

3 by 5

December 2003

PROGRESS

through

REPORT

June 2004



World Health Organization



Joint United Nations Programme on HIV/AIDS
UNAIDS
UNHCR • UNICEF • WFP • UNDP • UNFPA
UNODC • ILO • UNESCO • WHO • WORLD BANK

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Foreword

I believe that our collective response to the HIV/AIDS pandemic is the benchmark by which our generation will be judged. We cannot shirk this historic responsibility, nor can we afford to fail. Increasing the availability of HIV/AIDS treatment, prevention and care has been and must continue to be a central priority for the World Health Organization, UNAIDS and their partners.

For nearly a decade, a number of bilateral donors, NGOs, foundations, the private sector, people living with HIV/AIDS, faith based organizations, multilateral agencies and national governments have been engaged in advocacy, planning, research, capacity development and programming to enable the scale up of HIV treatment and care. This effort did not begin and does not end with "3 by 5". The immense work of activists to push us to where we are today cannot be underestimated. The UNAIDS secretariat and cosponsors have all contributed political and technical support along the way. Not least of all, the Global Fund to Fight AIDS, TB and Malaria, the U.S. President's Emergency Plan for AIDS Relief, the World Bank, the European Commission, the governments of Australia, Belgium, Canada, France, Germany, Ireland, Italy, Japan, the Netherlands, Norway, Spain, Sweden, the United Kingdom, other bilateral donors, nongovernmental organizations, the Gates and other Foundations, as well as the private sector, have all contributed resources and expertise. We recognize and commend their efforts through which new hope has been created that millions of lives can be saved.

In order to help move scale-up forward more quickly, in 2003 I joined with UNAIDS to declare the lack of HIV/AIDS treatment to be a global public health emergency. This move was precipitated by the recognition that with reduced drug prices and the demonstrated feasibility of delivering treatment even in resource-constrained settings, the continued lack of treatment for so many people who need it was unacceptable. On World AIDS Day 2003 we announced a strategy to facilitate reaching "3 by 5"— 3 million people in developing and transitional countries receiving antiretroviral therapy by the end of 2005. If countries and the international community continue to intensify their efforts, we will reach this target, and that will set us on the road towards our ultimate goal of universal access to treatment for all those who need it.

Since we published the "3 by 5" strategy, we have been working to help break through obstacles and ensure that the people in need of treatment can get it. We have established the AIDS Medicines and Diagnostics Service to assist countries with the information and technical assistance they need to purchase high-quality AIDS medicines and diagnostic tools. WHO has strengthened the antiretroviral prequalification project to assess the quality of medicines against rigorous international criteria. We have sent staff to more than 20 countries to respond to specific requests for help. We have worked to build a network of partners who have joined us in committing to the goal of delivering treatment to people where and when they need it. We believe that the building blocks, supported by many partners, are now in place to rapidly increase the availability of antiretroviral therapy on a large scale.

Countries were quick to respond to the promise of "3 by 5". Forty requested technical support almost immediately, and many more followed. However, the funding needed to implement WHO's contribution to the strategy did not become available as quickly as we had expected. We therefore reviewed our options and focused on using the staff and other resources already available within WHO as effectively as possible.

More funding has recently been made available, particularly from the Government of Canada, which made a generous pledge of CAD 100 million to fund the "3 by 5" initiative, and from the Governments of the United Kingdom and Sweden. The combination of this new funding and the political will needed to increase the availability of treatment, prevention and care strongly improves prospects for controlling the worst global epidemic the world has ever faced.

I am well aware that we and our partners have set an ambitious goal. That is just what we needed: a difficult, time-limited undertaking that would force us to change the way we work at WHO. "3 by 5" is the best way to challenge ourselves to make the contribution we should be making to the global effort against HIV/AIDS. We will continue to measure ourselves against specific targets to assess the progress we are making.

This progress report highlights the achievements of the first six months of the initiative to expand the availability of HIV/AIDS treatment as well as the many challenges that remain. This is based on a series of milestones included in the WHO “3 by 5” strategy. Considering the slow growth in the availability of treatment in developing countries, the actions of many partners over the past year – and especially the past six months – offer hope that we may at last turn the tide against this terrible pandemic.

A handwritten signature in black ink, reading "Jongwook Lee". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

LEE Jong-wook
Director-General
World Health Organization

Introduction

Changing contexts and responses

The "3 by 5" target builds upon the years of work of governments and civil society in many countries, supported by their bilateral and multilateral partners, to expand access to HIV treatment. People living with HIV in low and middle income countries have been pressing their demands for antiretroviral treatment since the mid 1990s, when it became clear that treatment was dramatically reducing AIDS mortality and morbidity in the high income countries where it was accessible. As early as 1997, UNAIDS and WHO launched the Drug Access Initiative in Cote d'Ivoire and Uganda, the first public sector pilot projects demonstrating that antiretrovirals could be delivered safely and effectively in resource-limited settings. Despite the subsequent successes of one after another small-scale pilot project, few countries have managed to deliver HIV treatment to all, or even the majority, of those in need. In the late 1990s and in 2000-2001, additional initiatives such as the International Therapeutic Solidarity Fund, the African Comprehensive HIV/AIDS Partnerships (ACHAP) in Botswana, and the work of Médecins Sans Frontières, U.S. Centers for Disease Control and Prevention, and many donor funded efforts, to name a few, added much knowledge to implementing HIV/AIDS treatment programs.

Excluding Brazil, which accounts for about one-third of all people on antiretroviral therapy in developing and transitional countries, access to antiretroviral medicines in 2002 increased by 50 percent globally, and by about two-thirds in sub-Saharan Africa. Whereas the initial base of numbers of persons treated was small, the pace of increased access to treatment has begun to grow. For example, Barbados, Cuba and Costa Rica provide free antiretroviral access to all those in need, while the Bahamas, Guyana, Senegal and Thailand have been making significant progress toward universal treatment access.

