



Progress on Global Access to HIV Antiretroviral Therapy

A Report on "3 by 5" and Beyond

March 2006



WHO Library Cataloguing-in-Publication Data:

Progress on global access to HIV antiretroviral therapy: a report on “3 by 5” and beyond, March 2006.

1.HIV infections - drug therapy. 2.Acquired immunodeficiency syndrome - drug therapy. 3.Anti-retroviral agents - supply and distribution. 4.Antiretroviral therapy, Highly active. 5.Program evaluation. 6.Treat 3 Million by 2005 Initiative. I.World Health Organization. II.UNAIDS.

ISBN 92 4 159413 6

(NLM classification: WC 503.2)

ISBN 978 92 4 159413 4

© World Health Organization 2006

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel: +41 22 791 3264; fax: +41 22 791 4857; email: bookorders@who.int). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; email: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Printed in Switzerland

Contents

Foreword	5
Executive summary	7
Introduction	15
Part 1. Global progress 2003–2005	
1. Scaling up access to HIV treatment	19
1.1 Number of people receiving treatment.....	19
1.2 Who is getting treatment?.....	21
1.3 Expansion of treatment sites.....	24
1.4 Treatment outcomes.....	26
1.5 Drug procurement and supply systems.....	26
1.6 Prices of drugs and other commodities.....	29
2. Strengthening health systems	32
2.1 Human resource capacity.....	32
2.2 Using existing entry points.....	33
3. Political commitment and partnerships	39
3.1 Political and financial commitment.....	39
3.2 Partnership and coordination.....	42
Part 2. Towards universal access	
1. Building on lessons learned	49
1.1 Targets mobilize commitment and action.....	49
1.2 Policy reforms maximize programme effectiveness.....	49
1.3 Key operational approaches facilitate scale-up.....	51
1.4 Persistent challenges must be overcome.....	55
2. Moving the agenda forward	65
3. Supporting the health sector response	66
Conclusion	69
Annex 1. Estimated number of people receiving antiretroviral therapy, people needing antiretroviral therapy, percentage coverage and numbers of antiretroviral therapy sites in low- and middle-income countries.....	71
Annex 2. Data by WHO region and methods used in estimating the number of people receiving and needing antiretroviral therapy.....	77
Annex 3. The “3 by 5” focus countries.....	80



Foreword

The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) jointly launched the "3 by 5" strategy in December 2003, with the objective of helping low- and middle-income countries provide treatment to 3 million people living with HIV/AIDS by the end of 2005. The "3 by 5" target challenged governments, foundations, corporations and the United Nations system to scale up access to antiretroviral therapy as quickly and effectively as possible. The objective was both to deliver drugs and to build health care capacity by mobilizing donor country and national resources, training health care workers, educating communities, expanding testing and counselling and scaling up HIV prevention.

The "3 by 5" target has not been met on time. However, the ongoing effort to expand access to antiretroviral therapy has brought about positive change and has paved the way for far greater advances towards the ultimate goal of universal access to HIV treatment and care. In two years, the number of people receiving antiretroviral therapy in low- and middle-income countries has more than tripled, and access to antiretroviral therapy in the world's hardest-hit region, sub-Saharan Africa, has increased by more than 800%. Today, more than 1.3 million people in low- and middle-income countries are receiving treatment. In 2005, between 250 000 and 350 000 deaths were averted because treatment is available. Every year of life gained provides greater economic stability, food security and educational opportunities for the families of those living with HIV/AIDS and strengthens their wider communities.

What we have learned since the initiation of this effort is both sobering and encouraging. First, the global public health paradigm does not change easily. Social and economic conditions that have caused the collapse of public health systems cannot be corrected overnight. Inadequate health care infrastructure and shortages of trained workers, affordable drugs and diagnostics will still hamper public health efforts for years to come. Stigma and discrimination remain two of our most stubborn obstacles. The response of international donors and national funders, while ever more robust, has not been sufficient to meet this enormous challenge.

At the same time, "3 by 5" has confirmed that HIV treatment can be provided even in the most challenging settings. Public health systems can be rebuilt, piece by piece. The global dialogue on access to treatment has changed for good and, with this, our hope of tackling not just HIV but other diseases of poverty as well. This change in our expectations has been one of the fundamental achievements of "3 by 5".

The challenge now is to build on the successes and overcome the obstacles outlined in this report. The goal is to come as close as possible to universal access to treatment by 2010, as recently endorsed by G8 (Group of Eight countries) leaders and United Nations Member States at the High-Level Plenary Meeting of the United Nations General Assembly in September 2005.

We will continue to learn from the experiences outlined in this report as we move forward towards our ultimate goal of providing universal access to HIV prevention, treatment, care and support for the millions of people who still need it.



LEE Jong-wook
Director-General
World Health Organization



Peter Piot
Executive Director
Joint United Nations Programme
on HIV/AIDS (UNAIDS)



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.

March 2006

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.



Introduction

The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) are involved with many partners in a global effort to rapidly increase access to HIV/AIDS prevention, treatment and care in the parts of the world where they are needed most.

When the “3 by 5” strategy was launched on 1 December 2003, the number of people newly infected with HIV had reached 5 million per year. At the same time, only about 7% of people who immediately needed HIV antiretroviral therapy in low- and middle-income countries had access to it. Increases in treatment access were measured at the pace of dozens, or perhaps hundreds of people per month. “3 by 5” aimed to move that rate of increase from the hundreds to the tens of thousands every month, an enormous undertaking that had never been attempted in any setting.

In 2001, an analysis of resource needs² prepared for the United Nations General Assembly Special Session on HIV/AIDS determined that, with optimal funding and technical capacity, access to lifesaving antiretroviral therapy could be expanded to reach 3 million people globally – half of those estimated to need it – by the end of 2005. In September 2003, WHO and UNAIDS declared the gap between those in need of treatment and those actually receiving it to be a global public health emergency. On 1 December 2003, WHO and UNAIDS launched their “3 by 5” strategy, committing to work with global partners towards achieving the “3 by 5” target. The 3 million target was, and remains, an interim milestone on the road to the ultimate goal of achieving access to antiretroviral therapy for everyone who needs it.

The WHO and UNAIDS strategy to support country implementation of “3 by 5”, *Treating 3 million by 2005: making it happen*,³ set out the five core pillars that provided focus and direction to the organizations’ work. These pillars remain essential to expanding access to antiretroviral therapy and related care and support. They are:

- global leadership, alliances and advocacy;
- providing urgent, sustained country support;
- simplified and standardized tools for delivering antiretroviral therapy;
- creating an effective, reliable supply of medicines and diagnostics; and
- rapidly identifying and reapplying new knowledge and success.

“3 by 5” was not a centrally coordinated initiative. WHO, as the United Nations specialized agency for health with responsibility for HIV treatment and care, assumed primary responsibility for coordinating efforts to reach the target, but efforts to reach the target involved the contributions of a wide variety of stakeholders collaborating to achieve shared objectives while also pursuing independent or agency-specific programmes, goals and milestones. In addition to the more than 200 organizations that have partnered or collaborated with WHO and UNAIDS towards achieving “3 by 5”, global funding partners committed an estimated US\$ 8.3 billion in 2005 to fighting HIV/AIDS, nearly double the 2003 level.

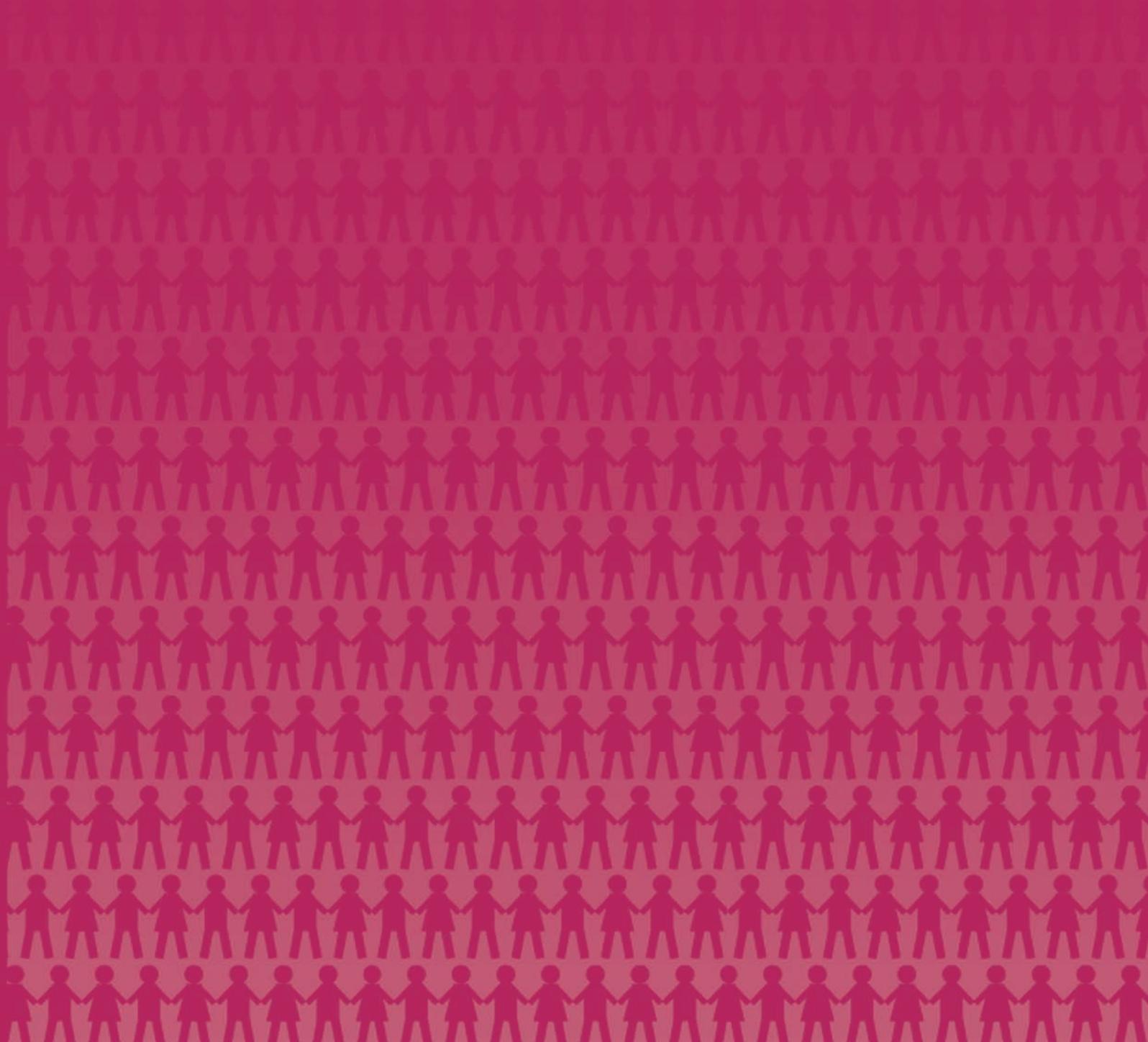
This report describes global progress in scaling up access to antiretroviral therapy and outlines the areas in which important progress has been made and lessons learned. It also outlines the remaining challenges and roadblocks to treatment access. The report will be complemented by the results of an independent evaluation of WHO’s contribution to achieving the “3 by 5” target as well as a WHO report on country action on HIV/AIDS that will describe WHO’s work in more detail and provide updates on progress made in the 49 “3 by 5” focus countries.

² Schwartländer B et al. Resource needs for AIDS. *Science*, 2001, 292:2434–2436.

³ World Health Organization and UNAIDS. *Treating three million by 2005: making it happen*. The WHO strategy. Geneva, World Health Organization, 2003 (<http://www.who.int/3by5/publications/documents/isbn9241591129/en>, accessed 13 February 2006).

PART 1.

Global Progress 2003–2005



1. Scaling up access to HIV treatment

Global efforts to expand access to antiretroviral therapy increased significantly as a result of “3 by 5”, with substantial gains in the numbers of people receiving life-saving antiretroviral therapy achieved in every region of the world. This section provides an overview of global progress and country efforts that took place between the time the “3 by 5” strategy was launched in 2003 and the end of 2005.

1.1 Number of people receiving treatment

From a baseline of about 400 000 people receiving antiretroviral therapy in low- and middle-income countries when WHO and UNAIDS launched the “3 by 5” strategy in December 2003, WHO estimates that more than 1.3 million people were receiving treatment at the end of December 2005 (Table 1). This represents a more than tripling of the number of people receiving treatment over the two-year reporting period. Overall, antiretroviral therapy coverage in low- and middle-income countries increased from 7% at the end of 2003 to 12% at the end of 2004 and 20% at the end of 2005. Over the past year, the number of people receiving treatment globally increased by about 300 000 every six months. Scale-up in Africa was most dramatic, increasing from 100 000 people receiving treatment 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 now receiving treatment in low- and middle-income countries are living in Africa compared with one quarter of those receiving treatment two years ago.

Table 1. Estimated number of people receiving antiretroviral therapy, people needing antiretroviral therapy and percentage coverage in low- and middle-income countries according to region, December 2003 to December 2005^a

Geographical region	Estimated number of people receiving antiretroviral therapy, December 2005 [low estimate–high estimate] ^b	Estimated number of people 0–49 years old needing antiretroviral therapy, 2005 ^a	Antiretroviral therapy coverage, December 2005 ^c	Estimated number of people receiving antiretroviral therapy, December 2004 [low estimate–high estimate] ^b	Estimated number of people receiving antiretroviral therapy, December 2003 [low estimate–high estimate] ^b
Sub-Saharan Africa	810 000 [730 000–890 000]	4 700 000	17%	310 000 [270 000–350 000]	100 000 [75 000–125 000]
Latin America and the Caribbean	315 000 [295 000–335 000]	465 000	68%	275 000 [260 000–290 000]	210 000 [160 000–260 000]
East, South and South-East Asia	180 000 [150 000–210 000]	1 100 000	16%	100 000 [85 000–115 000]	70 000 [52 000–88 000]
Europe and Central Asia	21 000 [20 000–22 000]	160 000	13%	15 000 [13 000–17 000]	15 000 [11 000–19 000]
North Africa and the Middle East	4 000 [3 000–5 000]	75 000	5%	4 000 [2 000–6 000]	1 000 [750–1 250]
Total	1 330 000 [1 200 000–1 460 000]	6 500 000	20%	700 000 [630 000–770 000]	400 000 [300 000–500 000]

Note: some numbers do not add up due to rounding.

^a See Annex 2 for an explanation of the methods used.

^b Data on children are included.

^c The coverage estimate is based on the estimated number of people receiving antiretroviral therapy and need for antiretroviral therapy.

By the end of 2005, data reported from 18 countries⁴ indicate that they had met the “3 by 5” target of providing treatment to at least half of those who need it. Annex 1 shows individual country figures.

⁴ 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.

WHO/UNAIDS modelling indicates that the expansion of access to treatment since the end of 2003 led to between 250 000 and 350 000 deaths being avoided in 2005. The full effects of scale-up, especially during 2005, will only be seen in 2006 and subsequent years.

Fig. 1. Number of people receiving antiretroviral therapy in low- and middle-income countries according to region, end 2002 to end 2005

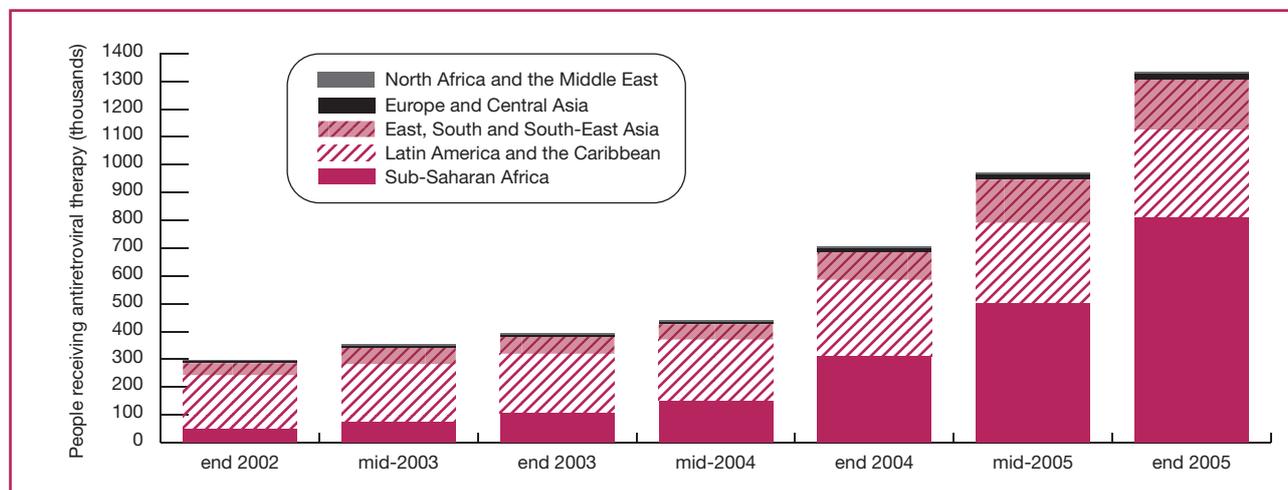


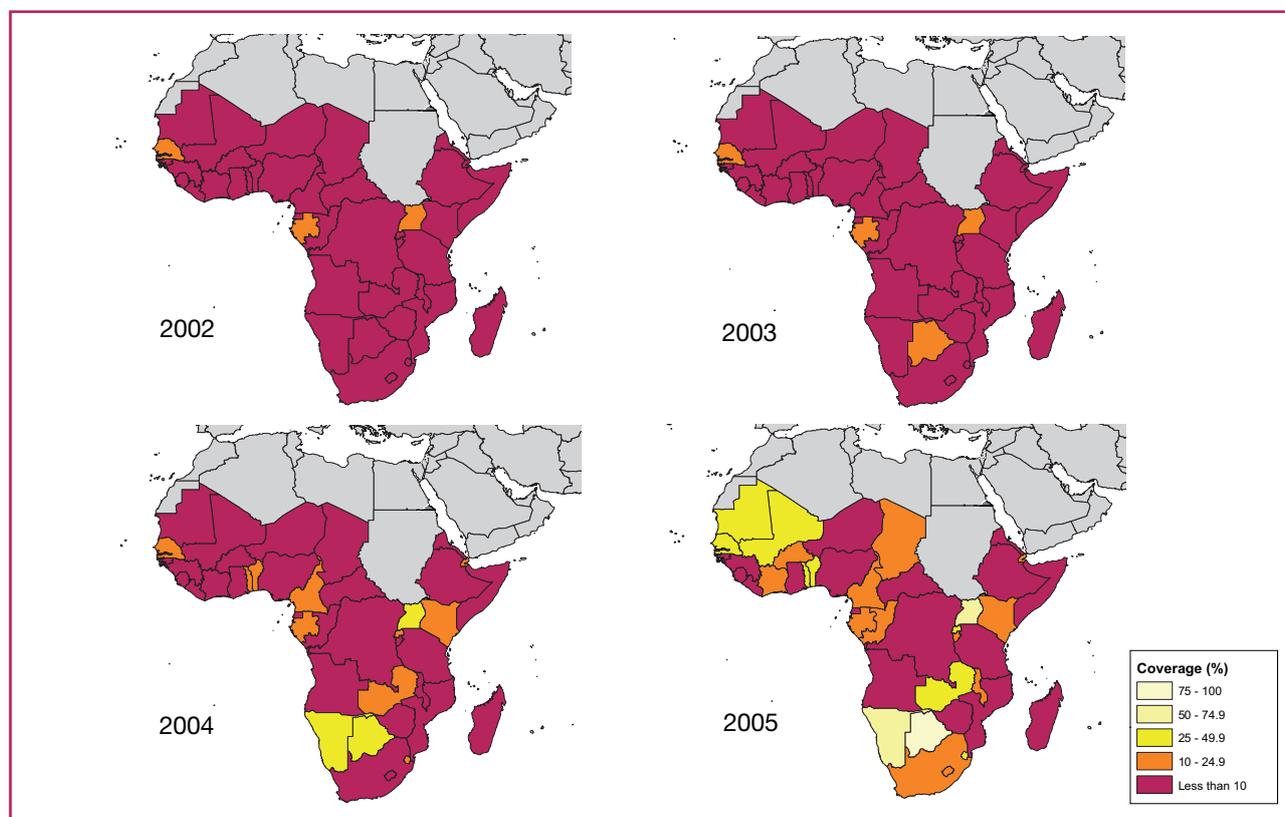
Figure 1 shows the increase in the number of people receiving treatment by geographical region. The most significant increase has occurred in sub-Saharan Africa, where the number of people receiving treatment more than doubled from 310 000 to 810 000 within the last year. Over the two-year reporting period, the number of people receiving treatment in this region increased more than eight-fold. Coverage has risen to 17% from just 2% in 2003, with about one sixth of the 4.7 million people who need treatment now receiving it. Fig. 2 shows the rapid scale-up within Africa during the past two years but also shows major differences in progress between countries. Coverage has increased very rapidly to levels of 50% or higher in some countries, such as Botswana and Uganda, while others still have coverage levels below 10%. South Africa now accounts for one quarter of those receiving treatment in the region, with approximately half provided through private sector facilities.

The number of people receiving antiretroviral therapy in East, South and South-East Asia has continued to increase, up to 180 000 (estimated coverage 16%) from 70 000 people receiving treatment two years earlier. Thailand has been a major driver of this increase, particularly during 2004 and the first half of 2005. India, which accounts for more than 70% of the total need for treatment in this region, still has a coverage level well below 10%, most of which is provided through private sector facilities.

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. Treatment coverage varies considerably between countries in this region. For example, Argentina, Brazil and Mexico have high levels of coverage, whereas the Dominican Republic, Haiti and Nicaragua have coverage levels below 25%. In this region, 13 countries with over 1000 people who need treatment are treating at least half of those in need.

In the low- and middle-income countries in Europe and central Asia and in North Africa and the Middle East, progress has been less dramatic. Some 21 000 people in Europe and Central Asia and 4000 people in North Africa and the Middle East are receiving treatment as compared to 15 000 and 1000 respectively at the end of 2003. An important factor is that virtually all countries in these regions are experiencing concentrated and low-level epidemics, which involve difficult-to-reach populations such as injecting drug users and sex workers.

Fig. 2. People in sub-Saharan Africa receiving antiretroviral therapy as a percentage of those in need, 2002–2005



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 supported 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 disbursement from the Accelerating Access Initiative, which includes seven research-based pharmaceutical companies,⁵ show that, by the end of December 2005, more than 716 000 people in low- and middle-income countries were receiving treatment with at least one antiretroviral drug provided by the Accelerating Access Initiative companies. The total number of people receiving treatment using drugs produced by the Accelerating Access Initiative companies increased by 77% from the previous year.

Annex 2 describes the methods used to estimate the number of people receiving antiretroviral therapy.

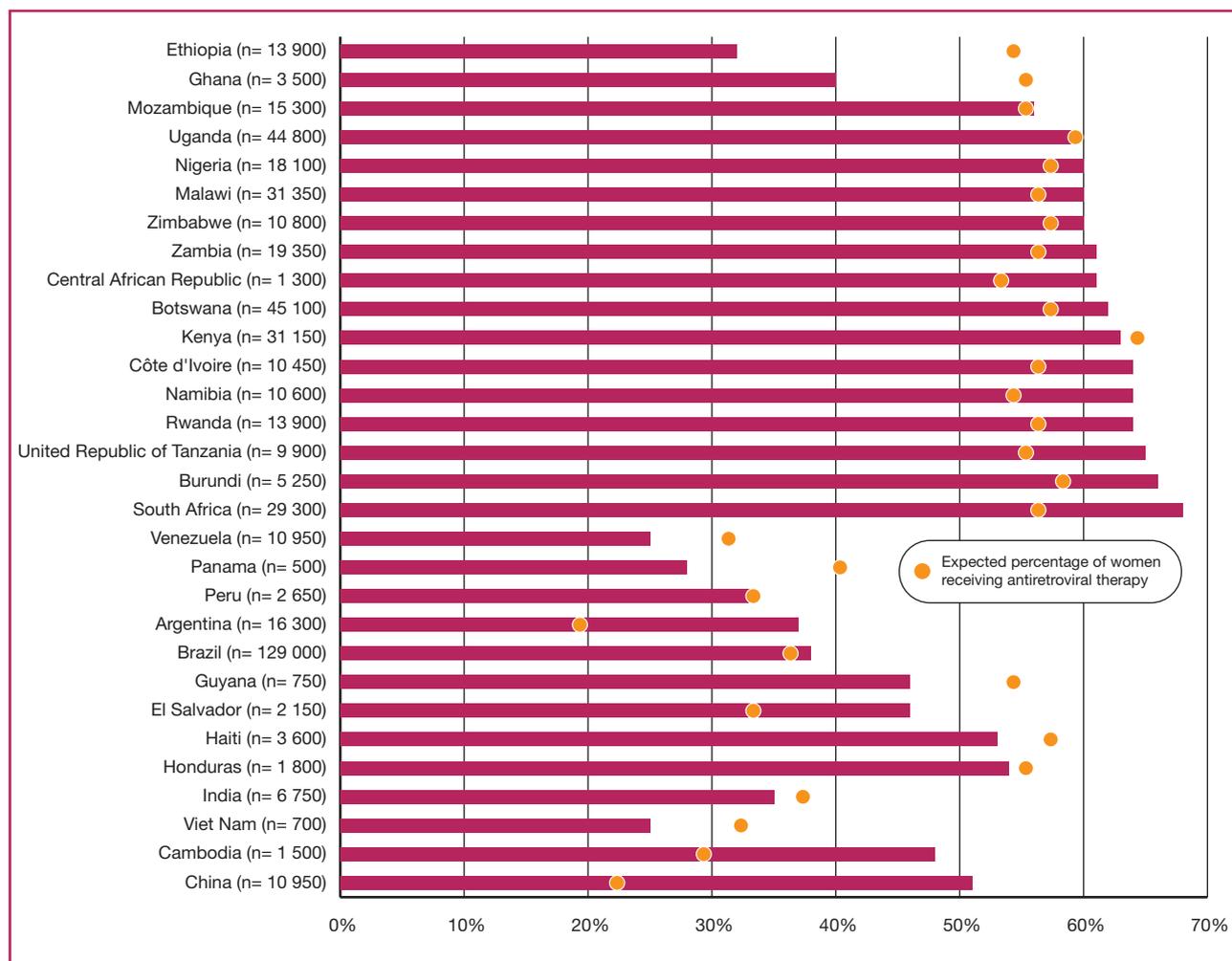
1.2 Who is getting treatment?

