliminate bottlenecks at the country level. Lessons learned from the work of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors and the Global Joint Problem-solving and Implementation Support Team (GIST) highlight the need for greater coordination between United Nations agencies, major donors and implementing country-level partners. Strengthening the capacity of national HIV/AIDS coordinating mechanisms and consolidating regional and national technical capacity and regional and subregional knowledge hubs are also important.

Although international support increased substantially between 2003 and 2005, the funding gap for 2005–2007 will widen to an estimated total of US\$ 18 billion. At least US\$ 22 billion will be required each year by 2008 to fully fund the global response. The uncertainty of future funding increases concerns about treatment sustainability and has the potential to serve as a brake on scaling up to universal access. Innovative financing mechanisms, such as France's tax on airline tickets and the United Kingdom's International Finance Facility, are ways in which donor countries can complement traditional efforts to finance development cooperation.

More attention to releasing resources is also required. Procurement and supply management weaknesses have caused substantial delays in releasing Global Fund resources. Global Fund proposals prepared with WHO or UNAIDS technical assistance have been more successful than those that did not receive such assistance. Countries urgently need more effective country-level forecasting of technical support needs and adequate monitoring and evaluation systems, and technical agencies must receive sufficient funding to continue this assistance. The proposed upcoming Round 6 of the Global Fund in April 2006 presents an important opportunity to ensure that adequate resources to achieve universal access are made available to countries.

The supply of essential drugs and other commodities continues to constrain the scaling up of antiretroviral therapy. Major challenges to improving the effectiveness of procurement and supply systems include pricing, financing, production and inadequately performing supply chain management. The lack of assured financing beyond 2008 presents a serious hurdle, and there are currently no flexible funding mechanisms or adequate buffer stocks to deal with supply stock-outs during grant renewal periods that are often protracted.

The price of first-line antiretroviral therapy regimens remains high, and the cost of second-line regimens is prohibitive for most countries. The recent effort by the William J. Clinton Foundation to establish reference prices for groups of countries has the potential to improve the predictability of demand and create a stable market for second-line drugs and commodities in low- and middle-income countries.

Other pressing procurement needs include a rapid, reliable test to diagnose HIV infection among children younger than 18 months, improving the procurement of antibiotics to treat opportunistic infections and substance-replacement therapy for harm reduction programmes among injecting drug users.

Strengthening health systems is an urgent challenge. In sub-Saharan Africa the shortage of health workers has reached 1 million, and an additional 20 000 health workers are lost each year to emigration. The World Bank also estimates that a country with a 15% prevalence rate can expect to lose between 1.6% and 3.3% of its health workers every year due to AIDS. In addition to shifting routine tasks to trained, non-professional health workers, critical needs include recruiting and training large numbers of additional health workers, improving the retention of existing staff and protecting health workers from the impact of HIV/AIDS by providing them with access to HIV/AIDS prevention, treatment and care.

Programme planning and implementation need to address more comprehensively the barriers to equitable access to HIV prevention, treatment and care for women, children, rural dwellers and those in marginalized populations. Stigma and discrimination remain formidable obstacles, and policies that empower women and girls and address domestic violence are needed in addition to eliminating user fees and implementing a public health approach.

Systems that monitor the scaling up of antiretroviral therapy and other interventions are slowly improving. Nevertheless, few countries have a standardized outcome monitoring system to provide data on survival, health status and quality of life for people receiving treatment. Monitoring for drug toxicity and resistance with tools such as the Global HIV Drug Resistance Surveillance Network (HIVResNet) developed by WHO will also become increasingly important as people embark on life-long treatment. Improved collaboration and coordination on technical support are needed, and increased attention must be paid to monitoring population health and the impact of scaling up antiretroviral therapy on health systems. Increased operational research to disseminate best practices and expanded basic and clinical research are essential to making available simplified drugs, diagnostics, vaccines and microbicides.

Moving the universal access agenda forward

In the first quarter of 2006, UNAIDS is facilitating the development of nationally agreed road maps for working towards universal access to HIV/AIDS prevention, treatment, care and support services, including country-specific interim milestones and targets to be reached by 2010. By February 2006, more than 30 countries had convened national consultations on universal access, and nearly 100 other countries had initiated the planning process.

Where possible, targets for scaling up and frameworks for implementing universal access will be based on existing national plans on development and HIV/AIDS and will utilize existing processes for updating plans. These frameworks will need to include input from a broad range of stakeholders, including government ministries, the private sector, faith-based organizations, civil society, people living with HIV/AIDS and multilateral partners. A multi-partner Global Steering Committee on Universal Access, coordinated by UNAIDS, is overseeing this process and will develop recommendations for the United Nations General Assembly High-Level AIDS Review 2006.

WHO will continue to focus on scaling up antiretroviral therapy and providing guidance to assist countries in meeting current treatment targets. Universal access will, however, also require a strong health sector response that includes a comprehensive package of priority HIV/AIDS interventions, including prevention. In October 2005, WHO held a consultation to ensure that countries have the guidance and technical support to deliver an "essential package" of health sector services. This meeting sought a common definition for universal access and agreement on a proposed technical framework for HIV prevention, treatment, care and support that will form the basis of WHO's technical and strategic recommendations for universal access to be delivered at the World Health Assembly in May 2006.

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Although the target of treating 3 million people by the end of 2005 has not been achieved, the declaration by WHO and UNAIDS of a global health emergency on treatment access and the launch of the “3 by 5” strategy have helped to mobilize countries, communities and individuals to address the overwhelming and urgent need to provide antiretroviral therapy. Lessons learned in scaling up access to treatment have fundamentally altered the public health landscape and will continue to influence the choice of strategic approaches and actions as the world now moves towards the goal of universal access by 2010.