Despite the increasing political attention paid to HIV/AIDS, more than 8000 people are still dying every day from a disease that can be treated and prevented. However, some important progress is being made. Significant new resources are flowing to support the scaling up of antiretroviral therapy and are not simply being diverted from core prevention activities. More and more countries accept the need to provide antiretroviral therapy to the people who need it, and international and national partners across a diverse range of groups and agencies are coming together to support scale-up in accordance with "3 by 5" targets.

The unprecedented momentum for access to treatment poses challenges for many countries. Coordination around a common set of goals and objectives at the national level is critical. Accordingly, UNAIDS developed the "three ones" principles to highlight the need for one national programme, one coordinating body and one monitoring and evaluation framework. Partnerships have been an increasing focus of work for WHO, as "3 by 5" is increasingly embraced as a global target owned by everyone. "3 by 5" clearly cannot be the project of one or even several agencies; the task is far too large and complex.

The "3 by 5" target has been widely discussed and sometimes misinterpreted. A time-limited target is a proven method for mobilizing action and resources. Some people remain uncomfortable with the ambitious agenda of having 3 million people receiving treatment in the next 18 months. But WHO and UNAIDS believe that the target is achievable and are committed to supporting all Member States to achieve it. Anything less falls short of an appropriate response to the greatest global public health challenge of our times. Beyond 2005, the ultimate goal of providing treatment to everyone who needs it as a human right has not been questioned.

The WHO response to helping countries

In the past six months, WHO has worked strenuously to respond to the overwhelming demand from countries for urgent assistance. The original intention was to recruit "3 by 5" country officers and "3 by 5" country teams as soon as possible for each of the WHO-identified focus countries. Given the initial shortfall of funds to recruit new staff for these key positions, WHO instead focused on sending its existing staff to countries to provide interim support. Twenty-four teams from WHO headquarters and regional offices were sent in response to requests from countries. These missions mapped the local situation, identified key partners and technical assistance needs, prompted and reinforced political commitment and supported the process of developing national scale-up plans. In addition, 37 staff members from headquarters and regional offices were sent for 4 to 8 weeks to

countries that had requested urgent support, especially those preparing applications for Round Four funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Deployed staff also helped countries to identify obstacles to expanding access to the entire range of HIV/AIDS prevention, treatment and care services and, in some cases, began to develop initial plans for scaling up treatment. Much of this work has led to the creation of detailed country profiles developed with national counterparts and partners in each country. These profiles will be a practical tool to help guide countries in their scale-up efforts, to monitor progress and to clarify roles and responsibilities among the various actors at the country level.

Meanwhile, at WHO headquarters, at WHO regional offices and in consultation with partners, other key elements of the strategy were taking shape. The AIDS Medicines and Diagnostics Service (AMDS) was established as a multi-agency network linking WHO and the UNAIDS Secretariat more closely with other UNAIDS cosponsors the United Nations Children's Fund (UNICEF), the World Bank and the United Nations Population Fund (UNFPA), and now, the United Nations Development Programme (UNDP). Twenty-nine countries have already procured antiretroviral medicines through a combination of existing and new services under the AMDS umbrella. Member States have broadly endorsed WHO's prequalification process, which assesses the quality, safety and efficacy of drugs submitted by participating manufacturers. Further, WHO's Expert Committee on the Selection and Use of Essential Medicines has strongly recommended the use of fixed-dose combinations (fixed amounts of two or more active ingredients in one tablet or capsule), which simplify procurement and treatment and improve adherence.¹ Finally, the country-by-country availability of drugs and the related supply chain management issues are currently being mapped to identify specific gaps and technical assistance needs.

Technical and policy tools and guidelines were developed with unprecedented speed to help countries, donors and other partners in scaling up antiretroviral therapy within the context of a comprehensive health system response. Simplified and standardized approaches have facilitated the development of basic antiretroviral therapy training materials, and training packages and modules for health care and community workers have been under accelerated development. Key stakeholders have also agreed on a harmonized set of measures and tools to monitor progress on the implementation of antiretroviral therapy scale-up.

Extensive work has also been undertaken to establish, broaden and engage more extensively a broad network of partners including donors, United Nations organizations, business and trade unions, pharmaceutical manufacturers, faith-based organizations, people living with HIV/AIDS, nongovernmental organizations and treatment activists supporting "3 by 5". Three major international meetings have been held during which a wide range of partners have committed to working towards the "3 by 5" target and the ultimate goal of universal access to HIV/AIDS treatment for everyone who needs it. The roles of UNAIDS Cosponsors have been clearly delineated. However, many of these partnerships have not yet been formalized but are based on a mutual commitment to the goal of increasing the access of people living with HIV/AIDS to treatment, support and care services.

Although this work has successfully built on the initial commitment of countries, donors and international organizations to the goal of increasing access to antiretroviral therapy, it has not yet led to a sharp rise in the number of people living with HIV/AIDS receiving treatment. This is disappointing but not a reason to hesitate. Increased resources combined with progress in addressing the barriers to scaling up identified during the past six months auger well for this number to rise significantly over the next six months. There are many reasons for optimism: a rapid increase in the number of countries developing and refining their national HIV/AIDS treatment plans, coupled with increased resource flows, is accelerating progress on access. For the first time, specific plans are now in place to strengthen WHO country offices in focus countries with dedicated "3 by 5" country officers, national programme officers, administrative staff and appropriate activity budgets. Negotiations underway should lead to further cuts in the price of antiretroviral medicines. Training courses have been designed, health workers are being trained and the certification of health workers competent to deliver and monitor antiretroviral therapy has been agreed upon.

Nevertheless, the modest increase in the number of people being treated over the past year clearly shows that progress is not rapid enough. To this end, WHO is taking steps to improve the documentation and reapplication of knowledge and best practices in accelerating the scaling up of antiretroviral therapy. A system for information and knowledge management to support antiretroviral therapy scale-up will begin in Uganda in 2004. The scope of this work includes collecting data about the people receiving antiretroviral therapy, collecting qualitative information about treatment and health systems performance and implementing processes to share information and learning across multiple treatment sites using collaborative quality improvement techniques. In September 2004, a team of experts will visit countries such as Brazil and Thailand that have successfully scaled up to document key lessons from their experience. The members of this team will then provide direct and immediate assistance in reapplying these approaches to several countries ready to scale up nationally.