Countries have made significant progress in reporting disaggregated data on access to antiretroviral therapy for women and children. By the end of 2005, most countries with large numbers of people receiving treatment reported on the numbers of men, women and children separately. Nevertheless, monitoring the extent to which the current scale-up of HIV treatment and care is reaching women, children and vulnerable populations remains a challenge.

⁵ Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, F. Hoffmann–La Roche and Merck & Co. Inc.

Current evidence shows no systematic gender bias in access to antiretroviral therapy. In some countries more women receive treatment, in others more men. In most countries, the proportion of people receiving treatment who are women corresponds well with the expected percentage of women receiving treatment according to the type of epidemic (25 of the 30 countries in Fig. 3). Ethiopia and Ghana are examples of countries with a possible male bias: the percentage of women among those receiving treatment is well below 50%, whereas at least half of those needing treatment are expected to be women. Burundi, Cambodia, China, El Salvador and South Africa show the reverse: women comprise a higher proportion of the adults receiving treatment than expected.

Fig. 3. Percentage of women among all adults receiving antiretroviral therapy versus the expected percentage based on country or site reports, 2005^a



^a The expected percentage of women receiving antiretroviral therapy is based on the percentage of people living with HIV/AIDS who are women. Values are sorted in ascending order within each WHO region.

One theory to account for the differences observed between countries focuses on the fact that men and women may have different entry points for treatment and different patterns in uptake of testing. For example, women's stronger connections to community networks in some settings may mean that they have more information about the availability of testing and treatment and how to access it, or they may be accessing treatment through sites providing services for preventing mother-to-child transmission or antiretroviral therapy that are integrated into public health systems. In contrast, men may have more access through workplace programmes in some countries. A recent study in Zambia showed that, even when they are receiving antiretroviral therapy, many women experience formidable barriers to adherence, including fear of disclosure, domestic violence and being required to share treatment with a non-tested husband.⁶ Although

⁶ Zulu KP. Fear of HIV serodisclosure and ART success: the agony of HIV positive married women in Zambia. *3rd IAS Conference on HIV Pathogenesis and Treatment 2005, Rio de Janeiro, Brazil, 24-27 July 2005.* (Abstract TuPe11.9CO3; <http://www.hiv-knowledge.org/iasmeps/119cultu.htm>, accessed 13 February 2006).

major differences in access to treatment based on gender have not been widely observed, this issue should continue to be monitored both to identify and eliminate gender bias where possible and to broadly improve understanding of how and why individuals access treatment.

More attention is being paid to the need to increase access to treatment and care for children. An estimated 660 000 children younger than 15 years needed treatment in 2005, just over 10% of the total number of people in need in low- and middle-income countries. Nine out of ten children needing treatment live in sub-Saharan Africa. Children comprise about 7% of all people receiving treatment in sub-Saharan Africa and about 4% in Asia, and in Latin America and the Caribbean the median value of nine countries is 8%. Although these figures indicate some progress during the last year, they should be interpreted with caution. Countries that do not provide data on children are more likely to have fewer children receiving treatment than countries that do provide such data. Table 2 summarizes data from 27 countries. Data on children need to be collected and reported systematically in all countries.

Table 2. Percentage of people receiving antiretroviral therapy who are children in selected countries, end 2005

Sub-Saharan Africa		Asia		Latin America and the Caribbean	
Ghana	3%	China	4%	Peru	2%
Nigeria	3%	India	4%	Venezuela	4%
Côte d'Ivoire	5%	Viet Nam	4%	El Salvador	5%
Malawi	5%	Cambodia	11%	Brazil	6%
Mozambique	6%			Guyana	8%
Rwanda	7%			Haiti	8%
Namibia	7%			Argentina	10%
Zimbabwe	7%			Honduras	12%
Kenya	8%			Panama	15%
South Africa	8%				
Zambia	8%				
Central African Republic	9%				
Uganda	9%				
United Republic of Tanzania	11%				
Median	7%	Median	4%	Median	8%

Data on both children (<15 years) and adults (15–49 years) were available for about 500 000 people from 27 countries. Data for the other regions were not available.

Researchers are only beginning to examine utilization patterns related to socioeconomic status, urban versus rural location and barriers to uptake for vulnerable groups. However, overwhelming evidence shows that urban residents have higher levels of access than rural residents in countries with generalized epidemics, as most facilities providing treatment are located in urban areas, a situation that will only change if concerted efforts are made to decentralize treatment sites.

A review of antiretroviral therapy in low- and middle-income countries⁷ reveals that about 36 000 injecting drug users were receiving antiretroviral therapy by the end of 2004: 30 000 in Brazil and 6000 distributed among 45 other countries. In eastern Europe and central Asia, injecting drug users account for more than 70% of the people living with HIV/AIDS but represent only about 24% of the people receiving antiretroviral therapy.

⁷ Aceijas C et al. Antiretroviral treatment for injecting drug users in developing and transitional countries: one year before the end of "3 by 5". *Addiction*.

1.3 Expansion of treatment sites

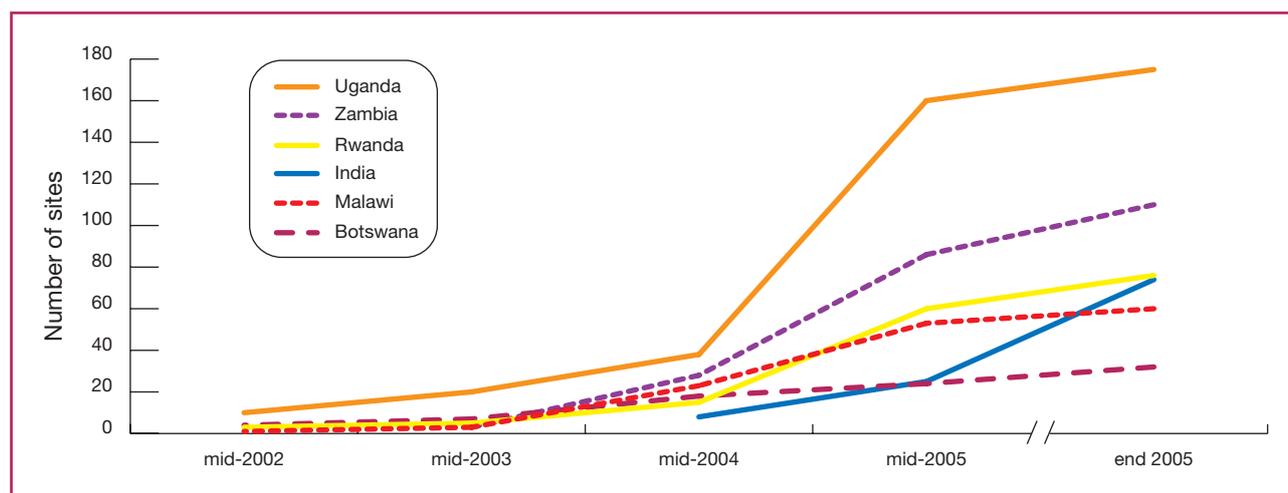
WHO estimated that at least 500 sites were providing antiretroviral therapy in low- and middle-income countries in June 2004, not including private outlets.⁸ By the end of 2005, low- and middle-income countries had an estimated more than 5100 sites for antiretroviral therapy service delivery (Table 3).⁹ The average client volume per site is at least twice as high in sub-Saharan Africa (399 people per site) as in most other parts of the world. The volume per site is 174 in Latin America and the Caribbean and 99 in East, South and South-East Asia. Some countries separately report private-sector data or include the private-sector figures in the overall numbers (see footnotes in Annex 2). Data from individual physicians are generally not included.

Table 3. Number of antiretroviral therapy sites and average number of people receiving treatment in low- and middle-income countries according to region, end 2005

Region	Number of reported antiretroviral therapy sites	Estimated number of sites for countries that did not report data	Total	Average number of people receiving treatment per site
Sub-Saharan Africa	1 646	118	1 764	399
Latin America and the Caribbean	1 557	254	1 811	174
East, South and South-East Asia	1 212	35	1 247	99
Europe and Central Asia	3	24	27	117
North Africa and the Middle East	262	0	262	78
Total	4 680	431	5 111	228

A survey by WHO, UNAIDS and partners in five African countries and India (Fig. 4) highlights the very rapid expansion of public-sector antiretroviral therapy services that has occurred in some countries since “3 by 5” was launched.¹⁰

Fig. 4. Number of antiretroviral therapy service delivery sites in five African countries and India, 2002–2005



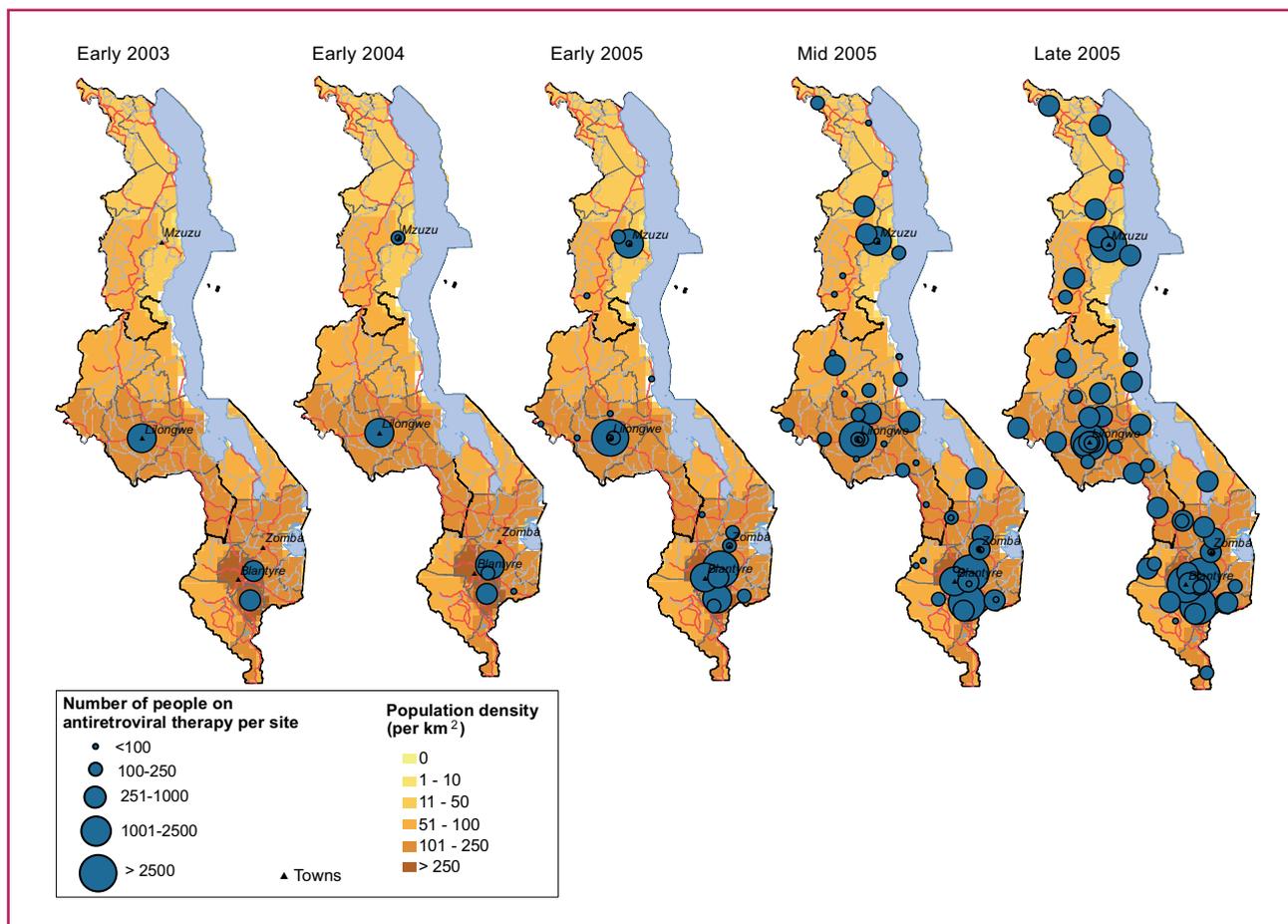
⁸ Public sector data often includes non-profit sector sites but does not include for-profit sites.

⁹ Most countries have reported the number of sites to WHO, mostly public service and service delivery sites supported by nongovernmental organizations. If no data on the number of sites were reported, the number of people receiving treatment was used to estimate the number of sites.

¹⁰ *Monitoring the output and outcomes of anti-retroviral therapy (ART) programmes. WHO, UNAIDS and partners. World Health Organization, 2005* (<http://www.who.int/healthmetrics/library/STARTOMS%20meeting%20report.pdf>, accessed 13 February 2006).

Malawi, for example, which began providing antiretroviral therapy in three facilities in January 2003, reported that 60 sites were providing antiretroviral therapy by September 2005 (Fig. 5). The number of antiretroviral therapy sites in Zambia increased from three in the first quarter of 2003 to more than 110 in just over two years. Although Botswana initially had extremely low human resource capacity, the national AIDS programme was able to mobilize international support to drastically increase the number of health facilities that provide antiretroviral therapy from seven sites in July 2003 to 32 public-sector sites by the fourth quarter of 2005. Rwanda, the smallest of the countries in the survey, has also performed well, having established 76 fully functioning antiretroviral therapy sites by September 2005 versus 16 sites at the end of 2003. Annex 1 shows the number of antiretroviral therapy sites by country in the fourth quarter of 2005.

Fig. 5. Scaling up of antiretroviral therapy in Malawi, 2003 – 2005



Where the epidemic is generalized (prevalence 1% or more), as in the five African countries in the survey, scaling up antiretroviral therapy has typically followed a pattern of site expansion from major urban, to urban, to rural to remote rural populations. In these five countries, antiretroviral therapy was initially only provided in referral hospitals in major cities. In 2004 rapid expansion to district hospitals in other urban areas occurred: for example, Uganda added 33 000 people receiving antiretroviral therapy in one year.

Most of the countries surveyed now have sites that report more than 1000 people receiving antiretroviral therapy ("mega-sites"). Some mega-sites serve more than 3000 people. Most mega-sites are urban, mostly in major hospitals, but some are in successful rural programmes. The proportion of the total number of people receiving antiretroviral therapy through mega-sites is declining over time, however, as more sites are opened.

Most countries with a generalized epidemic have linear growth in the number of people seeking antiretroviral therapy. This indicates that, although stigma and lack of perceived benefits of treatment may slow down the uptake of antiretroviral therapy, especially in the early stages of scale-up, demand is not the limiting factor

in scale-up. Instead, the rate of increase is determined primarily by supply-side factors such as drug supply, funding, identifying HIV status and human resource capacity.

It is reasonable to expect that most countries with generalized epidemics that are scaling up antiretroviral therapy programmes will experience quite similar phases of geographical and system roll-out to the five African countries in this survey, offering lessons for planning and benchmarking.

In low-level and concentrated epidemics, however, building awareness and creating demand for treatment are probably more important determinants of the pace of scale-up, as HIV is generally concentrated among vulnerable populations such as sex workers, injecting drug users and men who have sex with men who have more barriers to overcome to utilize treatment services.

1.4 Treatment outcomes

Research studies in many low- and middle-income countries have reported the dramatic impact of treatment on survival rates. In a multi-country study by the Antiretroviral Therapy in Lower Income Countries (ART-LINC) Collaboration,¹¹ responses to antiretroviral therapy were compared in two distinct groups of treatment-naïve people living with HIV/AIDS: 4810 from low-income settings in 18 countries in Africa, Asia and South America and 22 217 from high-income settings in Europe and North America. The researchers found that immune and viral responses were good and mortality reductions were similar in high- and in low-income settings. The main difference was higher early mortality in low-income settings, possibly because a larger proportion there presented with severe opportunistic infections and in a later stage of disease.

Similarly, a recent study in South Africa¹² reported that 93% of people living with HIV/AIDS were still alive after one year of treatment. Most deaths occurred within the first months of treatment or before initiation, highlighting the need to minimize delays in treatment initiation once eligibility for treatment has been established, as well as the importance of starting treatment before the terminal stage of disease.

Further analysis of the ART-LINC study shows that the adjusted hazard ratio of mortality for low-income versus high-income settings declined from 4.3 (95% confidence interval 1.6–11.8) during the first month to 1.5 (95% confidence interval 0.7–3.0) during months 7–12, thus confirming the good results of timely antiretroviral therapy.

1.5 Drug procurement and supply systems

Health systems must provide an uninterrupted supply of antiretroviral drugs to maximize the chances of good treatment outcomes and prevent the emergence of drug-resistant virus. In many countries, however, the systems to procure and distribute essential medicines of any kind to the district and facility levels have been chronically weak and, in some cases, virtually nonexistent.

Resources made available for scaling up antiretroviral therapy have provided an important opportunity to strengthen these systems. About half of the US\$ 3.5 billion allocated as of the end 2005 by the Global Fund, for example, has been designated for procuring drugs, and health care commodities for HIV/AIDS, tuberculosis (TB) and malaria. A major focus of the technical support being provided to countries, for example by the AIDS Medicines and Diagnostics Service (AMDS),¹³ has therefore been to ensure that investments made in systems to procure and distribute antiretroviral drugs also build local capacity to procure and supply other essential medicines.

11 Dabis F, Schechter M, Egger M. Mortality of HIV-1-infected patients during the first year of potent antiretroviral therapy: comparative analysis of databases from low- and high-income countries. *Lancet*, 2006, 367:817-24.

12 Lawn SD et al. Early mortality among adults accessing a community-based antiretroviral service in South Africa: implications for programme design. *AIDS*, 2005, 19:2141–2148.

13 As of December 2005, the AMDS consisted of 20 partner organizations. These were Centrale Humanitaire Medico-Pharmaceutique, William J. Clinton Foundation, Commonwealth Pharmaceutical Association, Crown Agents, Global Fund to Fight AIDS, Tuberculosis and Malaria, Ecumenical Pharmaceutical Network, ESTHER (Ensemble pour une Solidarité Thérapeutique Hospitalière En Réseau), International Pharmaceutical Federation, International Dispensary Association, John Snow, Inc., Management Sciences for Health, Partnership for Supply Chain Management, ReMed, UNAIDS, UNDP, UNFPA, UNICEF, United States Agency for International Development, WHO and World Bank. For more information on AMDS, please visit <http://www.who.int/3by5/amds/en>.

As part of the “3 by 5” strategy, WHO established the AMDS as a network of agencies specializing in procurement and supply management for drugs and diagnostics, strategic information and technical assistance to countries. To help countries obtain the most competitive prices for essential medicines and other supplies, the AMDS produces regular reports on drug prices and sourcing information, drawing on a broad range of market data from pharmaceutical producers around the world, and surveys the world market for active pharmaceutical ingredients, the raw materials for antiretroviral drugs. AMDS also maintains the Global Price Reporting Mechanism, which includes transaction data on more than US\$ 125 million worth of antiretroviral drug procurement. AMDS partners publish this information for the general public.

The AMDS also undertakes comprehensive market intelligence gathering, assisting countries in making sound choices in drug purchasing and advising governments on patent licensing. The AMDS maintains the most comprehensive map available of patent holdings for antiretroviral drugs in 85 countries. This map, which WHO first developed in 1999, is now regularly updated in partnership with the European Patent Office and is an invaluable resource for countries when determining which drugs can be purchased from generic manufacturers. AMDS technical experts also assist low- and middle-income countries with forecasting demand to prevent the wasteful purchase of expensive and unnecessary stocks of expensive drugs and supplies.

AMDS partners have advocated for reductions in the cost of drugs and diagnostics and worked to make supply and procurement practices transparent. By publishing price information, fostering price competition, lobbying to reduce import duties, supporting local production where possible and advocating for the inclusion of World Trade Organization and TRIPS (Agreement on Trade-related Aspects of Intellectual Property Rights) safeguards in national legislation, AMDS partners are helping to remove the remaining procurement and supply obstacles to treatment access.

Between December 2004 and December 2005, AMDS partners helped to train 504 medicine supply-chain managers – including both governments and nongovernmental organizations – from 74 countries to develop procurement and supply management plans. The training, undertaken in four cities in sub-Saharan Africa as well as in Lebanon and Thailand, was timed to coincide with Global Fund grant application deadlines and addressed critical issues such as drug selection, procurement, logistics and management of information systems, compliance with quality assurance guidelines and intellectual property rights. The training helped principal recipients to reduce the time needed to prepare procurement and supply management plans from many months to a few weeks and helped to unblock US\$ 500 million in Global Fund grants.

A major contract has recently been awarded to a consortium to provide technical support and strategic information on procurement and supply management in countries receiving funding from the United States President’s Emergency Plan for AIDS Relief. The Supply Chain Management System was established in September 2005 and includes 17 institutions, several of whom also participate in the AMDS.

As the examples of Cambodia and Burkina Faso show (Boxes 1 and 2), improvements in antiretroviral therapy procurement and supply systems which result from the contributions of AMDS and Supply Chain Management System partners are also helping countries to deliver medicines for a range of other diseases as well as HIV/AIDS.

Box 1. Strengthening procurement and supply of essential medicines in Cambodia

Cambodia's proactive approach to fighting the HIV/AIDS pandemic has received well-deserved international recognition. However, in early 2005, at least five individual procurement and supply management systems were operating in Cambodia, leading to inefficiency in efforts to expand access to antiretroviral therapy. While non-HIV-related essential medicines were procured by the Ministry of Health Procurement Unit and distributed by the Central Medical Store, medicines for HIV/AIDS were procured and distributed either by the National Center for HIV/AIDS, Dermatology and Sexually Transmitted Infections (NCHADS) or by the Global Fund Principal Recipient. In addition to these public procurement systems, Médecins Sans Frontières was procuring HIV medicines and diagnostics for their facilities in Cambodia through their logistical centres in Europe.

In 2005, with support from WHO and UNICEF, NCHADS assessed the procurement supply system for HIV care in Cambodia and identified several challenges.

- The magnitude of the planned or expected scale-up of antiretroviral therapy in Cambodia – including the progressive takeover by the Ministry of Health of services provided by Médecins Sans Frontières – exceeded current national capacity.
- Communication and information exchange between the various supply systems was poor.
- The steps between the creation of the quarterly order list by the operational district and the actual delivery of goods was overly bureaucratic and time-consuming.
- The Central Medical Store had an out-of-date information technology system and no cold storage and lacked managerial skills and capacity.
- The capacity of the current national distribution system at the NCHADS was limited.

The assessment made several recommendations:

- reducing the number of medicines or formulations for opportunistic infections and antiretroviral therapy;
- increasing funding for the Central Medical Store to help build skills and management capacity;
- implementing a National Drug Inventory Database for warehouse activities at the new Central Medical Store premises and strengthening its storage and distribution capacity with pallet racking and cold-room facilities as well as expanding the transport fleet; and
- transferring the storage and distribution responsibilities of NCHADS to the Central Medical Store as soon as acceptable standards and speed of operations are in place.

The Ministry of Health, NCHADS, WHO and the Global Fund Principal Recipient are working to secure resources to implement these recommendations. In the mean time, it has been reported that NCHADS has improved its capacity to monitor the antiretroviral therapy supplies across the country, including forecasting of drug and commodity needs and estimating the number of people on first- and second-line regimens. Along with these ongoing improvements, the implementation of the recommended activities will not only bring the Central Medical Store into a key position to take over the storage and distribution of supplies related to HIV/AIDS but also improve the provision of pharmaceuticals and medical supplies in Cambodia in general.

Box 2. Burkina Faso uses an independent agency to guarantee a steady supply of affordable, effective drugs and diagnostics

Weak systems for drug procurement and supply prevent many low- and middle-income countries from procuring HIV drugs at an affordable price, from forecasting the quantities of HIV medicines needed and preventing shortages (or stockouts) and from assuring the quality of purchased medications.

Burkina Faso has addressed many of these problems with a creative and pragmatic solution. The Centrale d'Achat des Médicaments Essentiels Génériques et des Consommables Médicaux, a stand-alone, not-for-profit agency, handles antiretroviral drug procurement and supply. The Centrale d'Achat has full legal status and its own director-general and is administered by representatives of the government and development partners (including WHO) as well as community-based organizations. The existence of this autonomous agency has allowed Burkina Faso to attract major funding and channel it quickly to a number of critical fronts: purchasing generic HIV drugs on the global market at discounted prices, conducting research on quality assurance throughout the chain of supply (manufacture, transport, storage and distribution) and expanding access to these medicines and commodities through a national network of 54 stores. The Centrale d'Achat now purchases and distributes no fewer than 500 products, including 253 generic essential medicines (14 of them active pharmaceutical ingredients used in antiretroviral drugs).

Since 2001, the Centrale d'Achat has negotiated with manufacturers to gain significant reductions in prices for HIV drugs and commodities. It has also fostered treatment scale-up by working in partnership with providers of antiretroviral therapy in the public health sector and community and religious organizations, which deliver up to 50% of all HIV treatment. And the Centrale d'Achat has emphasized training its personnel, with support from WHO and other technical agencies. The strength of the Centrale d'Achat has also contributed to the success of Burkina Faso in its grant applications: to the Global Fund, which is providing US\$ 12 million over four years to treat a further 6000 people; and to the World Bank, which is backing a major Treatment Acceleration Project proposal worth US\$ 18 million over three years to treat 7000 people. From December 2003 to December 2005, the number of people receiving treatment in the country increased from 1514 to 8214.

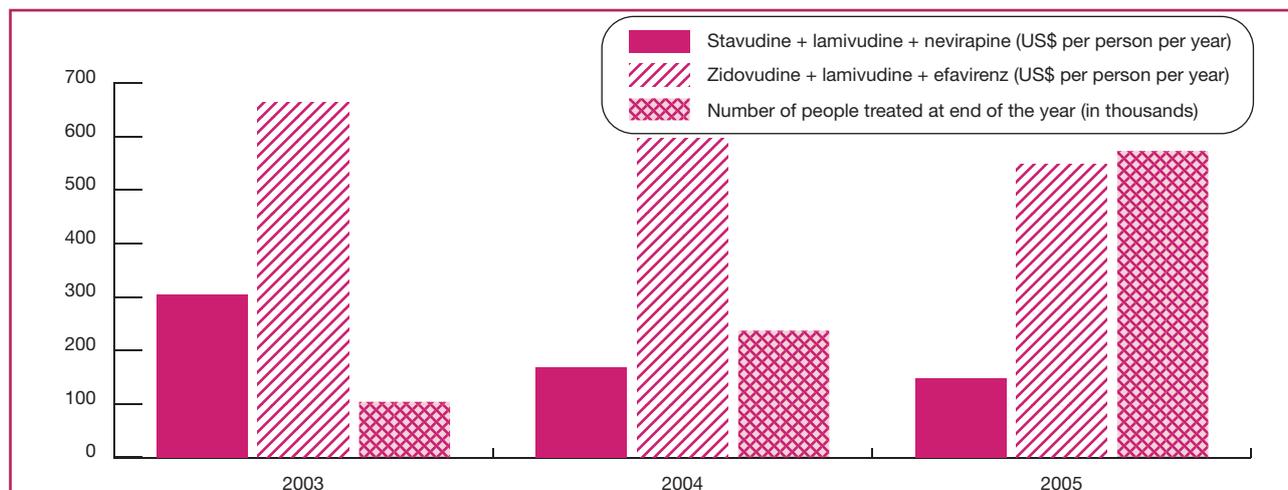
1.6 Prices of drugs and other commodities

Depending on the treatment regimen used, the price of first-line medication has decreased between 37% and 53% in the past two years. This has contributed significantly to wider availability of treatment, but prices remain unacceptably high in some countries, especially for second-line regimens.

In 2005, the average price paid for first-line treatment (prequalified by WHO) in low-income countries ranged from US\$ 148 per person per year for the fixed-dose combination of stavudine + lamivudine + nevirapine (the most widely used combination) to US\$ 549 for the fixed-dose combination zidovudine + lamivudine plus a single dose of efavirenz (Fig. 6). The average price of these two combinations was US\$ 268 per person per year in 2005.

The fall in drug prices between 2003 and 2005 has been fuelled by the ongoing scale-up of treatment programmes as well as by increased competition among a growing number of products prequalified by WHO. The price decrease is also attributable to negotiations between the William J. Clinton Foundation and major generic manufacturers.

Fig. 6. Trends in the cost of first-line antiretroviral therapy regimens in low-income countries, overlaid with the number of people treated, 2003–2005^a



^a The 2003 prices are those quoted in: World Health Organization, UNICEF, UNAIDS and Médecins Sans Frontières. *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS*. Geneva, World Health Organization, 2003 (http://www.who.int/hiv/pub/prev_care/edm/en, accessed 13 February 2006). The prices for 2004 and 2005 are the averages charged in transactions as recorded in the Global Price Reporting Mechanism. The numbers of people on treatment are drawn from WHO/UNAIDS data for 58 low-income countries. Annex 1 outlines country-specific data for all low- and middle-income countries.

In middle-income countries the price paid for first-line treatment was significantly higher and remained almost stable between 2004 and 2005. The average prices paid for first-line treatment in 2005 ranged from US\$ 371 per person per year for the cheapest regimen of stavudine + lamivudine + nevirapine to US\$ 838 per person per year for the most expensive regimen of zidovudine + lamivudine + efavirenz.

Second-line treatment was significantly more expensive than first-line treatment in low- and middle-income countries. In 2005, a regimen of tenofovir + abacavir + lopinavir or ritonavir cost on average US\$ 1888 per person per year in low-income countries and US\$ 4126 per person per year in middle-income countries. These are average prices; actual prices being paid for second-line regimens vary significantly from country to country. For example, Côte d'Ivoire is paying on average US\$ 1700 for this regimen per person per year, whereas El Salvador is paying US\$ 6788 per person per year.

There is reason to believe that the prices of antiretroviral medications will decline further. In January 2006, the William J. Clinton Foundation announced that it had negotiated a deal that would bring the price of generic formulations of efavirenz down to US\$ 240 per person per year (from the manufacturer's current price of US\$ 343 per person per year) and the price of generic abacavir to US\$ 447 per person per year (from the manufacturer's current price of US\$ 887 per person per year). For these drugs to become available at these prices to recipients of grants from the Global Fund and World Bank, these formulations need to be approved by a stringent regulatory authority or by the WHO prequalification project (Box 3). Most recently, in March 2006, Merck & Co. Inc. decided to cut the price for its efavirenz by 20% to US\$ 277.4 per person per year in low-income countries.

On the diagnostics front, progress has been slow. Although HIV serological tests have been available for some time at much reduced prices through WHO and UNICEF, with prices ranging from US\$ 0.47 to US\$ 2.76 per test, the volume procured by those agencies has been limited (slightly more than 3 million test kits were procured in 2004). It is encouraging that reduced prices for some serology test kits have become available to countries in the William J. Clinton Foundation procurement consortium and that the Foundation has enabled the market for CD4 cell count assays to become more transparent, with discounted CD4 cell determination reagents now becoming available at US\$ 3–5 per test. However, further price reductions are needed for both diagnostics and laboratory supplies.

Box 3. Prequalification of drugs and diagnostics helps countries scale up safely

It is believed that only 20% of all countries have the ability to monitor and control effectively the safety of their drug supplies. Assuring the quality and safety of drugs, therefore, is critically important to the success of scaling up HIV treatment in low- and middle-income countries.

The WHO Prequalification Project helps to address this need. A partnership created by WHO, UNAIDS, UNICEF and UNFPA in 2001 with support from the World Bank, the project has played an important role in providing an independent assessment of the quality, safety and efficacy of medical products and supplies. It allows bulk purchasers of medicines, especially United Nations agencies, countries without strong regulatory agencies of their own and other procurement agencies to make informed drug choices and to purchase stocks of safe, high-quality products on the world market with confidence.

To receive prequalification, a manufacturer must submit a full dossier on the quality, safety and effectiveness of the product to WHO. These dossiers are evaluated by teams of six to eight experts from regulatory authorities in high-, low- and middle-income countries, and a product sample may be sent for independent quality control testing at laboratories in France, South Africa or Switzerland. If the dossier is approved, a site inspection team visits the manufacturing facility to ensure that the producer meets all internationally accepted good manufacturing practices. If the site inspection is also satisfactory, the product is then added to the list of prequalified medicines. Prequalification certification lasts three years.

In 2005, WHO prequalified 31 additional antiretroviral drugs, bringing the number from 50 to 81 by December 2005. Of these, 63 were single products, 10 were double combinations and 8 were triple combinations. Because the Prequalification Project does not seek to duplicate the work of other reputable agencies, nine products were prequalified based on tentative approval by the United States Food and Drug Administration. The Food and Drug Administration has recently approved some non-branded – as well as branded – drugs.

The Prequalification Project has helped to ensure that people in resource-constrained countries do not receive substandard medicines and risk treatment failure and the development of drug resistance.

For a list of all prequalified medicines, please visit <http://mednet3.who.int/prequal>.

2. Strengthening health systems

“3 by 5” has prompted significant debate about the potential impact of introducing lifelong therapy for a chronic health condition such as HIV/AIDS on health systems that already lack resources. Although there have been fears that antiretroviral therapy programmes could divert resources from other, basic health services,¹⁴ antiretroviral therapy and the related scale-up of prevention are also widely seen as providing fresh opportunities to strengthen key components of health systems with benefits beyond the diagnosis and treatment of HIV/AIDS.

WHO has defined strengthening health systems as building capacity in critical components of health systems including policy, funding, human resources, service management and information and monitoring systems in order to achieve more equitable and sustained improvements across health services and health outcomes.¹⁵ “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 are in place.

Although it is too early to say that “3 by 5” has had system-wide impact, experience to date in many countries suggests that introducing antiretroviral therapy has begun to provide tangible benefits in some critical health system areas, as outlined in this section.

2.1 Human resource capacity

Using the opportunities afforded by the introduction of antiretroviral therapy to increase human resource capacity overall requires integrated approaches that include treatment for a range of common conditions as well as HIV/AIDS.

Some 29 countries have adopted such an approach in the form of the Integrated Management of Adult and Adolescent Illness (IMAI) curriculum developed by WHO and its partners as the key scale-up approach for “3 by 5”. Training on the general principles of good chronic care applies to all chronic diseases and therefore builds the capacity of health and community workers to manage a range of conditions in addition to HIV/AIDS. Health workers trained using the IMAI model learn an approach to the acute care of adults that, in addition to HIV/AIDS, can be applied to managing conditions such as pneumonia, diarrhoea, mental disorders, sexually transmitted infections and malaria. The training tools are readily adaptable to different contexts; for example, modules on drug substitution therapy and primary care for injecting drug users can be included.

IMAI also contributes to strengthening health systems by establishing “district networks” that enable efficient referrals between levels of the health system as well as case discussion during on-site visits by physician mentors (Box 4). With good preparation of mentors, this can strengthen all public health programmes that have a case management component.

The IMAI approach to task-shifting empowers clinical officers and nurses to take up simplified case management for adults as they have for children in many settings through the Integrated Management of Childhood Illness (IMCI) methods, which have also been developed by WHO. IMAI also promotes the expansion of clinical teams to include trained people living with HIV/AIDS in the role of counsellors and treatment supporters. These steps increase the number and range of providers, improve links with the community and contribute to more robust primary care.

IMAI has also helped to reinforce local health system capacity by reinvigorating local training institutions.

¹⁴ The following article provides a good overview of the debate on vertical versus horizontal approaches to public health: Mills A. Mass campaigns versus general health services: what have we learnt in 40 years about vertical versus horizontal approaches? *Bulletin of the World Health Organization*, 2005, 83:315–316.

¹⁵ *Opportunities for global health initiatives in the health system action agenda*. Geneva, Global Alliance for Vaccines and Immunization, 2005 (http://www.vaccinealliance.org/resources/17brd_5_HealthSystemsGHIs_6Dec2005.pdf, accessed 13 February 2006).

Box 4. IMAI supports health systems – three examples in Africa

"3 by 5" has encouraged many countries to adopt a public health approach for rapid scaling up of prevention, care and treatment services for HIV as well as other diseases.

In Senegal, where HIV prevalence is as high as 2.8% in rural regions, access to HIV care and treatment expanded from six sites in 2001 to 32 sites in 2005, greatly reducing the distance that people must travel for health care. HIV treatment regimens have been standardized and simplified, laboratory equipment has been purchased to monitor CD4-cell counts and nurses have been trained to take over from physicians the routine tasks of treatment and monitoring. To support this task-shifting, every day, in each of the country's 11 regions, a physician-mentor is on call (by phone or e-mail) to address urgent questions from nurses in district clinics and health posts. This public health approach helped Senegal to extend antiretroviral therapy to the most hard-to-reach parts of the country and provide treatment to 4200 people by the end of 2005. Senegal has accomplished this decentralization by making use of tools and training from the WHO IMAI programme. In 2005, health workers in 15 districts received IMAI training; in 2006, those in another 38 districts will be trained. Integrated training and follow-up using IMAI materials will increase the availability of provider-initiated routine offer of testing and counselling and intervention for preventing the mother-to-child transmission of HIV. This will also expand the treatment of other sexually transmitted infections and allow for more effective clinical co-management of TB and HIV.

Uganda's pioneering public health approach carefully integrates regional and district care programmes, engages communities and people living with HIV/AIDS in scale-up efforts and provides ongoing training and mentoring to develop the capacity of clinical teams. Here, the number of sites providing antiretroviral therapy expanded rapidly from 35, mostly in regional hospitals, at the end of 2003 to 175 sites, including district hospitals, large health centres and a number of smaller community health facilities, at the end of 2005. Since late 2003, Uganda has trained 1570 health care workers using the IMAI approach. From the end of 2003 to the end of 2005, the country increased the number of people receiving HIV treatment from 17 000 to 75 000 while also reinforcing drug supply systems and laboratory services.

In Swaziland, where adult HIV prevalence was estimated to be between 37.2% and 40.4% in 2003, clinical teams are now providing integrated services for HIV prevention, care and treatment using the IMAI approach. Recent innovations include routine offer of testing and counselling, training rural health workers to promote HIV treatment literacy in local communities and prevention education and support for people living with HIV/AIDS, which is provided through peer support groups.

2.2 Using existing entry points

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

Tuberculosis

In countries with high HIV prevalence, up to 80% of people with TB also test positive for HIV. Worldwide, TB is among the most common causes of morbidity and mortality among people living with HIV/AIDS. TB programmes have therefore emerged as important partners in HIV diagnosis, treatment, care and prevention. Many TB programmes have established close collaboration with HIV programmes to implement the activities recommended in the *Interim policy on collaborative TB/HIV activities*,¹⁶ including joint coordination and planning between TB and HIV services, TB screening for people who test positive for HIV and the routine offer of HIV testing to people with TB and more effective referrals between TB and HIV services and the provision of co-trimoxazole preventive therapy and antiretroviral therapy through existing TB services. Collaborative

¹⁶ *Interim policy on collaborative TB/HIV activities*. Geneva, World Health Organization, 2004 (<http://www.who.int/hiv/pub/tb/tbhiv/en>, accessed 13 February 2006).

TB/HIV activities are not only being adopted in settings with very high HIV prevalence in sub-Saharan Africa but also in countries in eastern Europe and Asia with concentrated HIV epidemics, such as Cambodia, India, Myanmar, the Republic of Moldova, the Russian Federation, Ukraine and Viet Nam.

Where TB programmes are strong, the TB facility can provide eligible people with TB with antiretroviral therapy, support adherence and monitor and supervise antiretroviral therapy delivery during the period of TB treatment. With the TB community as a partner, HIV diagnostic and treatment services can be more rapidly decentralized to the facility level and thus closer to those who need them.

Promoting and providing HIV testing for people with TB can act as a major entry point to antiretroviral therapy. In Rwanda, 53% of all people with TB were tested for HIV in 2004; in Malawi, this figure was 49%. A high proportion of people with TB who are found to be HIV-positive will be eligible for antiretroviral therapy. In Malawi, more than 35 000 people living with HIV have started on antiretroviral therapy since the antiretroviral therapy programme began, and in the last quarter of 2005, 1186 (18%) people starting to receive antiretroviral therapy were referred from the TB programme.

WHO has collected data from the 41 countries with the highest estimated proportion of people living with HIV/AIDS among people with TB from 2002 to 2004. Of the 32 countries that have provided data for each year, the number that reported having a national policy to offer HIV testing to all people with TB increased from 7 in 2002 to 20 in 2004, and those with a policy of providing antiretroviral therapy to eligible people living with HIV/AIDS who also have TB rose from 7 in 2002 to 21 in 2004. In these countries, the number of people with TB reported to have started antiretroviral therapy rose from zero in 2002 to more than 9000 in 2003. WHO estimates that both the number of people living with HIV/AIDS globally who were screened for TB and the number found to have TB increased ten-fold between 2002 and 2004, while the number who began isoniazid preventive therapy more than doubled.

Fig. 7. Development of policies for collaborative TB/HIV activities in 32 countries, 2002–2004

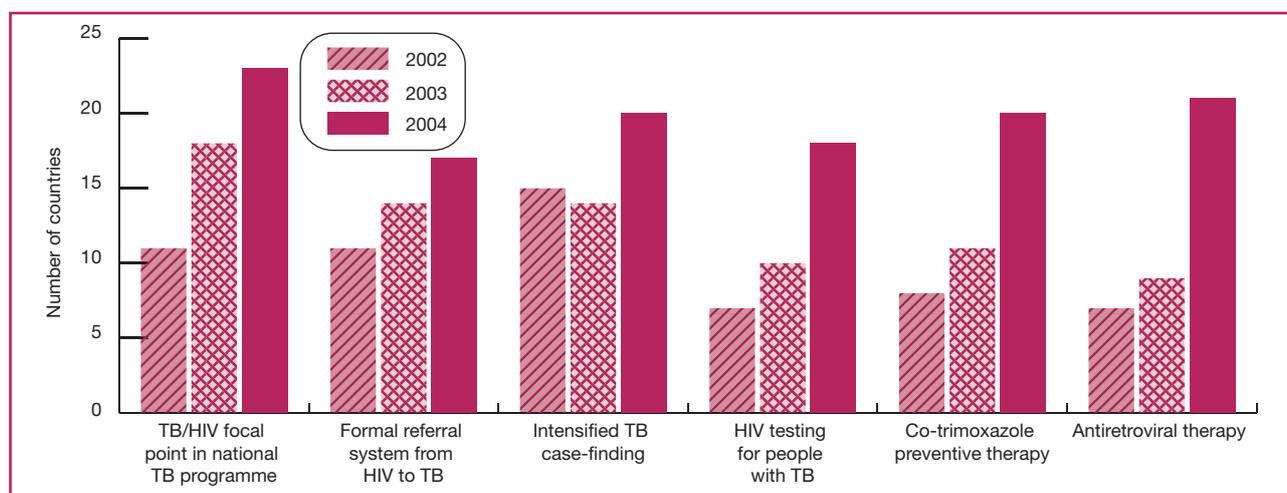


Figure 7 shows that the number of countries undertaking specific joint TB/HIV activities increased between 2002 and 2004. These include the number of countries that had appointed a TB/HIV focal person within the national TB programme, the number that had a formal system for referring people from HIV to TB services, the number that had a policy in place to carry out intensified TB case-finding among people living with HIV/AIDS, the number that had a policy to provide HIV testing and counselling for everyone with TB, the number that had a policy of providing co-trimoxazole therapy to people living with HIV/AIDS who also have TB and the number that had a policy of providing antiretroviral therapy to people living with HIV/AIDS who also have TB.¹⁷

Although much more attention is now being paid to joint TB/HIV programming, progress ultimately depends on the number of coinfecting people who receive appropriate treatment for both TB and HIV, and in general this still remains unacceptably low. More determined efforts must therefore be made to further scale up joint approaches to these two diseases.

¹⁷ *Second global plan to stop TB (2006–2015)*. Geneva, Stop TB Partnership, 2006 (<http://www.stoptb.org/globalplan/default.asp>, accessed 13 February 2006).

Malaria

The links between HIV and malaria are now receiving more attention.¹⁸ These are most apparent in areas with generalized HIV epidemics and stable malaria. Sub-Saharan Africa carries a high burden of both diseases, and coinfection is thus common in many areas. In Latin America and the Caribbean, malaria and HIV overlap somewhat in the general population in several countries. South-East Asian countries such as Myanmar and Thailand have a generalized HIV epidemic, but malaria distribution is heterogeneous in this region. Considering that an estimated 1 billion people in South-East Asia are exposed to unstable malaria, even small overlaps of malaria and HIV in these settings may have a large public health impact. Transmission of both malaria and HIV can also result from improper blood-transfusion practices and unsafe injections.

People with HIV-related immunosuppression, including pregnant women, living in areas of stable and unstable malaria are particularly vulnerable to malaria and need protection against malaria by insecticide-treated nets, prophylaxis or other preventive measures. In areas with stable malaria and high HIV prevalence, HIV should be suspected among people with repeated episodes of fever, and the treatment of fever as malaria alone (in particular among people other than young children) is inadequate; in addition to providing malaria treatment, health providers should offer HIV testing and counselling.

The simultaneous introduction of new medicines and diagnostics by malaria and HIV programmes offers opportunities for joint planning, training and service delivery in order to reduce the burden of the two diseases. Integration of services is particularly important within the framework of reproductive and children's health services. Reproductive health services, for example, need to ensure the delivery of the WHO-recommended antenatal care schedule of four visits (focused antenatal care), which includes a minimum package of interventions for preventing both malaria and HIV. HIV-infected pregnant women in areas with stable malaria should, depending on the stage of HIV infection, receive either intermittent preventive treatment with at least three doses of sulfadoxinepyrimethamine or daily co-trimoxazole prophylaxis. Because of potential drug interactions, malarial illness in HIV-infected pregnant women who receive co-trimoxazole prophylaxis should be managed with antimalarial medicines that do not contain sulfonamides or sulfones. In countries with generalized HIV epidemics, routine monitoring of antimalarial drug efficacy or effectiveness should also include assessing the effect of HIV on the outcome of antimalarial treatment.

Sexual and reproductive health

Most HIV infections globally are sexually transmitted or associated with pregnancy, childbirth or breastfeeding. The interactions between sexual and reproductive ill-health and HIV/AIDS are now widely recognized, including their common determinants such as poverty, gender inequality and social marginalization. Services for the prevention, care and treatment of HIV/AIDS now form an important component of family planning, sexually transmitted infections and other reproductive health services in most countries, as shown in Kenya, for example (Box 5). This is likely to lead to improved access to and uptake of key HIV/AIDS and reproductive health services and reduced related stigma and discrimination. For example, offering family planning clients in high-prevalence settings the opportunity to learn their HIV status is likely to enhance the quality of family planning services and make an important contribution to HIV prevention services.

¹⁸ *Malaria and HIV interactions and their implications for public policy: report of a technical consultation*. Geneva, World Health Organization, 2004 (http://www.who.int/hiv/pub/prev_care/malaria/en, accessed 13 February 2006).

Box 5. Kenya pioneers integrated HIV and sexually transmitted infection care

Kenya recently knitted together its HIV/AIDS and sexual and reproductive health programmes, with a significant positive impact on its efforts to scale up services for HIV treatment, care and prevention. For example, its Family Health Options Kenya programme provides voluntary HIV testing and counselling at 11 sexual and reproductive health sites, a move that has significantly boosted the uptake of testing. From January to November 2005, 16 311 people took advantage of testing and counselling at these clinics. Among other benefits, the programme has allowed thousands of pregnant women to know their status and access services for preventing mother-to-child transmission. It has also given many the opportunity to begin antiretroviral therapy in a timely manner. The programme also employs people living with HIV/AIDS as staff and managers, helping to reduce the stigma and discrimination associated with HIV disease. By bringing HIV prevention and care into sexual and reproductive health clinics, Kenya is scaling up treatment more swiftly and reducing HIV/AIDS mortality rates.

Prevention of mother-to-child transmission

In high-income countries, a full range of services for preventing mother-to-child transmission of HIV is nearly universal, and a proven package of measures has virtually eliminated this mode of transmission. Some low- and middle-income countries are also approaching this goal, having scaled up the prevention of mother-to-child transmission and incorporated treatment for women and children. Botswana (Box 6), Brazil and Thailand are prime examples, and countries throughout the Caribbean – Bahamas, Barbados, Belize and Bermuda, for instance – have also achieved impressive results. In most low- and middle-income countries, however, access to services for preventing mother-to-child transmission remains inadequate, with less than 10% of pregnant women living with HIV/AIDS estimated to be receiving antiretroviral prophylaxis. As a result, 1800 infants are infected with HIV every day, and 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.

To address this public health emergency, a growing number of countries and agencies have recently begun to push for a global initiative to swiftly scale up the prevention of mother-to-child transmission. In October 2005, UNICEF and UNAIDS launched *the Unite for Children, Unite against AIDS* campaign that aims, among other goals, to provide 80% of women in need with access to services to prevent transmission of HIV to their babies by 2010. In December 2005, a high-level meeting of governments, multilateral agencies, development partners, researchers and people living with HIV/AIDS jointly convened by WHO and UNICEF in Abuja, Nigeria, resulted in a Call to Action to eliminate mother-to-child transmission in low- and middle-income countries by focusing on gaps in services.