¹ For more information on the WHO Prequalification Project, please visit the website. <http://mednet3.who.int/prequal/>

Key findings

The key findings relate to progress against the key milestones included in the "3 by 5" strategy² launched in December 2003. The 15 specific milestones are grouped into categories that follow, and Annexes 1 and 2 more fully describe the relevant figures (the actual results versus objectives as of June 2004).

Providing treatment to the people in need

- **Number of men, women and children with advanced HIV infection receiving antiretroviral therapy**

As of 30 June 2004, 440 000 people with HIV/AIDS were receiving antiretroviral therapy in developing and transitional countries. This is 60 000 less than the target for the initial six months of the "3 by 5" Initiative. Although this is disappointing, the absolute increase of 40 000 people in a few months does indicate that country and international efforts to scale up HIV/AIDS treatment are resulting in progress. National and international efforts related to "3 by 5" have advanced national planning for antiretroviral therapy, reduced drug prices and increased political will. Following the intensive work over the past six months, many building blocks are now in place to facilitate a rapid increase in the number of people on treatment over the next 18 months.

Leadership, partnership and advocacy

Building political commitment

- **Amount of additional financial resources allocated to support WHO's contribution to "3 by 5"**
- **Number of countries appealing to WHO for support for "3 by 5"**

The "3 by 5" Initiative has helped to generate significant additional momentum and political commitment for expanded access to antiretroviral therapy over the past six months. A major accomplishment has been to increase the pressure on countries and all concerned partners to rapidly scale up treatment. Key examples include the following.

- **Individual government and health ministry responses.** These have been extremely positive. So far, 56 countries have appealed to WHO for help in increasing access to treatment. Further, several countries have recently improved national HIV/AIDS policies that encourage large-scale testing and counselling, address stigma and discrimination and, in some cases, significantly improve access by making antiretroviral drugs free of charge.
- **International endorsement.** At the WHO Executive Board Meeting in January 2004 and the World Health Assembly in May 2004, Member States strongly endorsed the "3 by 5" timetable and approved the expanded HIV/AIDS programme budget. Member States reaffirmed their commitment to HIV/AIDS prevention, treatment, care and support and further urged the Director-General to improve the access of developing countries to antiretroviral medicines and other products used in the diagnosis, treatment and care of HIV/AIDS, including by strengthening the WHO prequalification project.
- **The "three ones".** In April 2004, donors, developing countries and United Nations agencies broadly endorsed the UNAIDS "three ones" principles, which call for one national plan, one coordinating mechanism and one set of measures to monitor progress in scaling up antiretroviral therapy at the country level. The implementation of this concept is vital to ensure the coordination of national efforts.
- **Significant financial contributions to WHO.** Canada, Sweden and the United Kingdom have given WHO significant funding for "3 by 5" activities. This will enable WHO to move forward with a substantial part of its work in this biennium.
- **Broad-based financial support to combat HIV/AIDS.** WHO recognizes the significant contributions from many bilateral donors, along with the Global Fund to Fight HIV/AIDS, TB and Malaria, the World Bank, and foundations. Their contributions to date are presented in the UNAIDS Global Resource Tracking Consortium report "*Financing the Expanded Response to AIDS*", July 2004 (in press) and is available on the UNAIDS website www.unaids.org

² Treating 3 million by 2005 – making it happen. The WHO strategy. Geneva, World Health Organization, 2003 (<http://www.who.int/3by5/about/strategy/en/index.html>, accessed 25 June 2004).

Building effective partnerships and involving communities

- **Number of partner organizations whose role in “3 by 5” is agreed and published**
- **Number of partnerships between formal antiretroviral therapy service outlets and community-based groups**

Significant progress has been made during the past six months in building partnerships with a variety of organizations to strengthen and harmonize collective action towards achieving “3 by 5”. These include other United Nations organizations, donors, governments and related organizations such as national AIDS commissions, nongovernmental organizations, faith-based organizations, community-based organizations, treatment activists, pharmaceutical manufacturers and the private sector. In some cases the nature of these relationships is well understood and has been documented. In many other cases, although there is a general sense of alignment and a desire for cooperation and mutual support, more clarity is required to clearly identify the respective roles and responsibilities of the organizations involved. Consistent with the “three ones” principles, WHO wants to ensure that each country has one plan, one coordinating mechanism and one set of measures to monitor progress. Partners have a collective responsibility to ensure that all necessary roles are filled in countries with a minimum of redundancy. Highlights of progress include the following.

- **The “3 by 5” Global Partners Group.** Two meetings have been held, the most recent of which included more than 90 individuals and organizations expressing support for scaling up treatment and accelerating prevention.
- **United Nations agencies commit to cohesive, country-level “3 by 5” action.** The Committee of Cosponsoring Organizations of UNAIDS has agreed on the roles and responsibilities of the UNAIDS Secretariat and Cosponsors in scaling up antiretroviral therapy and their respective contributions to realizing the “3 by 5” target.
- **Technical partnerships.** Several important technical partnerships have been established. For example, WHO is collaborating with UNICEF, the World Bank, UNDP and nongovernmental organizations in purchasing drugs and diagnostics (see the discussion of AMDS below) and with UNAIDS, the United States President’s Emergency Plan for AIDS Relief and other partners to harmonize the monitoring and evaluation indicators required for increasing access to antiretroviral therapy.
- **Support for treatment preparedness.** Along with UNDP, the World Bank and the UNAIDS Secretariat, WHO has sponsored a number of interactions with and between various organizations of people living with HIV/AIDS and treatment activist groups with a view to encouraging and supporting the active involvement of community-based organizations in scaling up treatment. Specifically, in June 2004 WHO committed US\$ 1 million towards building capacity for treatment preparedness and treatment literacy among organizations of people living with HIV/AIDS to support their role in scaling up treatment.
- **Private-sector engagement.** WHO is working with the private sector to determine what forms of collaboration will be most productive, especially in broad-based programme communication to promote treatment awareness, testing and counselling.

Urgent, sustained country support

Strengthening national planning for scale-up

- **Number of additional WHO staff deployed and/or realigned to WHO country offices for "3 by 5"**
- **Number of countries establishing antiretroviral therapy targets in accordance with "3 by 5"**
- **Number of countries with a national plan for implementing scale-up in accordance with the "3 by 5" target**

Strengthening the capacity of countries to establish ambitious treatment targets and to develop and implement plans to achieve them is a critically important aspect of the overall "3 by 5" strategy. Although some important progress has been made in this area, objectives are not currently being realized to the degree required. This area will be an extremely important focus for WHO and many other partners in the coming six months.

- Twelve countries have now officially established treatment targets for the end of 2005 equal to or greater than the "3 by 5" target of providing treatment to 50% of those in need, but many other countries have significant targets that fall somewhat short of this.
- Three countries have completed national scale-up plans that, once implemented, will allow at least 50% of those in need to receive antiretroviral therapy.
- UNAIDS Cosponsors will be collaborating at the country level to support countries in implementing the "three ones" principles.
- The serious lack of funds for "3 by 5" from January to May 2004 restricted WHO from strengthening country and regional offices as planned. Only a small proportion of the incremental staffing planned was realized.
- However, WHO staff conducted 24 missions to countries at the request of governments to map the HIV/AIDS situation and to identify the support needed for scaling up antiretroviral therapy. In addition, 37 staff were deployed to countries for 4–8 weeks to assist in developing funding proposals for the Global Fund to Fight AIDS, Tuberculosis and Malaria and national scale-up plans. During the next six months, country and regional offices will be strengthened. These changes will better equip WHO country offices to support national governments in developing and implementing scale-up plans.
- Based on recently approved Round 4 grants by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the success rate was 50% for HIV/AIDS proposals in which WHO assisted the countries versus 30% for those without WHO assistance. Further, when both WHO and UNAIDS provided assistance, the success rate improved to 75%.

Strengthening national capacity

- **Number of countries that have introduced training using WHO-supported certification of competence**
- **Number of health providers and community treatment supporters trained to deliver antiretroviral therapy services in accordance with national standards**
- **Number of service outlets providing antiretroviral therapy services according to national standards**
- **Number of public and nongovernmental organization service outlets providing testing and counselling services**

Significant progress has been made during the past six months in building the capacity of countries to support a comprehensive health system response to HIV/AIDS. Numerous training programmes have been developed and successfully adapted for local use in a number of countries. To support this training and to ensure a consistent level of competence, WHO and its partners are developing standards and processes for certifying in-country health care workers. Encouragingly, WHO data indicate that the development of key infrastructure for antiretroviral therapy service delivery is progressing at a pace that could eventually support 3 million people on antiretroviral therapy by the end of 2005. Specifically, the number of health and community care workers trained in delivering and monitoring antiretroviral therapy, the number of sites providing antiretroviral

therapy and the number of sites providing testing and counselling are at or above the target level as of June 2004. Although a great deal more needs to be done, WHO estimates that about 15% of the staff trained in antiretroviral therapy, 5% of antiretroviral therapy delivery outlets and 24% of testing and counselling sites required to support the “3 by 5” target are now in place. Specific highlights are the following.

- **Training package.** A training package for health workers at first-level facilities has been developed based on the WHO Integrated Management of Adult and Adolescent Illness (IMAI) format, including a basic clinical training course in antiretroviral therapy, a short course on opportunistic infections, and accompanying aids such as a patient education flipchart. Eight countries have adapted and rolled out IMAI-based training.
- **Technical resource networks and knowledge hubs.** A series of regional technical resource networks and subregional knowledge hubs for capacity-building were created, including knowledge hubs for HIV/AIDS treatment and care in Burkina Faso, Sudan, Uganda and Ukraine.
- **Patient monitoring guidelines.** Simplified patient monitoring guidelines were developed and agreed upon, outlining a unified data collection system for individual patient management and for clinic, district and national monitoring. A corresponding patient card was developed and integrated into IMAI guidelines and training materials.
- **Service outlets.** In developing countries:
 - o 15 000 health care and community treatment supporters have been trained in delivering and monitoring antiretroviral therapy;
 - o 500 centres are now providing antiretroviral therapy; and
 - o 4880 sites are providing testing and counselling services.

Simplified, standardized tools and technical guidance

Equipping countries with the technical guidance and simplified approaches needed for scaling up

• Number of standard training packages and other key guidance documents published

Clear, standard and simplified technical guidelines and training materials are crucial in enabling antiretroviral therapy to be rapidly scaled up in resource-constrained settings. Simplification enables antiretroviral therapy to be implemented on a broad scale by allowing health care and community workers to play a more significant role and by simplifying the purchasing and supply chain management of drugs and diagnostics. Simplified and standardized approaches have also facilitated the development of basic antiretroviral therapy training materials, treatment guidelines and technical and operational guidelines for scaling up care and treatment. Here the partnership between WHO and UNDP is addressing social and community concerns.

Technical and policy tools and guidelines have been developed with unprecedented speed to help countries, donors and other partners with the building blocks to scale up antiretroviral therapy within the context of a comprehensive health-sector response. A harmonized set of measures and tools to track progress on implementing antiretroviral therapy scale-up agreed by WHO, UNAIDS, the United States President's Emergency Plan for AIDS Relief, the Global Fund to Fight AIDS, Tuberculosis and Malaria and other partners has simplified country level monitoring and reporting requirements. Highlights include the following.

- **Treatment guidelines.** Simplified treatment guidelines have been published that recommend four first-line and accompanying second-line regimens.
- **Technical and operational recommendations.** A set of technical and operational recommendations for scaling up antiretroviral therapy has been published covering topics including the essential package of care and prevention needed to support antiretroviral therapy delivery.
- **Testing and counselling.** Guidelines on HIV testing and counselling and the use of rapid HIV tests have been updated.
- **Monitoring and evaluation.** Monitoring and evaluation measures that have been harmonized with all key partners have been developed.
- **Care manuals.** Manuals on palliative, chronic and acute care have been developed.
- **Other guidelines.** Several other guidelines have been published outlining targeted interventions for vulnerable populations, including sex workers and injecting drug users.