These gaps are many. In sub-Saharan African countries, for example, pregnant women seldom visit an antenatal care clinic, and less than half of all deliveries are attended by a health professional. The women who do visit antenatal clinics may not have access to HIV testing and counselling or may choose not to accept testing. Few women who test negative receive prevention counselling, condoms, testing or treatment for other sexually transmitted infections, and few programmes for preventing mother-to-child transmission are well linked with HIV services for mothers living with HIV/AIDS, even when in the same facility. After giving birth, few mothers receive counselling or infant feeding support and other postpartum services.

“3 by 5” has nevertheless helped to address such gaps. It has increased access to antiretroviral services for women and children and, most likely, contributed to increased uptake of testing and counselling and services for preventing mother-to-child transmission. It has also strengthened health systems as a result of the training of health care providers in methods of integrating the delivery of health services, including preventive interventions.

The Abuja Call to Action: *Towards an HIV-free and AIDS-free Generation* has six key action points. These include improving standards of care and uptake of services for preventing mother-to-child transmission, with measurable time-bound targets, monitoring and evaluation; mobilizing national and external resources to strengthen health systems for the delivery of services for preventing mother-to-child transmission; integrating these services into mother and child health services; decentralizing programmes; engaging communities and people living with HIV/AIDS in programme expansion; and undertaking operational research to continuously improve programmes for preventing mother-to-child transmission.

Box 6. Scaling up the prevention of mother-to-child transmission

"3 by 5" has encouraged countries to scale up antiretroviral therapy with measurable targets and a public health approach. Similar strategies are being employed to scale up services for preventing the mother-to-child transmission of HIV.

In sub-Saharan Africa, Botswana, where HIV prevalence among pregnant women has ranged from 35% to 37% since 2001, is the furthest ahead in the effort to slow mother-to-child transmission. The country first developed a programme for preventing mother-to-child transmission in 1999. Ninety per cent of the programme's resources come from the government.

Services for preventing mother-to-child transmission are fully integrated with mother and child health care services and are available in all public antenatal clinics free of charge. This includes testing and counselling, zidovudine plus single-dose nevirapine for both mother and baby and safe obstetric practices. In recognition of the high levels of HIV transmission occurring through breastfeeding, Botswana has made a policy decision to provide mothers 12 months' infant formula free of charge for replacement feeding.

Through careful monitoring and evaluation, Botswana has been able to continuously improve the programme. When it was discovered in 2002, for example, that, despite freely available testing and counselling, only 49% of pregnant women were being tested for HIV, the government moved to train health care staff to manage supply chains of essential commodities; increase use of rapid HIV tests; and routinely offer HIV testing and counselling in health care settings. The country is now working to strengthen its national infant feeding policy and programmes and the links between its prevention and care programmes.

As a result of these initiatives, Botswana has swiftly scaled up services for preventing mother-to-child transmission since 2002 and is approaching universal access. The percentage of women delivering in hospitals who were tested for HIV during pregnancy or in the immediate postpartum period increased from 49% in 2002 to 92% in 2005. The proportion of pregnant women living with HIV/AIDS receiving zidovudine prophylaxis during pregnancy rose from 27% in 2002 to 79% in 2005; and, during the same period, those receiving nevirapine increased from 0% to 70%. The country is now also scaling up antiretroviral therapy for pregnant women. The preliminary results of a pilot study on dry-blood-spot testing, using rapid polymerase chain reaction HIV testing among babies in Francistown, indicates that mother-to-child transmission has been reduced to under 6%. Botswana estimates that, without interventions for preventing mother-to-child transmission, 40% of all infants born to seropositive mothers would be infected with HIV.

Services for injecting drug users

Integrated services that meet the needs of injecting drug users are being scaled up in several countries. 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 HIV/AIDS treatment and care services and the direct delivery and monitoring of antiretroviral therapy, including antiretroviral therapy adherence support from peer networks of drug users. With its model of triangular clinics, for example, the Islamic Republic of Iran is showing how antiretroviral therapy programmes can also effectively integrate harm reduction and sexually transmitted infection treatment and prevention with drug dependence prevention, treatment and care.

Triangular clinics are being established in communities across the Islamic Republic of Iran as well as in prisons, with plans to cover all large prisons in the country by 2010. China and Indonesia are also planning to rapidly expand harm reduction and methadone maintenance services as part of comprehensive responses to HIV/AIDS, which make more effective use of existing health systems capacity. Malaysia is piloting needle and syringe exchange and methadone maintenance programmes and has initiated antiretroviral therapy for injecting drug users through drug rehabilitation centres.

Drug injecting is driving the HIV epidemic in a wide range of countries, particularly in eastern Europe, central Asia, other parts of Asia and Latin America. In most of these countries, the majority of people needing treatment are drug users. New models of antiretroviral therapy delivery are therefore required that include a parallel scaling up of drug dependence treatment services (Box 7). For heroin and other opioid users, the most effective form of drug dependence treatment is methadone or buprenorphine substitution treatment. In recognition of this, methadone and buprenorphine were included on the WHO Model List of Essential Medicines in 2005.

Further challenges exist in providing integrated and comprehensive services for drug users, recognizing the high levels of coinfection with hepatitis B and C and TB, the comorbidity with mental disorders such as depression and the presence of multiple-drug use with substances such as cocaine and amphetamine-type stimulants that are not responsive to drug substitution treatment.

Box 7. Ukraine: using substitution therapy to boost HIV treatment scale-up

In the last two years Ukraine has begun to scale up HIV treatment. The number of people on antiretroviral therapy increased from less than 200 in July 2004 to more than 3000 in December 2005. As in many other countries, however, scaling up requires measures to ensure that people who inject drugs benefit from antiretroviral therapy.

Ukraine has an estimated 340 000–425 000 injecting drug users (1.2% of the population aged 15–64 years), and sentinel surveillance in 2005 estimates that between 10% and 66% of them are living with HIV/AIDS. To help this marginalized population, Ukraine has used part of a Global Fund grant to begin scaling up an ambitious opioid-substitution therapy programme. Starting in seven regions, this will provide substitution therapy to 6000 injecting drug users by September 2008. Among other benefits, the programme helps people who inject drugs to stabilize their lives and adhere to antiretroviral drug regimens. The programme also provides substitution therapy to injecting drug users who are HIV-negative or of unknown status, as this therapy has been shown to be an effective way to prevent HIV among drug users.

In Ukrainian prisons, meanwhile, authorities have announced the implementation of an ambitious HIV prevention programme for injecting drug users, including needle and syringe exchange projects in several of them.

Established in the Ukrainian capital, Kiev, with the support of WHO and the German Gesellschaft für Technische Zusammenarbeit (GTZ), the Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia is also playing an important role in expanding treatment and care capacity in the region. More than 500 Ukrainian caregivers and 350 health and social workers from Kazakhstan, Republic of Moldova, Russian Federation and Tajikistan have been trained at the Knowledge Hub since late 2004.

3. Political commitment and partnerships

3.1 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 and other interventions for HIV/AIDS both at the global and national levels since December 2003. When the “3 by 5” strategy was launched, only 3 of the 49 most heavily burdened and vulnerable countries – the “3 by 5” focus countries (Annex 3) – had developed national plans to scale up access to antiretroviral therapy. By December 2005, 46 of these countries had either developed or were in the course of developing national treatment plans. The number of “3 by 5” focus countries that had declared a national treatment target increased from 4 to at least 40 in the same two-year period. Many more countries have reported that the “3 by 5” target has contributed significantly to mobilizing and accelerating treatment scale-up.

In recent months, several countries have demonstrated their commitment to ensuring not only that treatment programmes are scaled up but that they are sustained over the long term (Box 8). The Russian Federation, for example, has recently increased its federal AIDS budget 18-fold, from less than US\$ 6 million in 2005 to nearly US\$ 107 million in 2006, about half of which will be for treatment. The Russian Federation has also recently doubled its contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria.

In China, the central government has continued to increase its investment in HIV/AIDS prevention and care, with the total national budget for HIV/AIDS prevention and care (including international sources) rising from about US\$ 49 million in 2003 to US\$ 100 million in 2005. Domestic spending on HIV/AIDS has risen from less than US\$ 12.5 million in 2003 to US\$ 26 million in 2005. The Government of China has strengthened cooperation and exchange with UNAIDS, WHO and other United Nations agencies as well as with the United Kingdom, the United States, Australia and other countries. Currently, international cooperation projects are underway in all 31 provinces and autonomous regions of the country.

In sub-Saharan Africa, many countries are showing their commitment to tackling AIDS by increasing domestic budget allocations for the disease. 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, much of which is for antiretroviral therapy.

Box 8. Guyana scales up with strong commitment to universal access

With 2.4% of its population of 800 000 infected by HIV, Guyana has the second highest HIV prevalence in Latin America and the Caribbean. The country is facing this challenge, however, with a multifaceted response, backed up by strong political leadership and international support. As a result, 1200 Guyanese were receiving antiretroviral therapy at the end of 2005 – a two-fold increase from the end of 2004. (This represents 50% of those who needed antiretroviral therapy in 2005.)

Leadership, planning and partnerships account for much of this progress. Guyana established a policy of universal access to prevention, treatment and care in 2001; however, real scale-up only became possible in 2004, when the country began to attract major funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank, the United States President's Emergency Plan for AIDS Relief and the Canadian International Development Agency. A Presidential Commission on HIV/AIDS oversees programming, and the Minister for Health is personally involved, working closely with fellow ministers and international partners to harmonize their work.

With the support of United Nations technical agencies, the United States Centers for Disease Control and Prevention and nongovernmental organizations, Guyana has provided intensive training to health care workers to expand voluntary counselling and testing, which is now routinely offered free of charge at clinics for TB, malaria and elective surgery. Health care workers have also been trained in preventing mother-to-child transmission, and the country is intensifying efforts to build capacity for HIV treatment and laboratory support (including CD4 testing). Support from the United States President's Emergency Plan for AIDS Relief and the Global Fund has allowed Guyana to provide antiretroviral therapy free of user charges and to improve drug procurement, storage capacity and distribution systems. The country recently developed a National HIV/AIDS Strategic Plan, which aims for universal access to HIV prevention, treatment and care by 2010 and calls for more concerted efforts to expand access to these services among sex workers, prisoners, men who have sex with men and other marginalized groups.

Globally, the “3 by 5” target has also had an important catalysing effect and is being acknowledged as an important step in a longer-term global effort to realize the Millennium Development Goals. In May 2004, 192 WHO Member States unanimously endorsed the “3 by 5” target at the World Health Assembly. To maintain momentum and build upon the progress made so far, in July 2005 leaders of the 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.

The commitment of international donors to an expanded response to HIV/AIDS has grown markedly in recent years, with global expenditure on HIV/AIDS increasing from US\$ 4.7 billion in 2003¹⁹ to an estimated US\$ 8.3 billion in 2005 (Box 9).²⁰ A significant proportion of funding is now being provided by the World Bank's Multi-Country HIV/AIDS Program for Africa and Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Lending Program, the United States President's Emergency Plan for AIDS Relief and the Global Fund. However, UNAIDS estimates that up to US\$ 22 billion per year will be needed to finance a comprehensive response by 2008.

WHO has benefited directly from the growing commitment of international donors. The leadership of the Government of Canada in supporting its HIV/AIDS work, with CDN\$100 million over two years, gave a major boost to the “3 by 5” effort. This commitment encouraged a host of new government donors to come forward – such as Iceland, Luxembourg and Spain – while traditional donors maintained or increased their levels of support for WHO. Italy, Norway, Sweden, the United Kingdom and the United States, for instance, each contributed between US\$ 5 million and US\$ 23.5 million during 2004–2005, and about a dozen other governments and nongovernmental donors contributed a total of US\$ 23.9 million to WHO

19 *Report on the global AIDS epidemic*. Geneva, UNAIDS, 2004 (<http://www.unaids.org/bangkok2004/report.html>, accessed 13 February 2006).

20 *Resource needs for an expanded response to AIDS in low- and middle-income countries*. Geneva, UNAIDS, 2005 (<http://www.unaids.org/en/Coordination/FocusAreas/MobilizationResources.asp>, accessed 13 February 2006).

HIV/AIDS programming. This increased support allowed WHO to recruit more than 120 professional staff at the regional and country levels, including dedicated officers or teams to assist on the ground with scaling up treatment in 41 of the 49 "3 by 5" focus countries.

Activists and civil society groups played a pivotal role in making the case for funding of the "3 by 5" effort, and their influence will continue to be critical in ensuring that the resources needed to achieve universal access are forthcoming.

Box 9. Leaders in mobilizing resources for HIV treatment

The Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund was established in 2002 to rapidly mobilize significant additional international funds to fight the three diseases in low- and middle-income countries. Raising funds through public-private partnerships, the Global Fund disburses grants to governments, communities and nongovernmental organizations.

The Global Fund's approach stresses national ownership and country-driven initiatives, stringent, independent technical reviews of proposals and a quick disbursement process for programmes that are currently inadequately funded.

At present, the Global Fund receives support from more than 45 countries as well as private foundations, corporations and individuals. As of December 2005, the Global Fund had allocated US\$ 3.5 billion to 323 initiatives in 130 countries. The future value of all currently awarded Global Fund grants totals an estimated US\$ 8.9 billion. Of the money awarded, more than half is for HIV/AIDS and 60% is for programmes in sub-Saharan Africa.

The Global Fund's major contributors (contributing US\$ 100 million or more) are Canada, the European Commission, France, Germany, Italy, Japan, the Netherlands, the United Kingdom, the United States and the Bill & Melinda Gates Foundation.

For more information, visit www.theglobalfund.org/en.

The United States President's Emergency Plan for AIDS Relief

The United States President's Emergency Plan for AIDS Relief is a five-year, US\$ 15 billion programme to fight HIV/AIDS in 15 focus countries launched by United States President George W. Bush in 2003. It is the largest international health initiative ever undertaken by one country to address a single disease.

The Emergency Plan seeks to encourage bold leadership at every level to battle HIV/AIDS. In the 15 focus countries, the Emergency Plan aims to provide treatment to 2 million people, prevent 7 million HIV infections and provide care to 10 million people infected and affected by HIV/AIDS by 2008. The Emergency Plan also aims to allocate US\$ 9 billion to support programmes in the 15 focus countries, US\$ 5 billion to support ongoing bilateral relationships in more than 100 other countries and provide US\$ 1 billion to the Global Fund.

For more information, visit www.usaid.gov/our_work/global_health/aids/pepfar.html.

The World Bank

The World Bank's HIV/AIDS work focuses on preventing the further spread of HIV; promoting development of countries' health policies and multisectoral approaches (such as by working in education, social safety nets, transport and other vital areas); and expanding care, treatment and support for those affected by HIV/AIDS and their families.

In the past five years, the World Bank's commitments to HIV/AIDS have exceeded US\$ 2.5 billion. Funding for AIDS in Africa has risen from an average of US\$ 10 million annually in 1995 to US\$ 300 million annually from 2002 to 2005. The World Bank Multi-Country HIV/AIDS Program for Africa has committed US\$ 1.12 billion for 29 countries and four regional projects, and the Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Lending Program has committed US\$ 118 million for nine countries and one regional project.

For more information, visit <http://www.worldbank.org>.

Canadian International Development Agency (CIDA)

The Canadian International Development Agency, the development agency of the Government of Canada, was the largest donor to WHO's programme in support of "3 by 5". Its CDN\$ 100 million grant enabled WHO to undertake the technical guidance and support to countries set out in the "3 by 5" strategy, including the unprecedented strengthening of its capacity at the country level by recruiting dedicated "3 by 5" officers and other staff.

The Canadian International Development Agency also supports a variety of other HIV/AIDS programmes. Canada has contributed more than CDN\$ 550 million to the Global Fund, of which more than CDN\$ 250 million was pledged for the period 2006–2007. The Agency also provides substantial support to both the International AIDS Vaccine Initiative and the International Partnership for Microbicides. Along with the other members of the G8, Canada has pledged its support for the goal of coming as close as possible universal access to antiretroviral therapy by 2010.

In August 2006, Canada will host the XVI International AIDS Conference in Toronto.

For more information, visit www.acdi-cida.gc.ca/index-e.htm.

3.2 Partnership and coordination

Efforts to achieve the "3 by 5" target have helped to mobilize a broad-based partnership including governments, UNAIDS Cosponsors and Secretariat, bilateral and multilateral donors, community- and faith-based organizations, academic institutions and international nongovernmental and philanthropic organizations working to expand access to HIV/AIDS treatment at the global, regional and country levels. 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 unions, employers' associations and technical agencies addressing HIV/AIDS. For example, two of the world's largest groupings of trade unions, the Global Unions Federations and the International Confederation of Free Trade Unions (which together represent 332 million workers), joined with WHO, UNAIDS, the International Labour Organization, leaders of major unions in sub-Saharan Africa and the International Organization of Employers to identify ways to mobilize their memberships to advocate for universal access to HIV prevention, care and treatment. Major employers in South Africa have shown leadership in developing HIV prevention and treatment programmes for their employees.

"3 by 5" has also fostered new ties among faith-based organizations, major HIV/AIDS donors and technical agencies (Box 10). It is estimated that faith-based organizations provide up to 40% of the health care infrastructure in sub-Saharan Africa. Catholic Relief Services, the international relief and development agency of the United States Catholic community, for example, is the consortium leader for a US\$ 335 million antiretroviral therapy project funded by the United States Centers for Disease Control and Prevention through the United States President's Emergency Plan for AIDS Relief aiming to provide antiretroviral therapy to 138 000 people in Africa, the Caribbean and Latin America by 2008. Catholic organizations are also sub-recipients of Global Fund grants in a number of countries, including Gambia, Kenya, Namibia, South Africa and Thailand.

Box 10. Mapping faith-based HIV/AIDS services

Which churches and religious organizations are providing antiretroviral therapy? How many people are they treating? And what other services, such as support groups, sewing groups, child care and subsidies for basic food and provisions, are these organizations providing? Few low- and middle-income countries have detailed answers to these questions, even though it is estimated that faith-based organizations provide up to 40% of the health care infrastructure in sub-Saharan Africa. A first-ever mapping initiative led by a group of researchers from Africa and the United States, including the Rollins School of Public Health in Atlanta, in collaboration with WHO, is working to fill this knowledge gap. The initiative focused first on Lesotho and Zambia in 2005. Its findings about the level and quality of services provided by faith-based organizations will help decision-makers and major funders to assess coverage and gaps and to accelerate scaling up of prevention, care and treatment. The Governments of Botswana and Kenya are undertaking similar mapping exercises.

"3 by 5" has also encouraged new partnerships among health care providers and people living with HIV/AIDS that have helped create the conditions for more patient-centred care in a growing number of low- and middle-income countries. These approaches are preparing thousands of people to manage their adherence to treatment, which will likely result in better clinical outcomes for people receiving antiretroviral therapy and stronger health care systems as people become increasingly able to oversee their own treatment, freeing up health care workers to help others. People who are well informed about their treatment options are also better equipped to advocate for their rights.

A successful initiative in this area is the Collaborative Fund for HIV Treatment Preparedness, a joint venture of 20 international donors, WHO, the International Treatment Preparedness Coalition and the Tides Foundation. In 2005, the Collaborative Fund provided technical and financial support to more than 200 community groups around the world to undertake treatment literacy activities. 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 treatment and prevention services. As a result of early successes, the Collaborative Fund has attracted additional resources to work in partnership with the International Community of Women Living with HIV/AIDS on treatment-preparedness activities specifically targeting women in sub-Saharan Africa.

Community-based organizations are making an important contribution to scaling up antiretroviral therapy in many countries. In Burkina Faso, for example, they have taken the lead in providing HIV testing and counselling, doing an estimated 90% of the 120 000 tests conducted in the country in 2004. Community-based, nongovernmental and faith-based organizations are also delivering up to 50% of HIV treatment.²¹

In early 2004, all UNAIDS Cosponsors agreed to contribute to realizing the "3 by 5" target in their respective areas of expertise,²² helping to ensure that "3 by 5" became an effort of the entire United Nations System (Box 11). At the same time, as more stakeholders became involved in scaling up treatment and prevention, the need for better coordination between donors and technical agencies both at the global and country levels became evident. A Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors was therefore established in 2005 to consider how countries could be better supported, and its final report²³ recommended measures the United Nations should take to assist countries in optimally utilizing their resources.

21 These organizations include ALAVI, Vie Positive, Responsabilité-Espoir-Vie-Solidarité, REV+, Centre de Traitement Ambulatoire, Association African Solidarity, la Bergerie, Saint Camille and Médecins sans Frontières.

22 Roles and responsibilities of UNAIDS Cosponsors and the UNAIDS Secretariat in the "3 by 5" Initiative. In: *Investing in a comprehensive health sector response to HIV/AIDS: scaling up treatment and accelerating prevention*. WHO HIV/AIDS Plan January 2004–December 2005. Geneva, World Health Organization, 2004 (<http://www.who.int/3by5/publications/documents/hivplan/en>, accessed 13 February 2006).

23 *Final report of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors*. Geneva, UNAIDS, 2005 (<http://www.theglobalfund.org/en/files/about/replenishment/GTT%20final%20report.pdf>, accessed 13 February 2006).

These recommendations included working more closely with national AIDS coordinating authorities to support high-priority national AIDS action plans; establishing joint United Nations teams on AIDS at the country level; creating a problem-solving team with members from bodies in the United Nations system and the Global Fund to overcome obstacles to implementation at country level; a clear division of labour among the UNAIDS Cosponsors and the Global Fund; and both increasing and refocusing UNAIDS programme acceleration funds²⁴ to enable greater financing of technical support.

Many of the Global Task Team recommendations are now being implemented. Since June 2005, work has begun to develop an expanded programme acceleration fund mechanism, a plan for the division of labour among UNAIDS Cosponsors has been agreed and a problem-solving mechanism is now in place (the Global Joint Problem-solving and Implementation Support Team (GIST)) (see Box 18).

Box 11. UNAIDS Cosponsors: a multisectoral effort on “3 by 5”

In addition to WHO's focus on scaling up treatment and prevention in the health sector, the UNAIDS Secretariat and Cosponsors all worked to ensure that “3 by 5” was a multisectoral effort. The Secretariat has played a leading role in all aspects of “3 by 5” policy development and implementation globally and at the country level. Core funds were advanced in early 2004 to support the initiation of activities, and field staff were instructed to actively support “3 by 5” by establishing joint United Nations activities and by collecting strategic information. UNAIDS also played a key role in developing a policy position paper on accelerating global prevention efforts and is currently coordinating a series of country and regional consultations on planning for universal access.

The Office of the United Nations High Commissioner for Refugees (UNHCR) has been working with governments, United Nations agencies and nongovernmental organizations to advocate for and provide refugees with antiretroviral therapy when it is available to the surrounding host communities. By the end of 2005, a limited number of refugees in 26 countries were receiving antiretroviral therapy through a variety of informal and formal mechanisms.

The United Nations Children's Fund (UNICEF) has been working to address barriers to children's access to antiretroviral therapy by quantifying the burden of disease among children, simplifying dosing schedules, documenting child care experiences, strengthening links between preventing mother-to-child transmission and care and treatment programmes, integrating child care issues in home-based care programmes and developing monitoring and evaluation systems. UNICEF collaborates with the AIDS Medicines and Diagnostic Service (AMDS) and is currently procuring antiretroviral drugs and related supplies for over 40 countries.

The World Food Programme (WFP) is working with WHO to design nutritional guidelines for care and treatment of people living with HIV/AIDS to optimize the benefits of antiretroviral drugs and has worked with governments, nongovernmental organizations and other United Nations agencies to expand access to food and nutritional support for people living with HIV/AIDS and their families by supporting antiretroviral therapy and programmes for preventing mother-to-child transmission in several countries.

The United Nations Development Programme (UNDP) supported the “3 by 5” effort through a community capacity enhancement programme involving training of trainers in eight African countries. At the policy level, UNDP worked to develop the capacity of governments and civil society in Africa, Asia and Arab countries to adapt TRIPS flexibilities and safeguards to ensure access to affordable medicines. In several regions, special focus was placed on the impact of free trade agreements on the production and importation of medicines. For example, at the request of the Partner States of the East African Community, UNDP and the Third World Network supported national experts in assessing and analysing national patent laws for their impact on access to medicines.

²⁴ Programme acceleration funds are made available from the UNAIDS core budget to United Nations theme groups in countries for joint programming on HIV/AIDS by United Nations System organizations. The purpose of programme acceleration funds is to enable United Nations theme groups to make a strategic contribution to an effective and efficient scaled-up national response.

The United Nations Population Fund (UNFPA) has focused on building knowledge and capacity for integrating prevention and treatment services. UNFPA promotes the utilization of reproductive health services (such as maternal and child health, prevention of mother-to-child transmission, adolescent friendly services, sexually transmitted infections and family planning sites) as entry points for voluntary counselling and testing and antiretroviral therapy delivery or as conduits for referral to treatment; the procurement and inclusion of preventive commodities, especially male and female condoms; equitable access to treatment with emphasis on young people and women; priority access for pregnant women living with HIV/AIDS; and meeting the sexual and reproductive health needs of women living with HIV/AIDS.

The United Nations Office on Drugs and Crime (UNODC) has been advocating for and recommending a full and comprehensive range of treatment and care services for injecting drug users, increasing access to voluntary counselling and testing in drug dependence treatment programmes and establishing drug dependence treatment in antiretroviral therapy clinics. WHO has been collaborating with UNODC on developing appropriate indicators for monitoring the coverage of HIV/AIDS prevention, treatment and care services for drug users.

The International Labour Organization (ILO) contributed to the attainment of “3 by 5” by ensuring effective implementation of the ILO Code of Practice on HIV/AIDS and the world of work,²⁵ including providing technical assistance and advisory services to governments, workers’ and employers’ organizations and the private sector in relation to workplace policies, building workplace capacity and promoting public-private partnerships.

The United Nations Educational, Scientific and Cultural Organization (UNESCO) has contributed to the development of treatment education materials and is supporting its Member States in addressing stigma and discrimination, promoting knowing one’s HIV status, integrating HIV and AIDS in curricula and supporting educators through strengthened teacher training and all education-sector employees through the implementation of workplace policies, in collaboration with the ILO.

The World Bank contribution comes in many different forms depending on a country’s needs, which may include technical assistance, analytical work, capacity-building, community links, research, public-private partnerships for service delivery, monitoring and evaluation, the promotion of adherence and strengthening health systems. The Bank continues to provide major resources to support the scale-up of national HIV/AIDS programmes through its Multi-Country HIV/AIDS Program for Africa and Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Lending Program.

The need for mechanisms to coordinate the activities of local stakeholders at the country level has long been evident. A 2005 survey by the UNAIDS Secretariat among 66 countries with a UNAIDS presence revealed that 63 had established national HIV/AIDS coordinating authorities consistent with the “three ones” principles.²⁶ Several of these, including countries such as Kenya and Uganda, have recently established subcommittees or special task forces specifically to coordinate the scale-up of antiretroviral therapy.

²⁵ *ILO Code of Practice on HIV/AIDS and the world of work*. Geneva, International Labour Organization, 2001 (<http://www.ilo.org/public/english/protection/trav/aids/code/languages/index.htm>, accessed 13 February 2006).

²⁶ One national strategic framework for HIV/AIDS; one national AIDS coordinating authority; and one national monitoring and evaluation mechanism.

Box 12. Horizontal cooperation fosters scale-up among low- and middle-income countries

Scaling up national HIV/AIDS responses has provided low- and middle-income countries with new opportunities to collaborate and learn from one another's experiences. Brazil, China, Nigeria, the Russian Federation and Ukraine, for example, are cooperating in research, development and production of HIV medicines, diagnostics and other commodities through their Technological Network on HIV/AIDS. The UNAIDS Secretariat, meanwhile, is leading a drive to establish regional technical support facilities that will contribute to strengthening and better coordinating the provision of technical support by building on regional synergy.

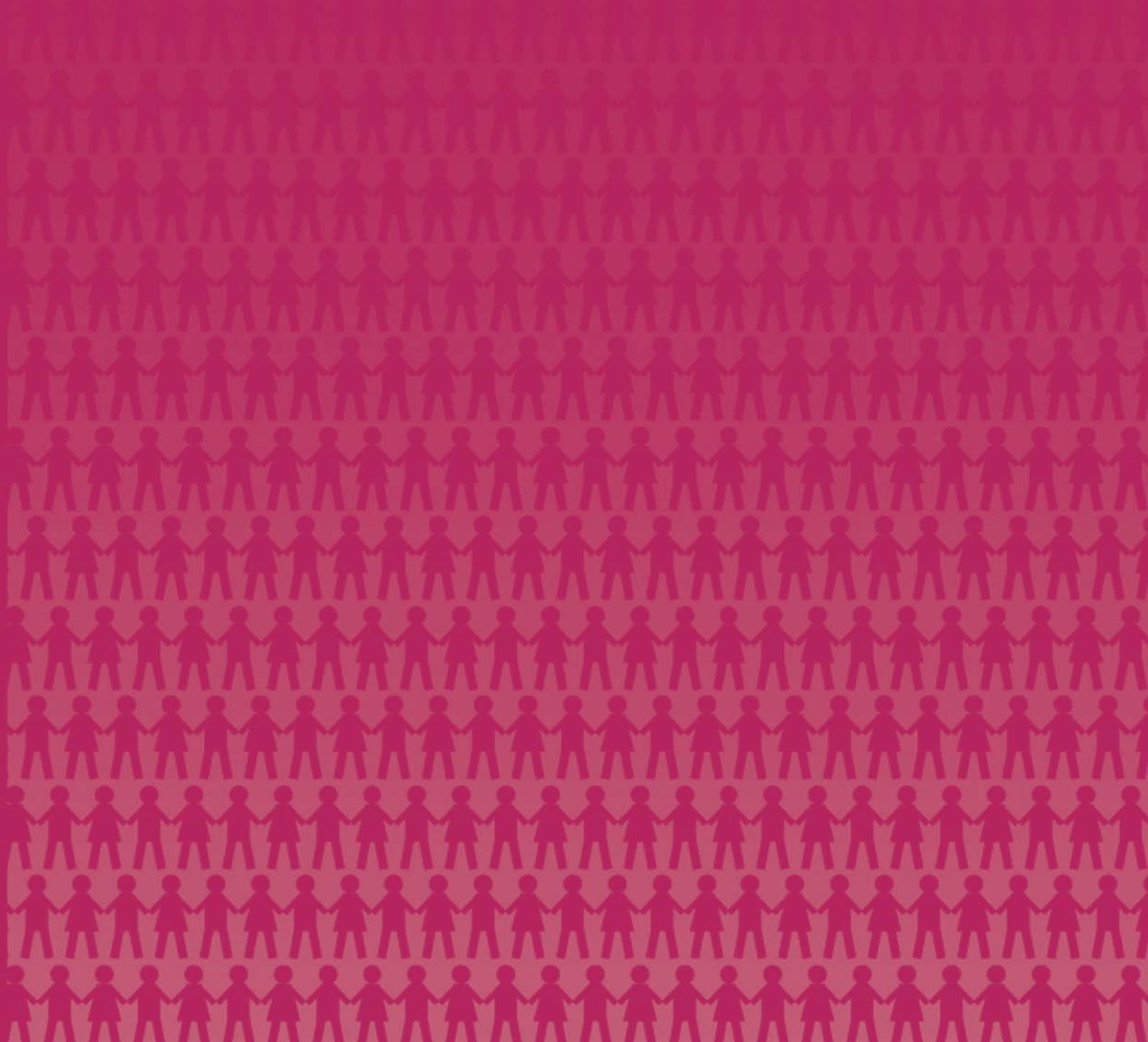
Knowledge hubs, supported by WHO and the German Gesellschaft für Technische Zusammenarbeit (GTZ), serve a similar role. Rather than relying on expensive and sometimes inappropriate technical assistance from institutions and consultants from high-income countries, WHO has been investing in existing local training institutions in low- and middle-income countries to act as regional centres for capacity building and development of technical networks. Various hubs have been established in Europe and Africa, including a Knowledge Hub on Second Generation HIV/AIDS Surveillance (Zagreb, Croatia), the Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia (Kiev, Ukraine), the Harm Reduction Knowledge Hub for Europe and Central Asia (Vilnius, Lithuania), the Knowledge Hub for the Care and Treatment of HIV/AIDS in West Africa (CIFRA, in Ouagadougou, Burkina Faso) and the Knowledge Hub for the Care and Treatment of HIV/AIDS in Eastern and Southern Africa (JCRC, in Kampala, Uganda).

The Sudan provides an example of the establishment of a new knowledge hub: the Knowledge Hub for the Care and Treatment of HIV/AIDS in the Eastern Mediterranean. The Sudan is experiencing the early stages of a generalized HIV epidemic, with adult prevalence of 0.7–7.2% of its 34.3 million people. Health systems are weak, in part owing to 21 years of civil strife. As of December 2005, 400 Sudanese were receiving antiretroviral therapy, while an estimated 50 000 needed it. To address this public health emergency, in September 2005, the Sudan sent teams of physicians, nurses, laboratory technicians and programme managers from six locations in the country for four weeks of intensive training to the Knowledge Hub for the Care and Treatment of HIV/AIDS in Eastern and Southern Africa in Kampala, Uganda.

By the end of 2005, these core trainers had facilitated the training of 48 counsellors and 200 lay counsellors, and in the first months of 2006, the physicians among them will have trained another 30 physicians. These newly trained staff will allow for the establishment of 12 new antiretroviral therapy centres, many of them outside Khartoum, the capital. By 2008, the Sudan aims to have trained enough health care workers to support 27 antiretroviral therapy centres throughout this large country. The Sudan hopes to become a resource centre for all Eastern Mediterranean and North African countries that are seeking to scale up.

PART 2.

Towards Universal Access



1. Building on lessons learned

As WHO and UNAIDS noted in the “3 by 5” strategy,²⁷ the “3 by 5” target needs to be seen as an interim step “towards the ultimate goal of universal access to antiretroviral therapy for those in need of care, as a human right and within the context of a comprehensive response to HIV/AIDS”. The commitment of G8 leaders and United Nations Member States to working with WHO and UNAIDS to develop and implement a package for HIV treatment, care and prevention with the aim of coming as close as possible to universal access to treatment by 2010 now provides the strategic framework for scale-up over the next five years. In particular, the goal of universal access will help to mobilize and focus efforts on overcoming the remaining challenges to scaling up HIV/AIDS programmes and to ensure that scaling up contributes to attaining broad health and development goals, including stronger health systems. Universal access to treatment cannot be accomplished without a comprehensive approach that also includes appropriate targets for prevention.

“3 by 5” and the experience gained in these early years of HIV treatment delivery in low- and middle-income countries offer valuable lessons for the future. Above all, it has been shown beyond doubt that antiretroviral therapy can be delivered efficiently and effectively in diverse settings, including countries with different types of epidemic, in severely resource-constrained communities, in rural settings and in a wide variety of health care systems. In most countries where scale-up is occurring, critical – and usually long-standing – weaknesses in health care systems are being identified. These include gaps in current systems to manage and supply drugs and diagnostics, laboratory infrastructure and human resource capacity. Experience to date and operational research are helping to inform the development and implementation of new policies, strategies, programmes and approaches that will help to overcome these bottlenecks and ensure that scaling up HIV/AIDS prevention, treatment and care contributes to the overall strengthening of health systems.

This section focuses on the major lessons learned so far from scaling up antiretroviral therapy programmes.

1.1 Targets mobilize commitment and action

The “3 by 5” target has played an important role in prompting a large number of countries to set time-limited national treatment targets as part of national scale-up plans and to mobilize resources and partnerships accordingly. Many countries were encouraged to aim higher than would have been the case in the absence of an ambitious, global benchmark such as “3 by 5”, and national targets have been shown to play a valuable role in mobilizing action and increasing accountability among stakeholders, including international technical agencies, donors and governments.

Nevertheless, it is clear that treating half of those in need by the end of 2005 was not realistic for all countries, particularly those with very weak health infrastructure and a very high burden of disease. Future country-level targets will need to be sufficiently ambitious to mobilize action, will need to be country-driven and should take into account factors other than burden of disease, such as local capacity. Targets for treatment need to be complemented by achievable targets for the other elements of a comprehensive response to HIV/AIDS, including prevention and impact mitigation.

1.2 Policy reforms maximize programme effectiveness

- *Human resources*

The model of health care provider training developed by WHO and its partners strongly encourages adopting a public health approach to scale-up involving decentralization of services to bring treatment sites as close as possible to the community and delegating routine aspects of care to clinical officers, nurses and trained community health workers. In light of the human resource constraints facing many countries, this policy shift has been critical in making the most of available human resources and, in many cases, enhancing access, equity and the participation of affected communities. Implementing this approach may require reviewing national health legislation and policy in several key areas.

²⁷ World Health Organization and UNAIDS. *Treating three million by 2005: making it happen. The WHO strategy*. Geneva, World Health Organization, 2003 (<http://www.who.int/3by5/publications/documents/isbn9241591129/en>, accessed 13 February 2006).

- *User fees*

User fees for health care have become a common feature of health care funding in many low- and middle-income countries over the past two decades. Recent evidence indicates, however, that user fees at the point of service for HIV treatment, even with means testing, can do more harm than good. User fees, however small, impose a significant financial burden on many people and their families, thus undermining adherence to drug regimens. This has now been documented in many countries.²⁸ User fees appear to be less equitable and less efficient, as they require more bureaucracy. Studies also suggest that user fees generate little revenue at the national level, although they could play an important role at the district and local levels.

Several countries – including Botswana, Brazil, Ethiopia, Senegal, Thailand, the United Republic of Tanzania and Zambia – are showing that policy on health care funding can be adjusted to eliminate user charges for HIV treatment (Box 13). This helps to overcome the significant socioeconomic barriers to the uptake of treatment and increases rates of long-term adherence to medication.²⁹

Box 13. Countries explore alternatives to user fees

As they work to eliminate user fees, several countries are also exploring alternative funding mechanisms to cover some of the costs of antiretroviral therapy. Two basic models of alternative funding strive to provide universal coverage to treatment through risk-pooling, in which many people share the costs associated with health care. Tax-funded health care funding draws on general tax revenue to support the costs of antiretroviral therapy. Social health insurance taps into contributions collected from workers, self-employed people, enterprises and the government that are pooled into one or several social health insurance funds.³⁰ Entitlement is linked to a contribution made by or on behalf of specific individuals in the population. Burundi, Ghana, Kenya, Nigeria, Senegal and Zambia are some of the countries that are considering such models.

Burundi is one of the countries with the lowest average income and is recovering from years of civil war. It has a population of 7 million, and the HIV prevalence was estimated to be 6% among adults in 2003. The same year, the government abolished user fees for antiretroviral therapy and began to scale up access to treatment swiftly, increasing from 1210 people being treated in 2003 to 6416 in 2005. This policy shift and rapid scale-up was underpinned by Burundi's treatment solidarity funds. Since 2000, 22 solidarity funds have been created by workers in government ministries, public and private enterprises. About 5000 public-sector workers and more than 30 000 police and military personnel contribute to these funds, and the government and employers make annual contributions. The government also contributes to a national special fund for HIV/AIDS treatment and is now considering establishing a national solidarity fund, a type of social health insurance fund, to support the long-term provision of antiretroviral therapy.

- *Testing and counselling*

Data from the most recent demographic surveys in several countries in sub-Saharan Africa³¹ indicate that less than 10% of people in these countries know whether they have been infected with HIV. Much wider knowledge of serostatus is essential if many millions of people are to access treatment, care and prevention.

Since 2004, WHO and UNAIDS policy has recommended that an HIV test be routinely offered to people in all clinical and community-based health care settings in which HIV is prevalent and antiretroviral therapy is available. In all cases, people must retain the right to refuse the test and give informed consent to be tested, and confidentiality must be ensured.

28 Laniece I et al. Adherence to HAART and its determinants in a cohort of Senegalese adults. *AIDS*, 2003, 17(suppl 3):S103–S108. Byakika-Tusiime J et al. Adherence to HIV antiretroviral therapy in HIV+ Ugandan patients purchasing therapy. *International Journal of STD and AIDS*, 2005, 16:38–41.

29 *The practice of charging user fees at the point of service delivery for HIV/AIDS treatment and care*. Geneva, World Health Organization, 2005 (<http://www.who.int/hiv/pub/advocacy/freeaccess/en>, accessed 13 February 2006).

30 *Social health insurance: sustainable health financing, universal coverage and social health insurance*. Report by the WHO Secretariat to the World Health Assembly, 7 April 2005. Geneva, World Health Organization, 2005 (WHA document A58/20; http://www.who.int/gb/e/e_wha58.html, accessed 13 February 2006).

31 Botswana AIDS Impact Survey II 2005, Burkina Faso Household Survey 2002, Cameroon District Health Survey 2004, Ghana District Health Survey 2003, Mozambique District Health Survey 2003 and Nigeria District Health Survey 2003.

The routine offer of testing and counselling is being implemented in a growing number of high-burden countries (Box 14). A recent study in Zimbabwe, where 25% of pregnant women are living with HIV/AIDS, found that most women accept the introduction of routine offer of HIV testing in antenatal care.³² Pilot studies in Mulago and Mbarara teaching hospitals in Uganda also found high acceptance of the routine offer of testing, and the approach is now being scaled up across the country.³³ Lesotho has recently announced plans to offer an HIV test to every person older than 12 years by 2007. These and other innovative approaches to testing, including for example, home visits and other types of outreach,³⁴ need to be explored.

Box 14. Routine offer of testing and counselling opens new doors for prevention

The conventional model for testing and counselling requires that people come forward voluntarily to request these services. This is known as voluntary or client-initiated testing and counselling. Reaching more people in need of treatment, preventing more cases of mother-to-child transmission and providing intensive prevention services, however, requires conducting tens of millions of tests among people who may have been exposed to HIV. Client-initiated testing seldom encourages enough people to come forward to fulfil this need. As a result, a growing number of high-burden countries are opting for a new approach in which health care providers routinely offer HIV testing to increase opportunities for HIV prevention and treatment.

Countries that are routinely offering testing and counselling are increasing the number of people who know their HIV serostatus. In Botswana, where an estimated 37% of the population is living with HIV/AIDS, introducing the routine offer of testing and counselling using rapid HIV testing in 2004 led to a rapid increase in the number of people knowing their HIV status. For example, at a prenatal clinic in Francistown, in the first three months of routine testing from February to April 2004, 314 of 347 pregnant women (90%) were tested for HIV. By contrast, from October 2003 to January 2004, the last four months of client-initiated voluntary counselling and testing at the site, 381 of 506 pregnant women (75%) were tested.

Scaling up the routine offer of testing in clinics across Botswana has produced similar results, as the percentage of pregnant women receiving testing and counselling rose from 73% to 85% between March 2004 and December 2005. Botswana now estimates that 25% of its population of 1.7 million now know their HIV status. Coupled with rapid HIV tests, the routine offer of testing is thus opening a gateway to both HIV treatment and prevention for tens of thousands of Botswanans.

1.3 Key operational approaches facilitate scale-up

- *A public health approach to scaling up contributes to strengthening health systems*

A public health approach is one that strikes an acceptable balance between the most intensive, individually tailored treatment and laboratory monitoring used in high-income countries and those likely to be most effective, equitable and feasible for treating large numbers of people in resource-constrained settings. Such an approach has been used with great success in TB treatment for several years and is now the basis of successful national antiretroviral therapy programmes in most of the countries that are rapidly scaling up, including Botswana, Kenya, Senegal, Thailand, Uganda, Ukraine, Zambia and Zimbabwe.

Elements of the public health approach that WHO recommends and that are proving successful in facilitating the rapid scale-up of antiretroviral therapy programmes include:

- use of appropriate national or international mechanisms to ensure the consistency and quality of the national supply of HIV-related drugs and diagnostics and their equitable and rational use;

32 Perez F et al. Acceptability of routine HIV testing in antenatal services in Zimbabwe. *3rd IAS Conference on HIV Pathogenesis and Treatment 2005, Rio de Janeiro, Brazil, 24–27 July 2005* (Abstract TuOa0304; <http://www.ias-2005.org/planner/ProgrammeAtAGlance.aspx?SessionID=26>, accessed 13 February 2006).

33 Wanyenze R et al. Establishment of routine HIV counseling and testing at Mulago and Mbarara teaching hospitals: acceptability and lessons learned. *3rd IAS Conference on HIV Pathogenesis and Treatment 2005, Rio de Janeiro, Brazil, 24–27 July 2005* (Abstract WeFo0106; <http://www.ias-2005.org/planner/ProgrammeAtAGlance.aspx?SessionID=235>, accessed 13 February 2006).

34 An approach using mobile testing vans in marketplaces was reported recently: Morin SF et al. Removing barriers to knowing HIV status: same-day mobile HIV testing in Zimbabwe. *Journal of Acquired Immune Deficiency Syndromes*, 2006, 41:218–224.

- simplification of treatment using standard treatment protocols and simplified clinical monitoring procedures;
- team-based approaches to patient management and the delegation of routine aspects of patient follow-up to trained nurses and community workers;
- increasing knowledge of HIV status through the use of rapid testing technology and the routine offer of HIV testing in high-burden settings;
- community mobilization and education to promote demand for testing, prepare communities for treatment and support long-term adherence;
- standardized patient tracking using standard patient registries, data cards and minimum data sets;
- improved integration of prevention and treatment interventions; and
- population-based surveillance of drug resistance to inform drug selection and programming.

All the normative guidance and tools for implementing antiretroviral therapy and other HIV/AIDS interventions as part of “3 by 5” have utilized such a public health approach, notably in the form of simplified treatment guidelines and the WHO IMAI training curriculum. Uptake of these tools has been high in the 49 “3 by 5” focus countries,³⁵ and evidence is emerging that such simplified approaches lead to effective public health outcomes.³⁶

Countries need significant ongoing technical support to comprehensively implement the public health approach. This will become increasingly evident as countries move to decentralize treatment services to primary care and first-level facilities. The approach may need to be refined further in low-prevalence settings and those with concentrated epidemics. More attention is also required to promoting the implementation of key elements of the public health approach in the non-state sector.

- *Treatment and prevention must go together*

Concerns persist that the benefits of antiretroviral therapy could be offset by factors such as increased unsafe sex and transmission of sexually transmitted infections, as has been seen in most industrialized countries.³⁷ Such trends underscore the need to intensify prevention efforts in parallel with scaling up treatment, using all approaches known to be effective and paying particular attention to the needs of vulnerable groups.³⁸ Thailand, for example, a pioneer in expanding access to antiretroviral therapy through its national public health system, has recognized the risks of complacency in HIV prevention and especially the need to target groups not explicitly addressed in its previous prevention efforts, such as injecting drug users and male sex workers.³⁹

In addition to new challenges, antiretroviral therapy also presents new opportunities and possibly new models for expanding HIV prevention, a number of which have been highlighted in previous progress reports.⁴⁰ These include opportunities resulting from the scale-up of HIV testing within the health sector and the wider community.

35 Beck EJ et al. Implementation of ART guidelines in resource limited countries: do they match with the WHO guidelines? *3rd IAS Conference on HIV Pathogenesis and Treatment 2005, Rio de Janeiro, Brazil, 24–27 July 2005* (Abstract MoPeLB11.10C01; <http://www.aegis.org/conferences/IASHIVPT/2005/MoPeLB11-10C01.html>, accessed 13 February 2006).

36 Severe P et al. Antiretroviral therapy in a thousand patients with AIDS in Haiti. *New England Journal of Medicine*, 2005, 353: 2325–2334.

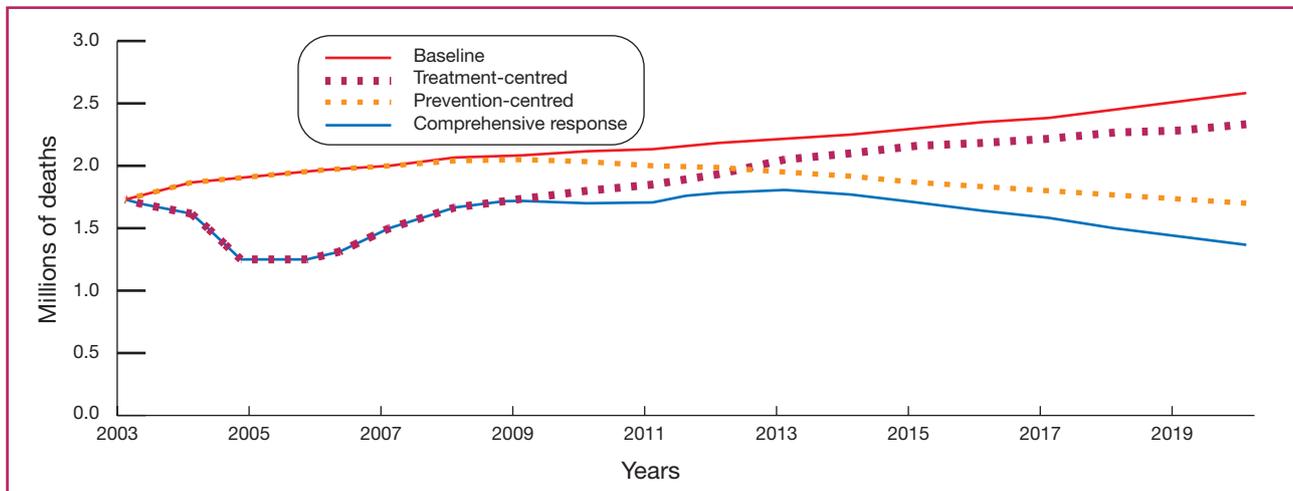
37 Elford J. Changing patterns of sexual behaviour in the era of highly active antiretroviral therapy. *Current Opinion in Infectious Diseases*, 2006, 19:26–32.

38 WHO and UNAIDS strongly endorse: *World AIDS Day – EU Statement on HIV Prevention for an AIDS Free Generation*. Brussels, Council of the European Union, 24 November 2005 (<http://register.consilium.eu.int/pdf/en/05/st14/st14925.en05.pdf>, accessed 13 February 2005).

39 *Expanding access to antiretroviral treatment in Thailand: achieving treatment benefits while promoting effective prevention*. Washington, DC, World Bank and Bangkok, Ministry of Public Health, Thailand, 2005 (<http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/WBThailandARTStudy.pdf>, accessed 13 February 2006).