An effective and reliable supply of medicines and diagnostics

Improving the supply and reducing the cost of necessary drugs and diagnostics

- **Average price per person per year for the first-line treatment regimen**
- **Number of countries using AMDS for procurement and/or distribution of drugs and/or diagnostics**

The timely and uninterrupted supply at reasonable cost of the required medicines and diagnostics including antiretroviral drugs, laboratory equipment and reagents, HIV test kits and antibacterial agents to treat opportunistic infections is clearly essential for scaling up antiretroviral therapy. In addition to logistical challenges, the costs involved in procurement and supply management are considerable and may represent up to 65% of the total cost of scaling up treatment.

Significant progress has been made in a variety of areas. The price of first-line treatment with fixed-dose combination formulations continues to decrease, with benchmark pricing now about US\$ 150 per person per year (a decrease of about US\$ 150 in less than 12 months). However, not all countries have adopted these low-cost regimens as their standard. Furthermore, generic antiretroviral drugs have not yet been registered in many countries. Thus, despite good progress on a number of fronts, the average price for first-line treatment remains above target. Finally, the cost of second-line treatments remains high.

WHO has improved its ability to offer normative and technical support both through AMDS and in its prequalification project. The highlights are the following.

- WHO has joined in partnership with the UNAIDS Secretariat, UNICEF, the World Bank, UNFPA and UNDP to create AMDS, a technical network to support the availability of high-quality and safe antiretroviral drugs and diagnostics for countries.
- Countries are increasingly requesting and receiving technical support through AMDS. Assistance is being provided in close cooperation with UNICEF and will soon include joint activities with other partners including Management Sciences for Health, John Snow Inc. and Médecins Sans Frontières.
- Countries are increasingly requesting and receiving procurement support through AMDS. UNICEF procures most of the antiretroviral drugs for United Nations agencies.
- Fixed-dose combinations of triple combination antiretroviral drugs have been prequalified by WHO's prequalification project. A database is being constructed that brings together in one place the necessary market information to enable decision-makers to procure high-quality products at a competitive price.
- UNICEF is creating a physical inventory of selected antiretroviral drugs to serve both emergency demand (avoiding stock-outs resulting from planning problems) and small customers.
- Over the next six months, WHO, UNICEF, Management Sciences for Health, John Snow Inc., Médecins Sans Frontières and other partners will create systems to facilitate demand forecasting at the institutional and national levels. Aggregating this information at a global level will help manufacturers in planning their production capacity.
- WHO is developing an electronic procurement system for diagnostics to facilitate a rapid procurement cycle for the products prequalified for its bulk procurement scheme.

Achieving targets for scaling up treatment: overcoming challenges

Progressive scaling up. Achieving targets for scaling up treatment involves building the required political commitment, health system and resource base to allow for rapid expansion. The number of people being treated rises more slowly in the beginning, with more rapid growth in the later phases of scaling up. Work to date has successfully built on the initial commitment and earlier work of countries, donors and international organizations. However, much needs to be done to realize the desired steep rise in the number of people on treatment. "3 by 5" is helping to mobilize global, national, and community action. This report emphasizes, however, that success in increasing treatment access to reach the stated targets will heavily depend on country and community action.

Looking ahead to 2005, a number of countries and their partners are heavily engaged in supporting the scaling up of treatment and prevention. Their leadership and action are critical to achieving the "3 by 5" target. The 34 countries with the highest burden of people living with HIV needing access to treatment have an estimated total treatment need of 4 677 000 by the end of 2005. Of these 34 countries, 24 have already declared a cumulative target of 1 061 900 people on treatment by the end of 2005.

Countries rely on their own resources as well as external resources to achieve these targets. Table 1 indicates the types of commitments that some partners have made to provide people with treatment. Although there may be some duplication among partners in individual countries, the net result of the commitments offers reason to be optimistic about achieving "3 by 5".

Table 1. Commitments made by partners towards scaling up antiretroviral therapy

Source of support	Comments
Government of the United States of America	The goal is to treat 2 million people by 2008.
Other bilateral partners	Several donors are supporting countries in scaling up treatment through their bilateral programming.
World Bank multi-country HIV/AIDS programmes	Over US \$1.7 billion has been committed through grants, loans and credits for HIV/AIDS worldwide, most of which has come through the Multi-Country HIV/AIDS Program for Africa and the Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Program Lending. These funds can be used to increase access to antiretroviral therapy. In addition, health infrastructure commitments can help strengthen health service delivery.
World Bank Treatment Acceleration Program	This is a new three-year project (US\$ 60 million) to support expansion of treatment access in Burkina Faso, Ghana and Mozambique.
Countries supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria	The Global Fund has reported that the recently completed Round 4 grant cycle will support antiretroviral therapy for 932 000 over five years. In addition, the Global Fund projects that grants from Rounds 1–3 will support 692 000 (Round 1: 232 000, Round 2: 283 000, Round 3: 177 000) people on antiretroviral therapy. This would yield a total support for more than 1.6 million people on antiretroviral therapy over the next five years.

Private sector	The Accelerating Access Initiative reports that it is covering 150 000 people with antiretroviral therapy now and could increase coverage. The Accelerating Access Initiative is driven by the research-based pharmaceutical industry. In addition, several corporations and businesses in affected countries are actively engaged in providing antiretroviral therapy to their employees and additional beneficiaries.
Faith-based organizations	The large reach of faith-based organizations in delivering health services represents major potential to expand antiretroviral therapy to people in need.
Nongovernmental organizations	Nongovernmental organizations such as Médecins Sans Frontières, Family Health International and others have contributed and will continue to contribute to delivering antiretroviral therapy. Médecins Sans Frontières estimates that it is currently providing treatment to 13 000 people in 19 countries.