40 World Health Organization and UNAIDS. *Progress on global access to HIV antiretroviral therapy: an update on “3 by 5”*. Geneva, World Health Organization, 2005:19–20 (<http://www.who.int/3by5/fullreportJune2005.pdf>, accessed 13 February 2006).

Fig. 8. Annual number of AIDS deaths projected among adults in sub-Saharan Africa under different intervention scenarios, 2003–2020



Many new infections occur between serodiscordant couples, but prevention efforts have been slow to respond to this situation until recently. A recent study in Uganda⁴¹ shows the potential benefits of intensifying prevention interventions for serodiscordant couples at the same time that antiretroviral therapy is introduced. During the first six months of antiretroviral therapy, risky sexual behaviour decreased by 70% and the estimated risk of HIV transmission decreased by 98% in a cohort of 926 HIV-infected adults who were enrolled in a home-based antiretroviral therapy programme that included prevention counselling, counselling and testing for cohabiting partners and providing condoms. Other opportunities to reinforce prevention for people living with HIV/AIDS need to be fully exploited in the health sector and beyond, for example, as part of adherence counselling and support for those receiving treatment.⁴²

There is now a very broad consensus that focusing on treatment or prevention alone is not an effective option and that both must be scaled up together (Boxes 15–17). Epidemiological modelling using different intervention scenarios consistently shows that more deaths can be avoided with a comprehensive response including both treatment and prevention than with a response that focuses on treatment or prevention alone (Fig. 8).⁴³

41 Bunnell R et al. Changes in sexual behavior and risk of HIV transmission after antiretroviral therapy and prevention interventions in rural Uganda. *AIDS*, 2006, 20:85–92.

42 Comman DH et al. Model for translation and dissemination of a provider-delivered risk reduction intervention for HIV-positive patients in clinical care. *3rd IAS Conference on HIV Pathogenesis and Treatment 2005, Rio de Janeiro, Brazil, 24–27 July 2005* (Abstract MoPe10.7P22; <http://www.aegis.org/conferences/IASHIVPT/2005/MoPe10-7P22.html>, accessed 13 February 2006). Crepaza N et al. for the HIV/AIDS Prevention Research Synthesis (PRS) Team. Do prevention interventions reduce HIV risk behaviours among people living with HIV? A meta-analytic review of controlled trials. *AIDS*, 2006, 20:143–157.

43 Salomon JA et al. Integrating HIV prevention and treatment: from slogans to impact. *PLoS Medicine*, 2005, 1(2):50–56. Johnson LF, Dorrington RE. The demographic and epidemiological impact of HIV/AIDS treatment and prevention programmes: an evaluation based on the ASSA2000 model. *2002 Demographic Association of Southern Africa Conference* (www.hsph.harvard.edu/bioethics/pdf/DEMSApaper.doc, accessed 13 February 2006).

Box 15. Scaling up prevention for people living with HIV/AIDS in Cambodia

HIV/AIDS prevention programmes are increasingly being tailored for people living with HIV/AIDS as well as for those at risk of infection.

One such approach, known as positive prevention, involves counselling and skills-building for people living with HIV/AIDS on subjects such as how to live a healthy and productive life after learning of HIV infection; how to have a healthy sex life, free from fear of transmitting the virus to loved ones; and how to become involved in prevention, care and treatment activities in the community.

In Cambodia, which has more than 123 000 people living with HIV/AIDS, providing accurate reproductive health and prevention information to people living with HIV/AIDS is a key element of the continuum of care. As part of an initiative known as MMM (Mondul Mith Chuoy Mith – “friends help friends”), hundreds of people living with HIV/AIDS take part in monthly community meetings led by health care workers at referral hospitals. Participants receive education and counselling on adherence to treatment and HIV prevention, among other topics.

Positive prevention is also part of the work done by many of the 150 nongovernmental and community-based organizations that provide home care, treatment education, counselling and psychosocial support in Cambodia. The Cambodian Network of People Living with HIV/AIDS (CPN+), for example, provides services through more than 415 self-help groups, with nearly 15 000 registered members living with HIV/AIDS. Harnessing these community resources is a critical part of Cambodia’s plan for scaling up HIV prevention, treatment and care.

Box 16. Treatment and prevention are mutually reinforcing in Lesotho

With nearly one third of adults infected, Lesotho faces one of the worst HIV/AIDS epidemics in the world. Widespread poverty and a weak health care system have undermined the efforts of this country of 1.8 million people to address this health emergency. Lesotho is scaling up antiretroviral therapy and recently began to push forward with an ambitious campaign to ensure that everyone older than 12 years is offered an HIV test and counselling by 2007.

The Know Your Status campaign addresses a major obstacle to scaling up treatment and prevention – too few people know their HIV serostatus. A shortage of testing and counselling sites and stigma and fear associated with HIV are behind this widespread lack of knowledge. As a result, those who are already infected are likely to continue to infect others unknowingly and are not obtaining access to care and support.

This is the first time a country will offer confidential and voluntary HIV testing and counselling door to door or in other ways agreed to by local communities. If successful, the Know Your Status campaign will allow tens of thousands of people to know their status. Seronegative people will thus be able to benefit from prevention services; seropositive people will be able to seek help, thereby accelerating treatment scale-up. (About 8400 people are now receiving antiretroviral therapy, and 58 000 were estimated to need treatment at the end of 2005.)

It is believed that, when more people know their status, the demand for prevention services, including information about safer sexual practices, will increase and, in turn, accelerate the scaling up of prevention services for both those who are HIV-positive and those who remain HIV-negative. The testing initiative is being coordinated with Lesotho’s treatment expansion programme in a way that emphasizes the voluntary aspect of testing and the need to respect the right of individuals to confidentiality and privacy. A major part of the campaign is to build the capacity of communities to address HIV/AIDS by engaging local chiefs and villagers in the process and training of 3000 community-health workers to provide HIV testing, counselling and prevention education.

Box 17. Countries in Asia promote harm reduction for injecting drug users

During the past two years, many countries have embraced comprehensive approaches to reducing HIV transmission, and other harms, related to injecting drug use. This shift has been most noticeable in Asia, where injecting drug use is a major mode of HIV transmission. Cambodia, China, Indonesia and Malaysia are among the leaders in this change of policy, but many other countries are taking action. Myanmar, for example, is introducing methadone substitution therapy, and Viet Nam is distributing hundreds of thousands of clean needles and syringes in 21 provinces with the help of peer-outreach workers—the first step in a national harm reduction strategy.

In Malaysia, the government has shifted from a singular approach emphasizing abstinence to a comprehensive approach including clean needle and syringe programmes, methadone substitution therapy and peer outreach in support of people who inject drugs. About 52 000 people were living with HIV/AIDS in 2003, the vast majority of them young and three quarters of them injecting drug users. In October 2005, the government launched a pilot national methadone maintenance treatment programme providing for 1200 clients. The programme covers four areas, including Kuala Lumpur, and is to be followed by a needle and syringe access programme that will provide initial access for up to 200 clients per site. Both programmes will be carefully monitored and evaluated with a view to expanding them. This work is a collaborative effort between the government and community-based organizations.

China estimates that, in 2005, 49% of known HIV infections were among people who had injected drugs, and needle-and-syringe reuse continues to account for most new infections. In 2003, China adopted a protocol to establish community-based methadone maintenance treatment, recognizing that illicit drug use is also a health issue. In 2004, the State Council called for increased efforts to combat HIV/AIDS at all levels, including expanding methadone maintenance treatment. National expenditure on prevention has been increased, and harm reduction has been enshrined as a key part of the national HIV/AIDS strategy. The country is now scaling up methadone maintenance treatment clinics to serve an estimated 300 000 drug users, with 128 methadone maintenance treatment clinics operational at the end of 2005 and 1500 methadone maintenance treatment clinics to be operational by 2008. Such clinics will also play a critical role in HIV/AIDS treatment and care and referral of drug users living with HIV/AIDS to HIV/AIDS services. China is also expanding needle-and-syringe exchange programmes to serve an estimated 100 000 injecting drug users, with 1400 programmes to be operational by 2008.

Asia's change in approach is reflected in a *Biregional strategy for harm reduction (2005–2009): HIV and injecting drug use*⁴⁴ recently published by the WHO Regional Office for South-East Asia and the WHO Regional Office for the Western Pacific. The strategy identifies the normative tools, methods of implementation and capacity-building needed for Member States to scale up an essential package of measures that have been shown to prevent HIV epidemics among injecting drug users and provides a number of targets and indicators. The publication states: “Without implementation of full HIV/AIDS prevention interventions by 2005, projections suggest that an additional 20 million HIV infections will occur in the two regions by 2010, together with associated social and economic problems.”

1.4 Persistent challenges must be overcome

Despite progress to date, some persistent challenges continue to thwart the scaling up of antiretroviral therapy and HIV prevention. These challenges – many of which have been emphasized in previous progress reports and independent analyses⁴⁵ – include partnerships, alignment and harmonization; sustainable financing; drugs and other commodities; constraints in health systems, including human resources; ensuring equitable access; and monitoring, evaluation and research.

⁴⁴ *Biregional strategy for harm reduction (2005–2009): HIV and injecting drug use*. New Delhi, WHO Regional Office for South-East Asia and Manila, WHO Regional Office for the Western Pacific, 2005 (http://w3.whosea.org/en/Section10/Section18/Section356_4609.htm or http://www.wpro.who.int/publications/PUB_9290611952.htm, accessed 13 February 2006).

⁴⁵ *Missing the target: a report on HIV/AIDS treatment access from the frontlines*. New York, International Treatment Preparedness Coalition, 2005 (<http://aidtreatmentaccess.org>, accessed 13 February 2006).

- *Partnerships, alignment and harmonization*

Although important steps have been taken to promote effective partnerships between technical agencies and to ensure harmonization of efforts in scaling up programmes, more can be done to address implementation bottlenecks being experienced at the country level. Lessons from 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) processes established by UNAIDS highlight the need for closer harmonization between United Nations System agencies, major donors and other implementing partners at country level (Box 18).

There is a risk that, by developing parallel structures and processes for donor and external technical support, agencies may undermine the national capacity and authority to coordinate and implement national responses. The capacity of national HIV/AIDS coordination mechanisms therefore urgently needs to be strengthened where these mechanisms remain weak. A further priority is consolidating regional and indigenous technical capacity, for example, by strengthening regional and subregional knowledge hubs. These knowledge hubs aim to strengthen local and regional technical support networks in low- and middle-income countries, ensuring that regional capacity-building is coordinated, is of high quality and uses coherent approaches.

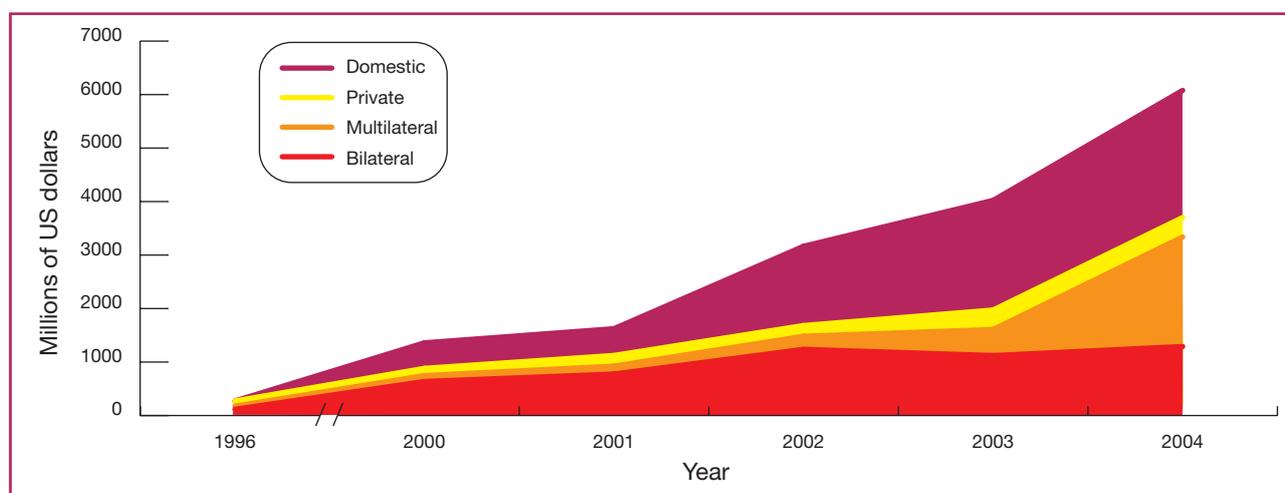
Box 18. New mechanisms to improve utilization of resources

The Global Joint Problem-solving and Implementation Support Team (GIST) was created on the recommendation of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors as a mechanism to rapidly identify obstacles to effective implementation of Global Fund and other large grant funding in countries and to provide coordinated technical assistance to overcome these obstacles. The GIST comprises representatives of major technical agencies (WHO, UNDP, World Bank, UNFPA, UNICEF and the UNAIDS Secretariat) and the Global Fund Secretariat and is currently chaired by WHO. In the second half of 2005, the GIST was able to expedite the development of national antiretroviral therapy protocols in Guinea-Bissau and initiate steps to reinforce national laboratory capacity, with technical assistance provided by WHO. The GIST also facilitated the strengthening of the local Country Coordinating Mechanism with the assistance of UNDP and the UNAIDS Secretariat, and an initiative was undertaken to strengthen national procurement and supply management capacity with technical assistance and funding provided by UNICEF and the World Bank respectively.

In Niger, the GIST was advised of the need for rapid, short-term assistance in laboratory support and procurement and supply management, and UNICEF recruited a short-term consultant to assist the Ministry of Health in these areas. The GIST has also helped to accelerate recruitment of a UNAIDS country coordinator and WHO staff to strengthen United Nations support to the country as well as an international consultant recruited by the German Gesellschaft für Technische Zusammenarbeit (GTZ) to support the national coordination mechanism.

- *Sustainable financing*

Rapidly scaling up treatment, prevention and care to achieve universal access requires sustainable and predictable financing. Given the life-long nature of antiretroviral therapy, it cannot be taken intermittently, and treatment regimens should not change for non-clinical reasons. Interruptions or changes to drug supply not only endanger people but create the potential for drug resistance.

Fig. 9. Global HIV/AIDS spending in millions of US dollars, 1996–2004

Despite the substantially increased global resources available for HIV/AIDS in recent years (Fig. 9), the continued scaling up of HIV treatment, prevention and care increases the pressure for additional funding in the next several years (Table 4).

Table 4. Estimated global resource needs for HIV/AIDS (in billions of US dollars), 2006–2008⁴⁶

	2006	2007	2008	Total for 2006–2008 ^a
Prevention	8.4	10.0	11.4	29.8
Treatment and care	3.0	4.0	5.3	12.3
Orphans and vulnerable children	1.6	2.1	2.7	6.4
Programme costs	1.5	1.4	1.8	4.6
Human resources	0.4	0.6	0.9	1.9
Total	14.9	18.1	22.1	55.1

^a The totals for 2006–2008 have been rounded to the first decimal place, with the result that there may be small differences with subtotals because of rounding.

The expected global annual cost of supporting comprehensive national HIV/AIDS programmes, including treatment, prevention and care, will amount to at least US\$ 22 billion per year by 2008. Based on past trends and currently known pledges and commitments, UNAIDS estimated in August 2005 that, for 2005–2007, the available funding would amount to US\$ 8.3 billion, US\$ 8.9 billion and US\$ 10 billion respectively. The gap between resources available and those needed is therefore estimated to be at least US\$ 18 billion for 2005–2007. However, this is likely to be a significant underestimate.

As of 2004, when the last UNAIDS resource tracking data were available, about half of all HIV/AIDS funding came from external donors. However, domestic spending is projected to be US\$ 2.6 billion for 2005, US\$ 2.8 billion for 2006 and US\$ 3 billion for 2007, representing a declining share of the total need. Moreover, as countries adopt policies to heavily subsidize or make antiretroviral drugs free of charge, the associated costs will need to be planned for.

⁴⁶ *Resource needs for an expanded response to AIDS in low- and middle-income countries*. Geneva, UNAIDS, 2005 (http://data.unaids.org/publications/irc-pub06/resourceneedsreport_en.pdf, accessed 13 February 2006).

Since countries rely on external sources of financing, the need for sustainable and predictable financing must urgently be addressed. Of the US\$ 2.7 billion provided by direct bilateral aid in 2004, one half came from the United States Government. The United States Congress will need to authorize new funding for the United States President's Emergency Plan for AIDS Relief in 2008.

In addition to bilateral aid, the Global Fund provided US\$ 856 million. Currently agreed funding for the Global Fund will support a cumulative total of more than 1.5 million people receiving antiretroviral therapy. At the Twelfth Global Fund Board meeting in Marrakech, Morocco in December 2005, it became apparent that the number of Global Fund grants supporting antiretroviral therapy scheduled to end after their five-year individual grant period would increase from 10 in 2005–2006 to close to 70 in the period 2007–2010. Thus, new rounds of funding for the Global Fund – beginning with Round 6 in April 2006 – will be essential not only to allow scaling up towards universal access but also to guarantee continuation of services for those who have already started to receive treatment. However, the amount of money that will be available for any further funding rounds has not yet been determined.

Identifying new sources of aid revenue is also of paramount importance. Several new encouraging opportunities are emerging.

- There is a growing movement in the international community to support the development of innovative financing mechanisms to generate more stable and predictable revenue to meet long-term development needs. Some of these funds may be devoted to HIV/AIDS. Proposals by the United Kingdom for an International Finance Facility⁴⁷ could front-load significant resources for development by up to US\$ 50 billion. Plans by France and several other countries to introduce an Airline Solidarity Contribution to support health development projects – including the purchase of drugs and medical products – could also yield substantial resources.
- At the G8 Summit in Gleneagles, United Kingdom in July 2005, G8 countries agreed to write off US\$ 40 billion of debt in 18 low-income countries,⁴⁸ mostly in Africa. An additional nine countries may have their debts cancelled in the next 18 months, releasing US\$ 15 billion. These countries are in a unique position to use the proceeds of funds they would otherwise repay in debt to expand their national responses to HIV/AIDS.
- The G8 has also pledged to significantly increase aid to Africa in the coming years. Official development assistance, as measured by the Development Assistance Committee of the Organization for Economic Co-operation and Development, has been rising in real terms and as a share of the national income of donor countries in the past several years. The European Union, representing 25 countries, has pledged to increase its 2004 contribution by an additional US\$ 38 billion per year. The Development Assistance Committee further estimates that official development assistance could increase from US\$ 79.5 billion in 2004 to US\$ 128.1 billion in 2010, an increase of nearly US\$ 50 billion. This presents additional opportunities to help fund the global response to HIV/AIDS.
- A growing trend in development assistance is channelling aid to countries in the form of direct budget support and by new mechanisms such as the Millennium Challenge Corporation in the United States. Success in attracting more general aid funding for HIV/AIDS programmes lies in improving how HIV/AIDS programming is included in poverty reduction strategies, national plans and medium-term expenditure frameworks.

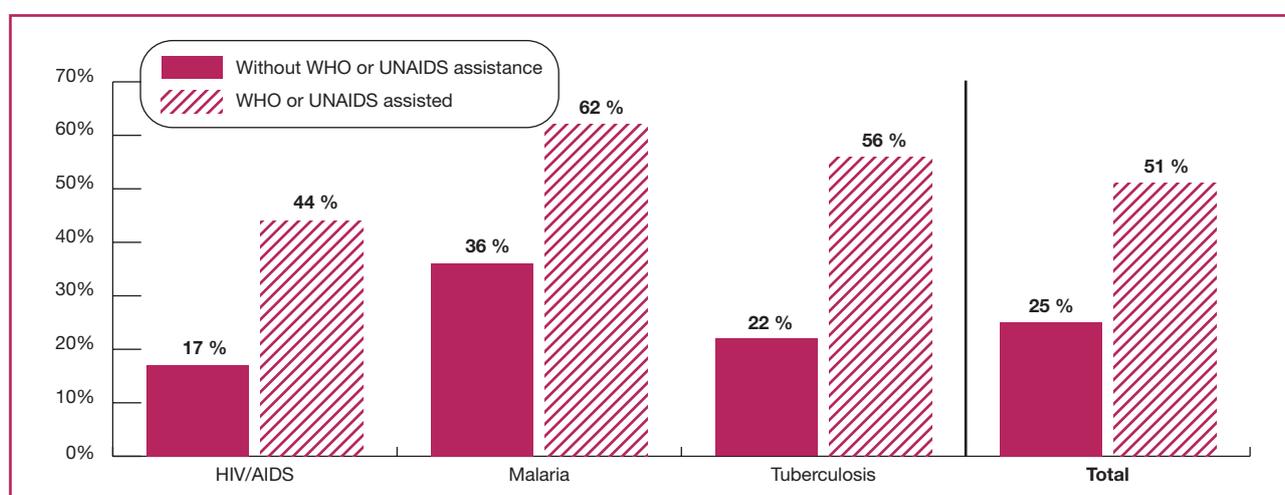
As donor countries continue to increase their financial commitments for health and development, contradictions remain between the higher levels of public spending required to meet the Millennium Development Goals and the amount of spending possible under the macroeconomic framework model favoured by the International Monetary Fund. This policy bottleneck needs to be urgently resolved so that countries have greater confidence in making the public-sector investment they need to scale up national HIV/AIDS efforts.

⁴⁷ If fully implemented, such a facility would borrow funds from the international capital markets based on an agreed stream of long-term donor payments in order to direct as much as US\$ 50 billion a year to development programmes in its first 10–15 years. See: Bryden D. *Call for a grand Anglo-French alliance to end the AIDS holocaust: launch the International Finance Facility (IFF) and the Airline Solidarity Contribution for urgent health and education programs*. Washington, DC, Global AIDS Alliance, 7 February 2006 (http://www.globalaidsalliance.org/Launch_IFF_Report.cfm, accessed 13 February 2006).

⁴⁸ Benin, Bolivia, Burkina Faso, Ethiopia, Ghana, Guyana, Honduras, Madagascar, Mali, Mauritania, Mozambique, Nicaragua, Niger, Rwanda, Senegal, Uganda, United Republic of Tanzania and Zambia.

More attention is also needed to ensure that the resources that are already available are used as quickly and efficiently as possible. Weaknesses in procurement and supply management systems, for example, have caused significant delays in releasing funds from the Global Fund; WHO and other agencies are providing technical assistance to unblock major funding in this area. WHO is also providing assistance to Global Fund principal recipients in developing plans for monitoring and evaluation of programmes, giving support to the Global Fund country coordinating mechanisms and acting as a sub-recipient for many grants. A recent analysis of 69 Global Fund proposals for HIV/AIDS, TB and malaria programmes showed that the proposals that received technical support from UNAIDS or WHO were more likely to be approved than those that did not (Fig. 10). More effective forecasting of technical support needs as a whole is needed, as is adequate funding for technical agencies to meet the growing demand for such support.

Fig. 10. Success rate of grant proposals to the Global Fund to Fight AIDS, Tuberculosis and Malaria in Round 4 with and without technical support from WHO or UNAIDS



Source: Global Fund to Fight AIDS, Tuberculosis and Malaria, WHO and UNAIDS

• *Drugs and other commodities*

Constraints in the procurement and supply of drugs and other commodities continue to present critical barriers to scaling up antiretroviral therapy and the health sector response to AIDS. Procurement and supply management systems are weak, inefficient or poorly managed in many countries, but the need to urgently invest resources in and increase technical assistance to strengthen these systems is only beginning to be acknowledged.

Some major challenges relating to supply security include the financing, pricing, production, procurement and supply of drugs and commodities.

The lack of secure funding for most national antiretroviral therapy programmes beyond 2008 remains a concern. Even if funding for procuring treatment can be assured, at country level there is difficulty guaranteeing the continuity of drug flows, especially at the end of procurement cycles (when forecasting underestimates drug needs) and grant cycles (when administrative procedures and approvals take more time than expected and grant funding might even disappear). At present, there are no flexible funding mechanisms or adequate buffer stocks to deal with the resulting drug stock-outs.

Compared with the cost of drugs for other diseases, the price of first-line antiretroviral drugs remains high, while the cost of second-line regimens remains prohibitive for most low- and middle-income countries. Treatment for children has received little attention so far, with high prices for the available formulations. Recent efforts to set reference prices for groups of countries – notably in Latin America, and by the William J. Clinton Foundation – offer potential to improve the predictability of demand and create a more stable market for drugs that are currently not widely available, such as second-line drugs or formulations for children. This should ultimately lead to the more rational use of antiretroviral drugs and lower prices (Box 19).

Forecasting demand at the global level is also critical to inform the production of antiretroviral drugs and their raw materials. A working group comprising WHO, UNAIDS, UNICEF, the Partnership for Supply Chain Management, Management Sciences for Health/Rapid Pharmaceutical Management Plus and John Snow Inc./Deliver has been established to produce global-level market forecasts. However, comprehensive data on which to base accurate forecasts are often not available or are incomplete due to poor supply chain monitoring at the country level. Improving the monitoring of commodity supply chains in the health sector is therefore very important. The new Partnership for Supply Chain Management, which was recently awarded a contract by the United States Agency for International Development to manage the commodity needs of the United States President's Emergency Plan for AIDS Relief, is expected to be a major contributor to this agenda.