Availability of resources. Globally, increased political commitment to treatment access, often promoted by civil society, results in increased focus on preventing and treating HIV/AIDS among governments, bilateral and multilateral donors as well as the United Nations system. Allocations from national budgets and debt relief funds are also increasing. The roll-out of treatment in South Africa will rely largely on domestic funding, and Cameroon is using millions of dollars in debt relief to support care and treatment programmes. In June 2004, the World Bank Board of Directors approved US\$ 60 million for a new Treatment Acceleration Program to scale up treatment in Burkina Faso, Ghana and Mozambique. This funding is in addition to the US\$ 1 billion being provided by the World Bank Multi-Country AIDS Program for Africa and the US \$155 million under the Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Program Lending. The money for the new Treatment Acceleration Program is largely in the form of grants and can be used flexibly for procurement, strengthening health system infrastructure, training and community preparedness. The Global Fund to Fight AIDS, Tuberculosis and Malaria has approved HIV-related grants that will support access to antiretroviral therapy for 1.6 million people. The United States President's Emergency Plan for AIDS Relief is expected to provide treatment for 2 million people in priority countries.

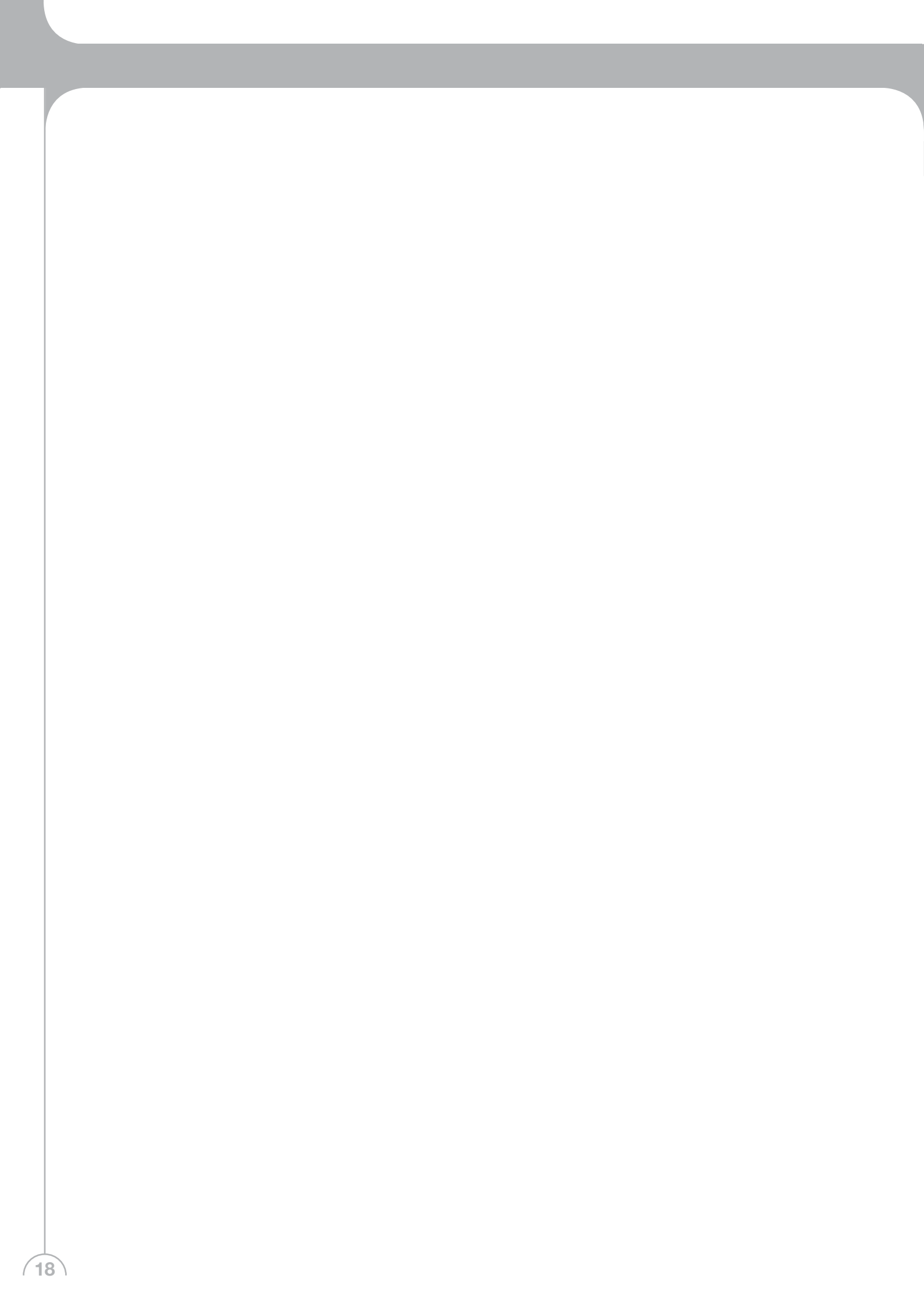
Affordability of AIDS medicines and diagnostics. The prices of some antiretroviral drugs have continued to drop in low-income countries. In October 2003, the William J. Clinton Foundation announced that it had obtained prices from several generic manufacturers, under certain conditions, as low as US\$ 140 per person per year for a WHO-recommended first-line regimen. The prices of some proprietary antiretroviral drugs have also continued to fall slightly, although they remain higher than the generic versions for most drugs.

Some governments have begun to utilize the flexibility in international trade agreements to make medicines more affordable and accessible. In May 2004, Malaysia and Mozambique announced that their national authorities had issued compulsory licences for certain antiretroviral drugs, and Canada reformed its patent legislation to allow its generic pharmaceutical producers to export under World Trade Organization rules to countries without adequate manufacturing capacity. More and more developing and transitional countries are exploring the possibility of producing HIV-related medicines locally, and a group of developing and industrialized countries agreed to support technology transfer in this area at the WHO Executive Board meeting in January 2004.

Engaging communities and civil society. In many countries, civil society – faith-based organizations and national and international nongovernmental organizations – continues to provide a major share of HIV/AIDS services. The reach of health care services is illustrated by the Catholic Church's claim that it provides more than one quarter of health care globally. As of April 2004, Médecins Sans Frontières was providing antiretroviral therapy to about 13 000 people in 19 countries in Africa, Asia and Latin America. Organizations such as The AIDS Support Organization in Uganda, Zanmi Lasanté (Partners in Health) in Haiti and small community-based organizations such as The Centre in Zimbabwe (a self-help drop-in, counselling, support, research and training project for people living with HIV/AIDS) continue to expand and improve their treatment programmes.