Other significant challenges in commodity procurement for the near future include the need for rapid, reliable tests to diagnose HIV infection among children younger than 18 months. These are essential if children are to be ensured an opportunity for treatment. More and inexpensive antiretroviral formulations for children are also urgently needed. The antibiotic co-trimoxazole provides highly effective protection against common opportunistic infections in children and can postpone the need to initiate antiretroviral therapy. It needs to be made more widely available.

Preventive commodities and certain hard-to-get drugs for opportunistic infections and palliative care require greater attention, as do efforts to ensure that newly listed essential drugs for treating substance abuse (methadone and buprenorphine) are procured and supplied in countries.

Box 19. TRIPS flexibilities may be needed to guarantee drug-price competition

Patents have become one of the most hotly debated issues in essential medicines since the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced in 1995. This was followed by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health of 2001, which clarified that the Agreement contains flexibilities that allow countries to enable both the import and production of generic versions of antiretroviral drugs under patent to protect public health. This, in turn, provides a mechanism for increasing competition among pharmaceutical manufacturers, reducing drug prices and expanding access to antiretroviral therapy. But the public health impact of the TRIPS flexibilities will depend on how effectively countries implement and use them within their national systems.

Competitive pressure from generic manufacturers has been possible for two reasons: the TRIPS Agreement has no retroactive effect and thus allowed countries to retain in the public domain products for which a patent had not been filed before 1 January 1995. Many low- and middle-income countries had not introduced patent protection for certain essential products, including pharmaceuticals, prior to the TRIPS Agreement. Some low- and middle-income countries, such as India, had also opted to delay providing patent protection for pharmaceutical and agrochemical products until January 2005 by making use of a transitional period permitted under the TRIPS Agreement. This transitional period permitted manufacturers in India to produce generic versions of pharmaceutical products, including antiretroviral drugs, patented elsewhere. In addition, it allowed these companies to produce fixed-dose combinations of antiretroviral drugs, which are easier to administer and use in low- and middle-income countries, including some combinations that are not available from the brand-name companies. These generic versions of patented medicines have come to play an important part, alongside brand-name products, in the global supply of antiretroviral drugs.

This transition period ended on 31 January 2005, however, and all World Trade Organization members, except for the least-developed countries, are now obliged to provide patent protection for products. There is concern that the ability of companies to patent new pharmaceutical products on a near-global scale could inhibit further competition and prevent the price reductions needed to make antiretroviral therapy more widely available. There will soon be increased pressure for people living with HIV/AIDS to move onto second-line antiretroviral drug treatments once they develop resistance to first-line treatments. Second-line regimens are still out of reach for people in most low- and middle-income countries, as prices remain 6–12 times higher than those of first-line antiretroviral drugs. The use of TRIPS flexibilities to enable generic competition among second-line regimens could, therefore, be critical to the success of efforts to provide universal access to HIV treatment in the coming years. ➔

TRIPS flexibility has been little used, however. Low- and middle-income countries often lack the capacity to effectively administer policies governing intellectual property rights. They also lack information about the status of patents on essential medicines, which is needed to make use of the TRIPS flexibility. WHO and its AIDS Medicines and Diagnostics Service (AMDS) partners have recently been working to help to fill these gaps in capacity.

A number of countries have made use of the TRIPS flexibility, however, by granting compulsory licences or the government use of patents. Mozambique and Zambia granted compulsory licences in 2004 to enable the local production of antiretroviral drugs. In 2002, Zimbabwe declared a national emergency to allow for production or import of generic antiretroviral medicines. In 2003, Malaysia allowed the import of generic didanosine, zidovudine and the lamivudine + zidovudine combination, under government use. In 2004, Indonesia authorized government use of patents to enable the local production of nevirapine and lamivudine. Kenya and Malawi have also made use of the flexibility to procure HIV drugs for their populations.

- *Constraints in health systems, including human resources*

Scaling up treatment has highlighted critical weaknesses in health systems that need to be addressed, notably infrastructure and human resources.

Laboratory capacity remains a major weakness in many countries. Many countries have simplified the monitoring of people receiving antiretroviral therapy to quickly scale up programmes and to provide therapy for people urgently in need, but achieving universal access will require wider access to CD4 technology for initiating and monitoring treatment. Additional resources and expertise will also be needed to assure the quality of laboratory infrastructure over the long term.

Lack of human resource capacity, including management capacity, is an old problem in health systems in many low-income countries, a weakness highlighted by the scaling up of HIV treatment. Lack of trained personnel, poor capacity in educational systems and loss of trained health care providers to the private sector, to high-income countries and to the epidemic itself are all taking their toll. In sub-Saharan Africa, the general shortage of health workers is estimated to be about 1 million.

Various studies have documented rising mortality statistics among health care workers in the era of HIV, and the World Bank has estimated that a country with a 15% adult seroprevalence rate can expect to lose between 1.6% and 3.3% of its health care providers to AIDS annually.⁴⁹ In addition, fear of HIV infection, stress and burnout have been shown to cause outward migration from public health services in AIDS-affected communities. Although clear data for the migration of health care workers is not available, it is estimated that about 20 000 qualified African health workers are lost every year.

Several decades of debate and discussion at the global and country levels have failed to yield concrete plans to address this global health workforce crisis. In addition to the task-shifting necessary to make more use of trained, non-professional health workers in HIV/AIDS, additional measures are urgently needed to overcome the barriers to scaling up presented by weak human resources for health. These measures should include enlarging and improving the skills of the health workforce through recruitment and training schemes; retaining existing health workers in the public health system through managed migration, incentives and interventions; and protecting health workers from the impact of HIV – in their personal lives and at work – by providing them with access to prevention, treatment and care for HIV/AIDS.⁵⁰

⁴⁹ Dovlo D. Wastage in the health workforce: some perspectives from African countries. *Human Resources for Health*, 2005, 3:6.

⁵⁰ *The World Health Report 2006 – Working for health* will include a detailed overview of current challenges in human resources for health.

- *Ensuring equitable access*

Ensuring equitable access to treatment, prevention, care and support will be a particular challenge as the world works towards universal access, especially for women, children, those living outside major urban centres and marginalized groups such as men who have sex with men, injecting drug users and sex workers.⁵¹ Stigma and discrimination remain formidable barriers to access in many countries and more practical efforts to address them need to be made.

Monitoring and evaluating equity in access to services need to be given higher priority as programmes are scaled up. User charges for treatment and related health services, such as laboratory monitoring, remain a significant barrier to access, and funding mechanisms need to be reformed in many countries to enable the elimination of user fees for HIV treatment and care at the point of service delivery. Policies and interventions that empower women and girls and reduce domestic violence are also needed to ensure equitable access for women and girls. Implementation of a public health approach, including decentralization of services, is also a key strategy to enhance equity.

- *Monitoring, evaluation and research*

Systems to monitor the scaling up of antiretroviral therapy and other interventions are slowly improving. More countries are able to accurately track the number of people benefiting from treatment and other interventions and to break down the data by service delivery site, basic characteristics (such as sex) and treatment characteristics (such as type of regimen). Nevertheless, multiple reporting systems often operate in parallel in the same country.

Developing a standardized system that provides the basic information for managing programmes and monitoring progress towards goals is essential. Very few countries have a standardized treatment outcome monitoring system in place that reports on survival, health status and the quality of life of people receiving treatment. Monitoring drug toxicity will also become increasingly important the longer people stay on treatment. International organizations and countries have started working together to develop the basic principles of a monitoring system that can be built on paper-based and electronic records, and these efforts need to move ahead as quickly as possible.

Further to the recommendations of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors,⁵² technical agencies need to improve collaboration and coordination of technical support on monitoring and evaluation. The monitoring and evaluation of programmes by civil society also requires additional resourcing and support, and demand for technical support to assist in evaluating national plans and programmes is growing. In the medium term, much more attention needs to be paid to fundamental evaluation questions such as the impact on population health and health systems of scaling up HIV/AIDS interventions.⁵³

Countries themselves can do more to invest in monitoring and evaluation. For example, the Global Fund recognizes that national health information systems form the backbone of performance-based funding and suggests that between 5% and 10% of available programme resources be dedicated to strengthening these systems. Nevertheless, few countries take advantage of the opportunity to access resources specifically for this purpose.

Operational research and dissemination of best practice are critical to help keep up with changing developments in the field and to address programmatic challenges in scaling up. Both basic research and clinical research remain essential to expanding the repertoire of available approaches, including new technologies such as simplified drugs and diagnostics, vaccines and microbicides (Boxes 20 and 21).

⁵¹ For a detailed description of the equity challenges in scaling up antiretroviral therapy, see: World Health Organization and UNAIDS. *Guidance on ethics and equitable access to HIV treatment and care*. Geneva, World Health Organization, 2004 (http://www.who.int/ethics/en/ethics_equity_HIV_e.pdf, accessed 13 February 2006).

⁵² *Final report of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors*. Geneva, UNAIDS, 2005 (<http://www.theglobalfund.org/en/files/about/replenishment/GTT%20final%20report.pdf>, accessed 13 February 2006).

⁵³ Bennett S, Boerma T, Brugha R. Scaling up HIV/AIDS evaluation. *Lancet*, 2006, 376:79–82.

Box 20. Surveillance of HIV drug resistance moves ahead

Monitoring drug resistance will become increasingly important as more people begin and stay on treatment. In 2001, the Global HIV Drug Resistance Surveillance Network (HIVResNet), a global network of clinical, laboratory and epidemiology experts and organizations, was created to support WHO in developing and implementing a global HIV drug resistance strategy. The Network has developed a global, comprehensive HIV drug resistance strategy focusing on countries scaling up antiretroviral therapy. The strategy is designed to implement and coordinate HIV drug resistance prevention, surveillance, monitoring, analysis and information dissemination activities and to produce evidence-based public health recommendations and action that enhance efforts to scale up antiretroviral therapy. It features an essential package of HIV drug resistance elements to complement the scaling up and monitoring of antiretroviral therapy in countries through the following activities:

- forming a national HIV drug resistance working group within the health ministry to develop and implement a national strategy for preventing and evaluating HIV drug resistance;
- conducting surveillance of transmitted HIV drug resistance and monitoring HIV drug resistance emerging in treatment;
- developing a national database to hold and analyse HIV drug resistance data;
- implementing a data analysis and evaluation plan for systematic population-based assessments of the transmission of HIV drug resistance; and
- making evidence-based recommendations to policy-makers and the planners of antiretroviral therapy regimens and programmes.

By December 2005, HIV drug resistance surveillance and monitoring using WHO methods was being planned or implemented in more than 20 countries in Asia, Africa, Latin America, the Eastern Mediterranean, East Asia and eastern Europe. A WHO national database application was developed, including HIV drug resistance monitoring and surveillance modules and a linked module to hold HIV drug resistance genotyping data. A regional and central coordinating database application was planned; analyses will help to guide decision-making on the population-based efficacy of antiretroviral therapy regimens and information relevant for preventing HIV using microbicides, prophylactic regimens and vaccines. WHO HIVResLab, a criteria-based HIV drug resistance genotyping network of national, regional and specialist laboratories, was formed to provide quality-assured laboratory results for HIV drug resistance surveillance and monitoring. WHO and its HIVResNet partners continue to provide technical assistance, training, and operational documents to assist countries in HIV drug resistance prevention, surveillance and monitoring.

Box 21. Facilitating operational research: generic tools on adherence, equitable access, costs and links between treatment and prevention

Learning by doing requires that public health strategies to scale up treatment and prevention be continuously reviewed, evaluated and revised and that best practices be promoted. One of the main stumbling blocks to implementing operational research on HIV treatment and prevention is the lack of tools to collect and analyze data. To facilitate countries' efforts in this area and foster comparative analyses, WHO has initiated a process to define the essential information needed and to produce a set of tools to collect it.

The notion of generic tools refers to standardized approaches to collecting and analysing data; it covers the entire process from the development of data collection instruments to adaptation, training and support. Tools combine quantitative and qualitative items and include core and country-specific sections. They build on existing country information systems and collect data mainly by surveying the general population, vulnerable groups, service users, health care personnel and people living with HIV/AIDS and by conducting health facility surveys.

Generic tools are developed around issues that have been identified as priorities across settings. Work has been initiated on a first set of priority issues: 

- adherence, with emphasis on simple measures of adherence and ways to investigate its determinants;
- equitable access: measuring the access to and use of essential care, treatment and prevention services both at health facilities and through population-level household surveys;
- links between treatment and prevention: specifically, whether risk perceptions and behaviour change when people have access to antiretroviral therapy and the extent to which treatment and prevention services are integrated; and
- costing of HIV treatment and prevention services: which information on the use and cost of HIV therapeutic, laboratory, and preventive services needs to be regularly collected and aggregated to measure the costs of scaling up at the facility and national levels.

Draft instruments are currently being produced. They will be revised based on field tests in selected countries. Guidance documents will be produced to help countries adapt and use the tools, and a process of exchanges between low- and medium-income countries will be put in place to facilitate comparisons and foster collaboration.

2. Moving the agenda forward

In the first quarter of 2006, UNAIDS is facilitating the development of nationally agreed road maps towards universal access to HIV/AIDS prevention, treatment, care and support. The road maps will include country-specific targets to be achieved by 2010 as well as interim process targets to measure progress. By early February 2006, some 30 countries had convened inclusive national consultations on universal access, and nearly 100 other countries had initiated such a process. In addition to promoting country ownership in planning and setting priorities, the process aims to ensure the alignment of external support around country priorities as stressed by the Global Task Team recommendations.⁵⁴

These road maps will build on existing country-level efforts to accelerate the national AIDS response and national development within the harmonization and alignment principles embodied by the “three ones” concept and spelled out in international resolutions on the effective use of development aid such as the Monterrey Consensus of the International Conference on Financing for Development (2002)⁵⁵ and the Paris Declaration on Aid Effectiveness of the High Level Forum on Joint Progress toward Enhanced Aid Effectiveness (Harmonisation, Alignment, and Results).⁵⁶ Targets for scaling up and implementation frameworks for 2010 should be based on existing national development plans (such as poverty reduction strategies) and national HIV/AIDS plans, utilizing where possible the existing processes to review and update these plans. Critical to country-level work will be the input of a broad range of stakeholders, including ministries, the private sector, faith-based organizations, civil society, networks of people living with HIV/AIDS and bilateral and multilateral partners. Ideally, existing national partnership forums and joint reviews of national AIDS plans will be mobilized. Ongoing efforts by countries to collect and analyse data for their 2005–2006 progress reports on the 2001 Declaration of Commitment on HIV/AIDS of the United Nations General Assembly will also provide valuable information for target-setting and the development of implementation plans.

In addition to stimulating broad public debate at the country level, this process relies heavily on subregional groups facilitating and identifying common obstacles to universal access faced by their member countries. To the extent possible, these will involve forums already playing a leadership role in the HIV/AIDS response. A process of regional consultations will consolidate the road maps developed at the country level into regional reports.

A multi-partner Global Steering Committee on Universal Access, coordinated by UNAIDS, is overseeing this process and will consolidate country and regional reports to develop recommendations for consideration by the United Nations General Assembly High-Level AIDS Review in May 2006. The Global Steering Committee’s recommendations will reflect the shared accountability of all countries to scale up prevention, treatment, care and support services to come as close as possible to universal access by 2010.

⁵⁴ *Final report of the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors.* Geneva, UNAIDS, 2005 (<http://www.theglobalfund.org/en/files/about/replenishment/GTT%20final%20report.pdf>, accessed 13 February 2006).

⁵⁵ *Item 11 of the provisional agenda. Adoption of the Monterrey Consensus. Final outcome of the International Conference on Financing for Development.* New York, United Nations, 2002 (<http://www.un.org/esa/ffd/0302finalMonterreyConsensus.pdf>, accessed 13 February 2006).

⁵⁶ *Paris Declaration on Aid Effectiveness: Ownership, Harmonisation, Alignment, Results and Mutual Accountability.* Paris, Organisation for Economic Co-operation and Development, 2005 (http://www.oecd.org/document/43/0,2340,en_2649_3236398_34430443_1_1_1_1,00.html, accessed 13 February 2006).

3. Supporting the health sector response

In October 2005, WHO held a technical meeting to ensure that countries have the necessary guidance and technical support to implement an appropriate package of health sector interventions to achieve universal access by 2010.⁵⁷ The aims of the meeting were to develop a common understanding of the definition of universal access and its implications for sustained scale-up of HIV/AIDS services in the health sector and to review a proposed technical framework for HIV prevention, care, treatment and support. The framework that results from the meeting and further consultations will form the basis of WHO's technical and strategic recommendations for universal access that will be made available to the Fifty-ninth World Health Assembly in May 2006.

Although WHO will continue to focus on scaling up antiretroviral therapy and providing guidance to assist countries in meeting current treatment targets, universal access will require a comprehensive health sector response that includes prevention, treatment, care and support while contributing to the broader strengthening of health systems. WHO's contribution to realizing the goal of universal access will therefore be based on five strategic directions and a limited set of priority interventions in the health sector that are currently being developed (Table 5). These strategic directions will focus on areas where WHO has a clear mandate and comparative advantage and will be consistent with the division of labour agreed to by UNAIDS Cosponsors. The selection of priority interventions will be based on sound evidence of their ability to significantly influence the HIV/AIDS epidemic. Both the strategic directions and the priority interventions will also be consistent with the Global Health Sector Strategy for HIV/AIDS 2002–2007⁵⁸ and aim to build on the momentum generated by the “3 by 5” target. In addition, they will recognize that approaches need to be flexible and responsive to different epidemiological contexts.

Table 5. WHO strategic directions and priority interventions for universal access (under development)

Strategic direction	Priority interventions
Enabling people to know their HIV status through HIV testing and counselling	<ul style="list-style-type: none"> • Voluntary testing and counselling • Provider-initiated testing and counselling
Accelerating the scale-up of treatment and care	<ul style="list-style-type: none"> • Antiretroviral therapy • Prevention and management of opportunistic infections • Care including nutrition, palliative care and end-of-life care • Prevention for persons living with HIV/AIDS • TB/HIV
Maximizing the health sector's contribution to HIV prevention	<ul style="list-style-type: none"> • Prevention of mother to child transmission (PMTCT) • Prevention of sexual transmission • Prevention of HIV transmission through injecting drug use (harm reduction) • Prevention of HIV transmission in the health care setting • Research on new prevention technology
Investing in strategic information to guide a more effective response	<ul style="list-style-type: none"> • Epidemiology and surveillance of HIV/AIDS and STIs • HIV drug resistance transmission surveillance and monitoring in ART programmes • Monitoring and evaluation of the health sector's progress towards universal access • Operational research
Strengthening and expanding health systems	<ul style="list-style-type: none"> • National strategic planning and management • Procurement and supply management • Laboratory strengthening • Human resource management • Strategies for sustainable financing

⁵⁷ *Proceedings of a Technical Meeting for the Development of an Essential Package for Universal Access to HIV/AIDS Prevention, Care, Treatment and Support to the Health Sector, Geneva, 18–20 October 2005.* Geneva, World Health Organization, 2005 (http://www.who.int/hiv/universalaccess2010/concept_Dec05.pdf, accessed 13 February 2006).

⁵⁸ *Global Health Sector Strategy for HIV/AIDS 2002–2007: providing a framework for partnership and action.* Geneva, World Health Organization, 2002 (<http://www.who.int/hiv/pub/advocacy/ghss/en/index.html>, accessed 13 February 2006).

For each of the five strategic directions, WHO will:

- advocate for action and mobilize partnerships;
- support operational research and disseminate the evidence base on the effectiveness of each intervention and models of good practice for service delivery;
- articulate global and regional policy options;
- set norms and standards and develop, update and adapt assessment, policy, programmes, training as well as monitoring and evaluation tools and guidelines for their implementation;
- provide technical support to countries and build sustainable institutional capacity to scale up national HIV/AIDS responses;
- monitor and evaluate the implementation of the interventions, including assisting countries in selecting indicators and setting targets; and
- ensure that adequate attention is paid to gender and equity in designing and delivering the interventions.

Strong and responsive country offices will be the key mechanism by which WHO will continue to support countries. Collaboration will also be strengthened with key partners, investment will be made in local and regional capacity-building for institutions and technical networks and engagement will be ensured with stakeholders (including civil society, organizations of people living with HIV/AIDS and the private sector) and coordinating bodies such as national AIDS commissions, country coordinating mechanisms and United Nations theme groups on HIV/AIDS.



Conclusion

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. Although the target has not been met, 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 to HIV/AIDS prevention, treatment and care by 2010.

The experiences outlined in this report demonstrate that large-scale HIV treatment access is achievable, effective and increasingly affordable, even in the most resource-constrained and challenging settings. As the increased access to treatment transforms HIV infection into a chronic condition, maintaining people on treatment and supporting efforts to strengthen chronic disease management will be critical.

With the hope and reality of treatment, millions of people now have a growing incentive to be tested, opening new opportunities for effective HIV prevention. At the same time, the effort to rapidly scale up treatment and prevention programmes has highlighted some basic realities. Maintaining advances in the HIV/AIDS response and achieving the Millennium Development Goals in the next decade highlight the pressing need to strengthen health systems and to overcome the serious resource constraints many countries face.

In most high-prevalence countries, the number of people needing treatment still exceeds the capacity to provide it. The following key actions must therefore be urgently undertaken to continue and increase momentum in scaling up treatment.

- **Enhance funding.** Sustainable and predictable funding must be guaranteed to ensure the continuity of services. Current funding options under discussion must be implemented, including securing these funds through increased donor and domestic funding; innovative donor financing mechanisms such as the International Finance Facility; the Airline Solidarity Contribution; the proceeds from international debt relief; and the launch of a sixth round of the Global Fund with sufficient resources.
- **Enhance equity.** Treatment access must be accelerated in both urban and rural settings, with the commensurate need to guarantee the availability and affordability of first- and second-line antiretroviral drugs, including formulations for children. Barriers to access for women must be addressed.
- **Maximize programme links.** Links between HIV treatment programmes, TB, mother-to-child transmission, sexual and reproductive health, malaria and other health care entry points need to be strengthened.
- **Expand testing and counselling.** Testing and counselling must be rapidly expanded to ensure that individuals know their status and can access prevention, treatment, care and support.
- **Maximize prevention.** Prevention must be maximized through several key interventions, many of them in the health sector. These include robust prevention programmes targeting people living with HIV/AIDS, prevention in the health care setting (such as preventing mother-to-child transmission, blood safety and protecting and treating health care workers), controlling sexually transmitted infections and programmes to address the needs of populations at high risk, such as partners of people living with HIV/AIDS, commercial sex workers, injecting drug users and men who have sex with men.

- **Strengthen the health sector.** Enhanced efforts must be made to strengthen the health sector's ability to deliver treatment and prevention. Necessary steps include:
 - renewing efforts to broaden the numbers and skills of health care workers, improve management and planning skills, strengthen supply chain management systems and expand laboratory capacity;
 - increasing national donor and stakeholder coordination consistent with the “three ones” principles;
 - increasing mobilization and management of strong partnerships across the state and non-state sectors; and
 - expanding the involvement of people living with HIV/AIDS in planning and delivering programmes.
- **Improve information systems.** Strategic information systems capable of gathering epidemiological data on the epidemic, monitoring and evaluating the outcomes of prevention and treatment programmes, determining who is accessing treatment and detecting drug resistance and toxicity are urgently needed.
- **Confront budget constraints.** The reality of budget constraints on technical support agencies must also be addressed. Over the past several decades, countries have repeatedly relied on WHO technical guidance and support in launching and managing large-scale public health programmes. WHO, UNAIDS and other United Nations agencies have also increasingly utilized their own core budgets to provide technical support for countries applying for Global Fund grants. The rapid expansion of Global Fund grants and capitalization strains the capacity of WHO and other technical agencies to provide the support that countries need.

The target of placing 3 million people on antiretroviral therapy has tested the capability of the international community and has brought the world face-to-face with the gaps and inequities in global health. The gap between those who need treatment and those who receive it is still large and will grow as more people living with HIV become ill. The number of people vulnerable to HIV infection also continues to grow, and prevention efforts must increase dramatically if the future burden of disease and need for treatment are to be reduced.

This report is both cause for sober reflection and a call for increased action. Although much has been accomplished, much more remains to be done to address the complex behavioural, medical, social, economic and political challenge presented by the global HIV/AIDS epidemic. Achieving the Millennium Development Goals, and with them a large part of the vision for a world that is just, stable, healthy and secure, depends on whether or not we rise to meet this challenge.