Remaining challenges. Much still needs to be done. Recognizing the key challenges allows the world community to redouble its energy and commitment to overcoming them. They include:

- continuing momentum and avoiding complacency
- enhancing national planning
- improving data and surveillance
- building innovative partnerships
- accelerating prevention and care
- reinforcing health systems
- ensuring that drugs and diagnostics are affordable and available
- ensuring equity in coverage.



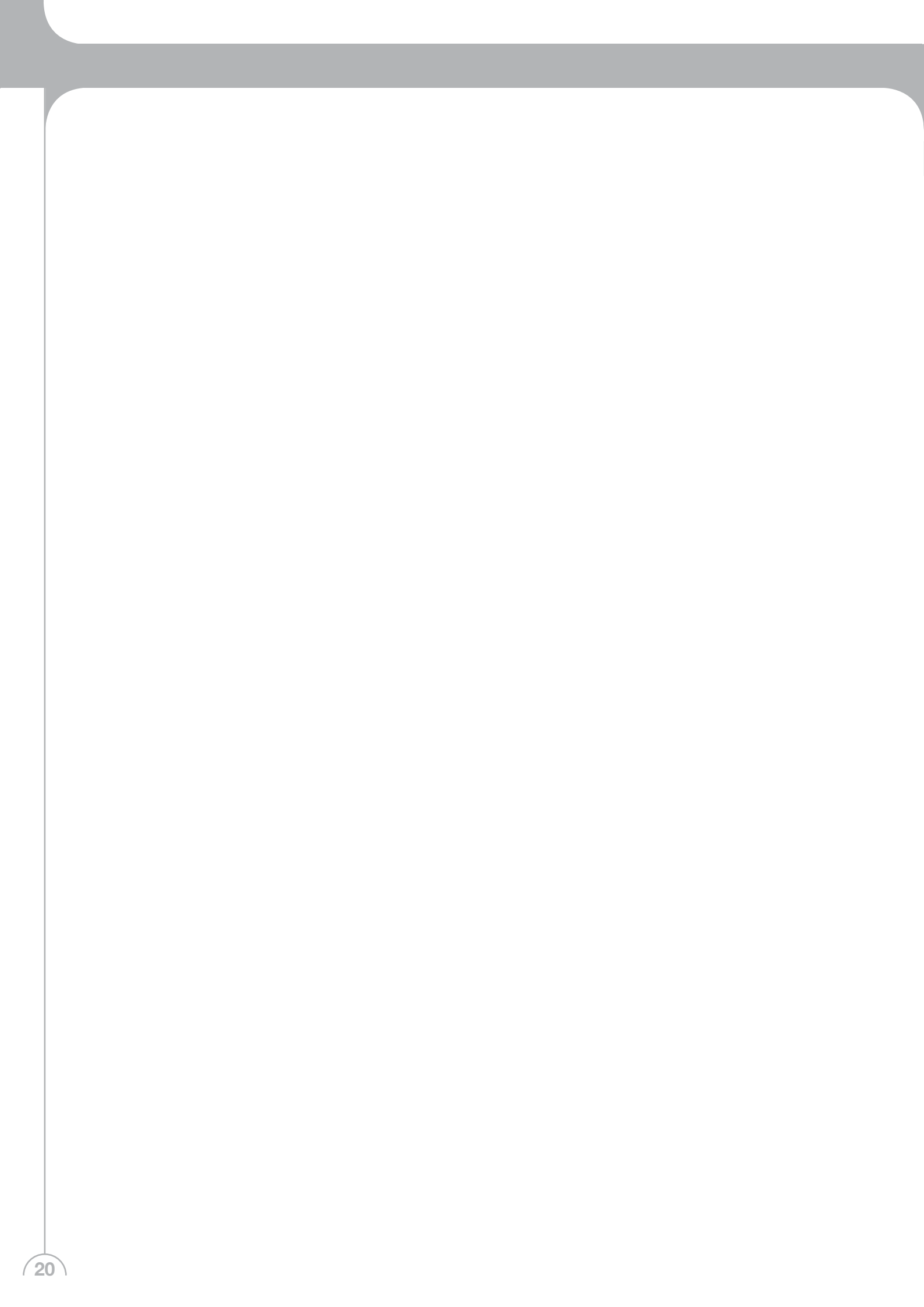
Annex 1.

Reporting of results versus objectives: June 2004

Status of country scale-up measures for June 2004

	Published milestones for June 2004	Result as of June 2004
Input		
1. Amount of additional financial resources allocated to "3 by 5" a) within WHO overall b) at WHO country offices	US\$ 86 million US\$ 54 million	US\$ 39 million US\$ 25 million
2. Number of additional WHO staff deployed and/or realigned to WHO country offices for "3 by 5"	200	58
3. Number of standard training packages and other key guidance documents published (not including revisions of documents)	15	33
4. Number of partner organizations whose role in "3 by 5" is agreed and published	90	15
Process		
5. Number of countries appealing to WHO for support for "3 by 5"	40	56
6. Number of countries establishing antiretroviral therapy targets in accordance with "3 by 5"	35	12
7. Number of countries with a national plan for implementing scale-up in accordance with the "3 by 5" target	25	3
8. Average price per person per year for the first-line treatment regimen	US\$ 100–350	US\$ 484
9. Number of countries using AMDS for procurement and/or distribution of drugs and/or diagnostics	20	29
10. Number of countries that have introduced training using WHO-supported certification of competence	30	0
Output		
11. Number of health providers and community treatment supporters trained to deliver antiretroviral therapy services in accordance with national standards	10 000	15 000
12. Number of service outlets providing antiretroviral therapy services according to national standards	500	500
13. Number of partnerships between formal antiretroviral therapy service outlets and community-based groups	1 500	not available ^a
14. Number of public and nongovernmental organization service outlets providing testing and counselling services	1 000	4 880
Outcome		
15. Number of men, women and children with advanced HIV infection receiving antiretroviral therapy	500 000	440 000

^a This could not be measured as initially stated. New qualitative measures for community involvement in scaling up antiretroviral therapy are being developed.