Annex 1. Estimated number of people receiving antiretroviral therapy, people needing antiretroviral therapy, percentage coverage and numbers of antiretroviral therapy sites in low- and middle-income countries^a

Country	WHO region ^b	Estimated number of people 0–49 years old needing antiretroviral therapy, 2005 ^c	Reported number of people receiving antiretroviral therapy, January–December 2005 ^d	Month of report ^e	Average monthly increase in the number of people receiving antiretroviral therapy, January–December 2005 ^f	Estimated number of people receiving antiretroviral therapy, December 2005 ^g		Antiretroviral therapy coverage, December 2005 ^g	Reported number of sites that are providing antiretroviral therapy, September–December 2005 ^h
						Low estimate	High estimate		
Afghanistan	EMR	<1 000	0	Dec	0%	...
Albania	EUR	...	50	Dec	1	<200	<200	...	1
Algeria	AFR	1 000	400	Sep	8	<500	<500	39%	...
Angola	AFR	52 000	2 700	Sep	0	2 500	3 500	6%	6
Antigua and Barbuda	AMR	...	40	Aug	0	<200	<200
Argentina	AMR	37 000	30 127	Aug	0	27 000	33 000	81%	396
Armenia	EUR	<200	29	Dec	2	<200	<200	15%	1
Azerbaijan	EUR	<200	0	Feb	0	0	0	0%	0
Bangladesh	SEAR	<1 000	5	<05	...	<200	<200	1%	...
Barbados	AMR	<1 000	522	Aug	15	<1 000	<1 000	95%	...
Belarus	EUR	2 500	120	Dec	6	<200	<200	5%	22
Belize	AMR	<1 000	180	Dec	1	<200	<200	31%	8
Benin	AFR	14 000	4 022	Sep	217	3 500	6 000	33%	...
Bhutan	SEAR	<200	5	<05	...	<200	<200
Bolivia	AMR	<1 000	260	Aug	10	<500	<500	37%	...
Bosnia and Herzegovina	EUR	...	22	May	1	<200	<200	...	4
Botswana	AFR	84 000	55 829	Sep	2 915	67 000 ⁱ	77 000 ⁱ	85%	32
Brazil	AMR	209 000	170 000	Oct	2 000	165 000	183 000	83%	>900
Bulgaria	EUR	...	154	Jan	3	<200	<200
Burkina Faso	AFR	34 000	8 214	Dec	387	7 500	9 000	24%	44

Country	WHO region ^b	Estimated number of people 0–49 years old needing antiretroviral therapy, 2005 ^c	Reported number of people receiving antiretroviral therapy, January–December 2005 ^d	Month of report ^e	Average monthly increase in the number of people receiving antiretroviral therapy, January–December 2005 ^f	Estimated number of people receiving antiretroviral therapy, December 2005 ^g		Antiretroviral therapy coverage, December 2005 ^g	Reported number of sites that are providing antiretroviral therapy, September–December 2005 ^h
						Low estimate	High estimate		
Burundi	AFR	46 000	6 416	Dec	299	6 000	7 000	14%	25
Cambodia	WPR	35 000	12 396	Dec	654	12 000	13 000	36%	32
Cameroon	AFR	108 000	17 940	Jun	980	21 000	26 000	22%	89
Cape Verde	AFR	...	200	Sep	5	<500	<500
Central African Republic	AFR	49 000	1 647	Dec	120	1 500	2 000	3%	23
Chad	AFR	38 000	5 000	Sep	522	5 000	8 000	17%	...
Chile	AMR	9 300	6 964	Dec	376	6 500	7 500	75%	31
China	WPR	78 000	15 500	Jun	547	18 000	20 000	25%	>157
Colombia	AMR	30 000	12 000	Dec	0	11 000	15 000	44%	...
Comoros	AFR	...	200	<05	...	<500	<500
Congo	AFR	18 000	2 550	Sep	139	2 000	3 500	17%	...
Cook Islands	WPR
Costa Rica	AMR	3 400	2 564	Jul	154	2 500	3 000	80%	...
Côte d'Ivoire	AFR	111 000	17 600	Nov	933	18 000	19 000	17%	79
Croatia	EUR	...	226	May	3	<500	<500	...	1
Cuba	AMR	1 500	1 963	Aug	29	2 000	2 500	100%	...
Czech Republic	EUR	...	322	Dec	3	<500	<500	...	7
Democratic People's Republic of Korea	SEAR	<1 000	0%	...
Democratic Republic of the Congo	AFR	209 000	6 695	Sep	342	7 000	8 500	4%	70
Djibouti	EMR	2 000	350	Dec	12	<500	<500	16%	8
Dominica	AMR	...	17	Aug	1	<200	<200
Dominican Republic	AMR	15 000	2 582	Dec	134	2 500	3 000	17%	...
Ecuador	AMR	4 200	1 508	Aug	64	1 500	2 000	42%	...
Egypt	EMR	2 000	200	Oct	9	<500	<500	12%	1
El Salvador	AMR	4 900	2 681	Sep	64	2 500	3 000	59%	18
Equatorial Guinea	AFR	4 200	5	Jun	...	<200	<200	0%	...
Eritrea	AFR	11 000	500	Sep	21	<1 000	<1 000	5%	...
Estonia	EUR	1 000	174	Mar	3	<200	<200	17%	5
Ethiopia	AFR	278 000	20 477	Dec	680	19 000	22 000	7%	73
Fiji	WPR
Gabon	AFR	8 650	2 000	Oct	...	2 000	2 500	23%	...
Gambia	AFR	1 500	150	<05	...	<200	<200	10%	...
Georgia	EUR	<500	140	Dec	5	<200	<200	49%	2
Ghana	AFR	61 000	3 584	Sep	248	4 000	5 000	7%	5
Guatemala	AMR	13 000	5 513	Nov	119	5 500	6 000	43%	7

Guinea	AFR	23 000	1 774	Sep	109	2 000	2 500	9%	8
Guinea-Bissau	AFR	4 800	62	Dec	20	<200	<200	1%	...
Guyana	AMR	2 500	1 200	Dec	111	1 000	1 500	50%	8
Haiti	AMR	34 000	5 572	Aug	331	6 500	7 000	20%	18
Honduras	AMR	12 000	4 305	Dec	176	4 000	4 500	35%	20
Hungary	EUR	...	371	Jan	6	<500	<500	...	1
India	SEAR	785 000	12 000 ^l	Aug	2 972	36 000 ^l	67 000 ^l	7%	74
Indonesia	SEAR	12 000	3 301	Sep	73	3 000	4 000	30%	61
Iran, Islamic Republic of	EMR	4 250	400	May	...	<500	<500	9%	...
Iraq	EMR	<200	75	Dec	6	<200	<200
Jamaica	AMR	2 600	1 348	Aug	27	1 500	1 500	56%	...
Jordan	EMR	<200	45	Dec	1	<200	<200	45%	...
Kazakhstan	EUR	1 500	240	Dec	7	<500	<500	15%	5
Kenya	AFR	273 000	55 000 ^k	Nov	2 773	60 000 ^k	72 000 ^k	24%	250
Kiribati	WPR
Kyrgyzstan	EUR	<500	46	Dec	3	<200	<200	12%	1
Lao People's Democratic Republic	WPR	<500	104	<05	...	<200	<200	49%	...
Latvia	EUR	<1 000	233	Jan	3	<500	<500	31%	1
Lebanon	EMR	<1 000	200	Dec	...	<500	<500	36%	...
Lesotho	AFR	58 000	8 400	Dec	369	7 500	9 000	14%	22
Liberia	AFR	15 000	397	Sep	...	<500	<500	3%	...
Libyan Arab Jamahiriya	EMR	1 500	450	Dec	10	<1 000	<1 000	35%	...
Lithuania	EUR	<200	58	Mar	3	<200	<200	64%	6
Madagascar	AFR	20 000	54	Dec	4	<200	<200	0%	...
Malawi	AFR	169 000	32 214	Dec	1 888	31 000	35 000	20%	60
Malaysia	WPR	10 000	2 700	<05	...	2 500	3 000	27%	...
Maldives	SEAR	<200	0	<05	...	0	0	0%	...
Mali	AFR	22 000	6 000	Sep	346	5 500	9 000	32%	...
Marshall Islands	WPR	0
Mauritania	AFR	1 500	400	Sep	33	<500	<500	40%	...
Mauritius	AFR	...	120	Sep	0	<200	<200
Mexico	AMR	43 000	30 000	Aug	156	28 000	34 000	71%	...
Micronesia, Federated States of	WPR
Mongolia	WPR	<200	0%	...
Morocco	EMR	2 000	880	Dec	69	<1 000	<1 000	48%	...
Mozambique	AFR	216 000	17 554	Oct	1 150	19 000	21 000	9%	32
Myanmar	SEAR	50 000	3 500	Dec	167	2 500	4 500	7%	...
Namibia	AFR	41 000	17 000 ^l	Jun	1 700	27 000 ^l	31 000 ^l	71%	29
Nauru	WPR
Nepal	SEAR	8 950	75	<05	...	<200	<200	1%	...

Country	WHO region ^b	Estimated number of people 0–49 years old needing antiretroviral therapy, 2005 ^c	Reported number of people receiving antiretroviral therapy, January–December 2005 ^d	Month of report ^e	Average monthly increase in the number of people receiving antiretroviral therapy, January–December 2005 ^f	Estimated number of people receiving antiretroviral therapy, December 2005 ^g		Antiretroviral therapy coverage, December 2005 ^g	Reported number of sites that are providing antiretroviral therapy, September–December 2005 ^h
						Low estimate	High estimate		
Nicaragua	AMR	1 000	163	Dec	1	<200	<200	16%	6
Niger	AFR	12 000	609	Dec	...	<1 000	<1 000	5%	...
Nigeria	AFR	636 000	31 694	Sep	1 510	37 000 ^m	45 000 ^m	7%	71
Niue	WPR
Oman	EMR	<500	225	Dec	4	<500	<500
Pakistan	EMR	8 450	132	Dec	...	<200	<200	2%	10
Palau	WPR
Panama	AMR	3 150	2 708	Aug	94	3 000	3 000	97%	2
Papua New Guinea	WPR	2 000	320	Dec	21	<500	<500	15%	4
Paraguay	AMR	2 000	640	Dec	17	<1 000	<1 000	29%	2
Peru	AMR	12 000	6 410	Dec	243	6 000	7 000	52%	50
Philippines	WPR	1 500	71	<05	...	<200	<200	5%	...
Poland	EUR	2 500	2 407	Jul	60	2 500	3 000	100%	12
Republic of Moldova	EUR	<1 000	222	Dec	10	<500	<500	39%	2
Romania	EUR	...	6 116	Dec	8	5 500	6 500	...	53
Russian Federation	EUR	99 000	5 000	Dec	142	4 500	5 500	5%	68
Rwanda	AFR	49 000	15 975	Sep	938	18 000	20 000	39%	76
Saint Kitts and Nevis	AMR	...	28	Aug	1	<200	<200
Saint Lucia	AMR	...	42	Aug	2	<200	<200
Saint Vincent and the Grenadines	AMR	...	56	Aug	2	<200	<200
Samoa	WPR
Sao Tome and Principe	AFR	...	17	Mar	...	<200	<200
Saudi Arabia	EMR	<1 000	100	<05	...	<200	<200	14%	...
Senegal	AFR	9 000	4 200	Dec	193	3 000	5 500	47%	32
Serbia and Montenegro	EUR	...	470	Jan	10	<500	<500	...	17
Seychelles	AFR	...	43	Sep	0	<200	<200
Sierra Leone	AFR	9 600	210	Jan	0	<500	<500	2%	...
Slovakia	EUR	...	65	Dec	0	<200	<200	...	23
Solomon Islands	WPR	0
Somalia	EMR	6 000	35	Dec	1%	1

South Africa	AFR	983 000	98 688	Oct	9 015	178 000 ⁿ	235 000 ⁿ	21%	183
Sri Lanka	SEAR	<500	25	<05	<200	6%	...
Sudan	EMR	62 000	400	<05	<500	1%	2
Suriname	AMR	<1 000	351	Aug	10	...	<500	55%	...
Swaziland	AFR	42 000	13 006	Dec	451	12 000	14 000	31%	17
Syrian Arab Republic	EMR	<1 000	60	Dec	<200	9%	...
Tajikistan	EUR	<200	5	Dec	<200	16%	1
Thailand	SEAR	135 000	61 000 ^o	Aug	1 227	72 000 ^o	91 000 ^o	60%	>800
The former Yugoslav Republic of Macedonia	EUR	...	7	Dec	1	...	<200	...	1
Togo	AFR	25 000	5 600	Sep	315	5 000	8 000	27%	...
Tonga	WPR
Trinidad and Tobago	AMR	4 500	1 700	Nov	0	1 500	2 000	38%	7
Tunisia	EMR	<1 000	229	Oct	<500	34%	...
Turkey	EUR	3 900	300	Jan	4	...	<500	9%	...
Turkmenistan	EUR	<200	0	Dec	0	...	0	0%	0
Tuvalu	WPR
Uganda	AFR	148 000	67 369	Sep	2 500	71 000	79 000	51%	175
Ukraine	EUR	53 000	3 022	Oct	214	3 000	4 000	7%	28
United Republic of Tanzania	AFR	315 000	19 600	Nov	1 943	20 000	23 000	7%	96
Uruguay	AMR	2 000	1 417	Jul	2	1 500	2 500	69%	24
Uzbekistan	EUR	1 000	0	Dec	0	...	0	0%	0
Vanuatu	WPR
Venezuela, Bolivarian Republic of	AMR	18 000	15 417	Dec	327	14 000	17 000	84%	60
Viet Nam	WPR	25 000	3 000 ^p	Dec	222	3 000 ^p	3 500 ^p	12%	74
Yemen	EMR	1 000	0	Dec	0%	...
Zambia	AFR	183 000	43 964 ^q	Nov	2 621	45 000 ^q	52 000 ^q	27%	>110
Zimbabwe	AFR	321 000	23 000	Nov	1 500	22 000	27 000	8%	48

... Data not available or not applicable.

^a All countries except those in western Europe and Australia, Bahamas, Bahrain, Brunei, Canada, Cyprus, Grenada, Israel, Japan, Kuwait, New Zealand, Qatar, Republic of Korea, Singapore, United Arab Emirates and United States of America.

^b This table includes 152 WHO Member States. AFR: WHO African Region ($n = 46$); AMR: WHO Region of the Americas ($n = 31$); EMR: WHO Eastern Mediterranean Region ($n = 17$); EUR: WHO European Region ($n = 27$); SEAR: WHO South-East Asia Region ($n = 10$); WPR: WHO Western Pacific Region ($n = 21$).

^c The needs estimates are based on the methods described in Annex 2. The estimates for individual countries may differ according to the local methods used.

^d An increasing number of countries report the number of children younger than 15 years of age receiving antiretroviral therapy, and they have been included in this table.

^e <05 means that data exist but no update has been received since December 2004. These data should be interpreted cautiously, as they may reflect the situation in early 2004 or even 2003.

^f The monthly increase in the number of people receiving antiretroviral therapy during, in most cases, the last six months of 2005, is calculated using two recent data points in 2005 with the longest period between them and applying a linear projection for each month up to December 2005. Except for India and Kenya, the calculated monthly growth rate only applies to the growth in the public sector.

^g The coverage estimate is based on the estimated number of people receiving antiretroviral therapy and the estimated need for antiretroviral therapy.

^h The reported sites reflect mainly the situation in the public sector. See also paragraph 1.3: Expansion of treatment sites.

ⁱ Includes a private-sector estimate of 7000. The national health authorities reported a number of almost 56 000 for the public sector in September 2005.

^j The government reported that 12 000 people were receiving antiretroviral therapy through the public sector by August 2005. About 10 000 people were treated in 40 sites in the private sector. A further 15 000 to 20 000 people were treated in the unorganized private sector. Overall, an estimated 52 000 people were receiving antiretroviral therapy by the end of 2005, including people enrolled through private facilities.

^k A public-sector estimate of almost 55 000 people receiving antiretroviral therapy is based on numbers reported by the Ministry of Health, nongovernmental organizations and mission facilities receiving direct or indirect support from the United States Government (as of November 2005). The estimated number of over 8000 people receiving treatment from private facilities is based on consultant reviews and reports from the Kenyan Business Council. This estimate was made in late 2003 or early 2004 and has not been re-estimated, as it is assumed that the number of people entering care in the private sector equals the number shifting to public-sector providers of antiretroviral therapy.

^l The Ministry of Health and Social Services in Namibia estimated that 17 000 people were receiving antiretroviral therapy through public facilities by the end of June 2005. An estimated 2000 people were provided with antiretroviral therapy through the private sector in 2005.

^m Includes a private-sector estimate of 5000.

ⁿ Includes a private-sector estimate of 90 000. The national health authorities reported a number of 98 688 for the public sector in October 2005.

^o The Ministry of Health in Thailand estimates that the number of people receiving antiretroviral therapy through private facilities is 25% of those enrolled through the public sector.

^p The figure is based on the quantity of antiretroviral drugs distributed to provinces; a patient monitoring system to track the number of people on antiretroviral therapy is currently being developed.

^q The Central Board of Health of Zambia reported that 43 964 people were receiving antiretroviral therapy through the public sector in November 2005. An additional 2000 people were estimated to be receiving antiretroviral therapy through private facilities.

Annex 2.

Data by WHO region and methods used in estimating the number of people receiving and needing antiretroviral therapy

Estimated number of people receiving antiretroviral therapy, people needing antiretroviral therapy and percentage coverage in low- and middle-income countries according to WHO region, December 2005^a

WHO region	Estimated number of people receiving antiretroviral therapy, December 2005 [low estimate–high estimate] ^b	Estimated number of people 0–49 years old needing antiretroviral therapy, 2005 ^a	Antiretroviral therapy coverage, December 2005 ^c
African Region	810 000 [730 000–890 000]	4 700 000	17%
Region of the Americas	315 000 [295 000–335 000]	465 000	68%
European Region	21 000 [20 000–22 000]	160 000	13%
Eastern Mediterranean Region	4 000 [3 000–5 000]	75 000	5%
South-East Asia Region	140 000 [115 000–165 000]	970 000	14%
Western Pacific Region	40 000 [35 000–40 000]	150 000	27%
Total	1 330 000 [1 200 000–1 460 000]	6.5 million	20%

Note: the numbers do not add up due to rounding.

^a See below for explanation of the methods used.

^b Data on children are included.

^c The coverage estimate is based on the estimated number of people receiving antiretroviral therapy and need for antiretroviral therapy.

Estimating the number of people receiving antiretroviral therapy

The methods for estimating the number of people receiving treatment, treatment need and coverage have been described elsewhere.⁵⁹ In this report, the same method was used except that WHO now solicited updates for all countries.

In brief, the current estimate of the number of people receiving antiretroviral therapy is based on the most recent report received from either the health ministry, the WHO or UNAIDS office in the country or another reliable source in the country. The estimated numbers involve some uncertainty for countries that have not yet established systems for regular reporting of numbers of new people receiving treatment, adherence rates, defaulters, people lost to follow-up and deaths. One particular source of uncertainty is that country-reported figures often do not distinguish between those who have ever started antiretroviral therapy and those who are still receiving treatment (continuing to pick up their medicines). The difference between the two numbers reflects losses due to discontinuation of treatment or death.

Another source of uncertainty is the difficulty in measuring the extent of treatment provision in the non-state sector. Many people are supplied with medicines through local pharmacies and private clinics that do not report through the usual channels. Private companies may have programmes that support treatment for workers with advanced HIV disease, but in some cases data are not easily accessible.

A third source of uncertainty arises from the time lag between global reporting, which is for December 2005, and country reporting, which usually relates to an earlier point in time. Given the current rapid expansion in numbers in many countries, monthly increases must be estimated and projected to December 2005. Thus, the end-of-the-year estimates are based on simple linear projections of reported numbers using the current trend as an indicator of growth. For most countries, this projection of the past trend was only needed for 1–2 months, as countries provided updates for October or later.

Because of the uncertainty involved in making the overall estimates by country, the table indicates uncertainty ranges for the December 2005 estimate of the number of people receiving treatment. For the country-reported data, public sector only or public and private sector combined, 5–25% uncertainty ranges have been used depending on the strength of the monitoring system. WHO and UNAIDS worked with countries in an attempt to obtain facility-specific data on the number of people receiving treatment to the extent possible. For non-state sector numbers, which were separately reported in a limited number of countries, uncertainty ranges from 10% to 40% were used.

The United States President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria are major funders of antiretroviral therapy programmes in low- and middle-income countries. The United States President's Emergency Plan for AIDS Relief works in over 120 countries around the world, with a special emphasis on 15 countries in Africa, Asia and the Caribbean. The Global Fund funds AIDS programmes with an antiretroviral therapy focus in more than 100 countries.

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 supported 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.

These numbers are used to cross-validate the reported country numbers. The two initiatives support more than half of the total number of people receiving treatment as reported by countries to WHO. WHO/UNAIDS estimates are based on country reports, not by adding up and double-counting data from other sources.

⁵⁹ Boerma TJ et al. Monitoring the scale-up of antiretroviral therapy programmes: methods to estimate coverage. *Bulletin of the World Health Organization*, 2006, 84:145–150.

Estimating treatment need

UNAIDS and WHO have developed a standard method to estimate the size and course of the AIDS epidemic that also generates estimates of the number of new HIV infections, AIDS cases and deaths.⁶⁰ These numbers are used to estimate the number of adults needing treatment taking into account the maturity of the epidemic. In a young and growing epidemic, a smaller proportion of people living with HIV/AIDS will need to start treatment than in a mature or declining epidemic.

As a small but growing number of countries are now able to provide treatment numbers for children younger than 15 years of age, this report includes treatment needs for the age group 0–49 years. These estimates were made in collaboration with UNICEF.

WHO recommends that, in resource-constrained settings, HIV-infected adults and adolescents should start antiretroviral therapy when the infection has been confirmed and there are signs of clinically advanced disease.⁶¹ Studies have shown that, in resource-constrained settings, the median survival time for people with AIDS not receiving antiretroviral therapy is just under one year. Ideally, people should start receiving treatment before developing AIDS, once they have advanced HIV infection. The number of people with advanced HIV infection who need to start treatment is estimated as the number of AIDS cases in the current year times two.

The total number of people needing antiretroviral therapy is calculated by adding the number of people who need to start antiretroviral therapy to the number of people who were receiving treatment in the previous year and survived into the current year. Since some of the people who are projected to develop AIDS in these two years may already have started treatment in the previous year, the number who need to start antiretroviral therapy is adjusted to subtract those who started treatment in the previous year. It is currently assumed that 80–90% of the people receiving treatment will survive to the following year, depending on when treatment is initiated, adherence, drug resistance patterns, the quality of clinical management and other factors.

Antiretroviral therapy coverage

The level of coverage is a measure of the number of people receiving antiretroviral therapy by December 2005 divided by the total number of people estimated to need treatment. This method slightly underestimates coverage, since the number of people estimated to need antiretroviral therapy includes both children and adults, and few countries provide treatment data for children. However, children account for a small proportion of the total number of people receiving treatment, probably less than 6%.

⁶⁰ Walker N et al. Methods and procedures for estimating HIV/AIDS and its impact: the UNAIDS/WHO estimates for the end of 2001. *AIDS*, 2003, 17:2215–2225.

⁶¹ HIV disease stage IV, regardless of CD4 cell count; stage III with CD4 cell count below 350 cells per mm³ or laboratory evidence of severe immunosuppression (CD4 cell count below 200 per mm³) or, if not available, lymphocyte count below 1200 mm³ with symptomatic disease. *Scaling up antiretroviral therapy in resource-limited settings: treatment guidelines for a public health approach*. Geneva, World Health Organization, 2003 (http://www.who.int/3by5/publications/documents/arv_guidelines/en, accessed 13 February 2006).

Annex 3. The “3 by 5” focus countries

Listed below are the 49 countries WHO identified in December 2003 as “3 by 5” focus countries due to their need for intensified technical support and dedicated resources to scale up antiretroviral therapy and accelerate HIV prevention. Overall, these 49 countries represent a mixture of global and regional priorities. Global focus countries are the 34 initially identified by WHO as having the highest unmet treatment need that together comprised 93% of the unmet need for treatment in low- and middle-income countries. WHO regional offices identified an additional 15 focus countries due to their special strategic significance as a result of factors such as size, location and epidemic profile (such as a rapidly spreading epidemic).

As of December 2005, the 49 countries accounted for 87% of all adults and children living with HIV/AIDS globally, 78% of mortality from AIDS globally and 89% of people needing treatment in low- and middle-income countries. Six countries comprised more than 50% of treatment need in low- and middle-income countries: Ethiopia, India, Nigeria, South Africa, the United Republic of Tanzania and Zimbabwe.

High-burden countries

- | | |
|--------------------------------------|---------------------------------|
| 1. Angola | 18. Lesotho |
| 2. Botswana | 19. Malawi |
| 3. Burkina Faso | 20. Mozambique |
| 4. Burundi | 21. Myanmar |
| 5. Cambodia | 22. Namibia |
| 6. Cameroon | 23. Nigeria |
| 7. Central African Republic | 24. Russian Federation |
| 8. China | 25. Rwanda |
| 9. Côte d'Ivoire | 26. South Africa |
| 10. Democratic Republic of the Congo | 27. Sudan |
| 11. Ethiopia | 28. Swaziland |
| 12. Ghana | 29. Uganda |
| 13. Guatemala | 30. Ukraine |
| 14. Guinea | 31. United Republic of Tanzania |
| 15. Haiti | 32. Viet Nam |
| 16. India | 33. Zambia |
| 17. Kenya | 34. Zimbabwe |

Regionally strategic countries

- | | |
|-----------------|----------------|
| 35. Belize | 43. Kyrgyzstan |
| 36. Costa Rica | 44. Nicaragua |
| 37. Djibouti | 45. Panama |
| 38. El Salvador | 46. Somalia |
| 39. Guyana | 47. Tajikistan |
| 40. Honduras | 48. Uzbekistan |
| 41. Indonesia | 49. Yemen |
| 42. Kazakhstan | |

For further information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int
<http://www.who.int/hiv/en/>

ISBN 92 4 159413 6