Annex 2.

Discussion of results and interventions planned

1. Additional financial resources allocated to "3 by 5" a) within WHO overall and b) at WHO country offices

In late 2003, the funding target for WHO's HIV/AIDS activities in the 2004–2005 biennium was initially established at US\$ 400 million, with US\$ 350 million for scaling up antiretroviral therapy and US\$ 50 million for prevention and other work. In January 2004, the WHO Executive Board revised the US\$ 400 million to US\$ 218 million given that partner organizations were expected to increase their contribution to scaling up treatment in the form of both human and financial resources.

Actual WHO spending on HIV/AIDS work during the 2002–2003 biennium was US\$ 59 million. Thus, the revised target for additional overall funding for WHO's HIV/AIDS work by the end of 2005 is US\$ 159 million (\$218 million minus US\$ 59 million), of which 65% (US\$ 103 million) is expected to be spent at the country level. Revised spending targets for the first six-month period in total and at the country level would therefore be US\$ 40 million and US\$ 26 million respectively. These have basically been met.

In the current biennium 2004–2005, WHO has received commitments for HIV/AIDS funding totalling US\$ 156 million, the main components of which are regular budget (US\$ 18 million), Unified Budget and Workplan allocations from UNAIDS (US\$ 16 million) and donations (US\$ 122 million – notably including US\$ 72 million from the Government of Canada). Since most of the pledged donations were not received during the December 2003 to June 2004 period, actual total funds available to be spent during the first six months amounted to US\$ 54 million. This represents an incremental US\$ 39 million (US\$ 54 million minus one quarter of the US\$ 59 million spent in 2002–2003) in additional financial resources versus the previous biennium.

An additional US\$ 62 million is required to enable WHO to fulfil its role as described in the WHO HIV/AIDS Plan for 2004–2005.³

2. Number of additional WHO staff deployed and/or realigned to WHO country offices for "3 by 5"

The reported number of 58 comprises the recruitment of the first 21 "3 by 5" country officers in focus countries by the end of June 2004 plus the 37 staff from headquarters and regional offices deployed to country offices for 4–8 weeks during April–May 2004. This is well below the target of 200 staff dedicated to "3 by 5" implementation.

The below-target progress in increasing WHO staff at the country level is directly attributable to the substantial shortfall in funding during much of the period from December 2003 to June 2004. Recently committed funds will now enable WHO to accelerate its efforts to recruit at country and regional offices during the second half of 2004.

3. Number of standard training packages and other key guidance documents published

Key guidance documents have been developed with unprecedented speed to help countries and partners with the building blocks to scale up antiretroviral therapy and accelerate prevention within the context of a comprehensive response to HIV/AIDS. The following list of documents published from December 2003 to June 2004 shows that the target of 15 packages and documents published has been exceeded.

³ Investing in a comprehensive health-sector response to HIV/AIDS: scaling up treatment and accelerating prevention. WHO HIV/AIDS Plan for January 2004–December 2005. Geneva, World Health Organization, 2004.

1. *Palliative care: symptom management and end-of-life care* (IMAI)
2. *General principles of good chronic care* (IMAI)
3. *Chronic HIV care with ARV therapy* (IMAI)
4. *Acute care* (IMAI)
5. *Emergency scale-up of antiretroviral therapy in resource-limited settings: technical and operational recommendations to achieve 3 by 5*. Report of the WHO/UNAIDS International Consensus Meeting on Technical and Operational Recommendations for Emergency Scaling-up of Antiretroviral Therapy in Resource-limited Settings, 18–21 November 2003, Lusaka, Zambia
6. *National AIDS programmes. A guide to monitoring and evaluating HIV/AIDS care and support*
7. *Evidence for action: effectiveness of community-based outreach in preventing HIV/AIDS among injecting drug users*
8. *Interim policy on collaborative TB/HIV activities*
9. *A public health approach for scaling up antiretroviral (ARV) treatment. A toolkit for programme managers*
10. *Training guide for HIV prevention outreach to injecting drug users. Workshop manual*
11. *Guidelines for effective use of data from HIV surveillance systems* (UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance)
12. Technical briefs on various topics (12) (<http://www.who.int/3by5/publications/en>)
13. *Guidelines for conducting HIV sentinel serosurveys among pregnant women and other groups* (UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance)
14. *Human capacity-building plan for scaling up HIV/AIDS treatment*
15. *The Lighthouse: a centre for comprehensive HIV/AIDS treatment and care in Malawi. Case study* (in press).
16. *Approaches to the management of HIV/AIDS in Cuba. Case study* (in press).
17. *Antiretroviral therapy in primary health care: experience of the Chiradzulu programme in Malawi*
18. *Antiretroviral drugs and the prevention of mother-to-child transmission of HIV infection in resource-limited settings*
19. *HIV/AIDS and sex work toolkit*
20. *HIV testing and counselling toolkit*
21. *HIV-related care, treatment and support for HIV-infected women and their children: summary of recommendations*
22. *Recommendations for HIV diagnosis in children born to HIV-infected women*
23. *Rapid HIV tests: guidelines for use in testing and counselling services in resource-constrained settings*
24. *Prevention of mother-to-child transmission of HIV generic training curriculum*
25. Evidence for action: four policy briefs
Provision of sterile injecting equipment to reduce HIV transmission
Reduction of HIV transmission in prisons
Reduction of HIV transmission through drug-dependence treatment
Reduction of HIV transmission through outreach
26. *Guidelines on ethical issues in second generation surveillance*
27. *Guide to monitoring and evaluating national HIV/AIDS prevention programmes for young people*
28. *Advocacy guide: HIV/AIDS prevention among injecting drug users*
29. *Integrating prevention and care services for HIV-positive drug dependents in the Americas* (Pan American Health Organization)
30. *HIV/AIDS treatment and care guide for implementation* (WHO Regional Office for the Western Pacific)
31. Basic start up training modules for HIV/AIDS care and treatment (WHO Regional Office for the Western Pacific)
32. HIV/AIDS clinical management training modules (WHO Regional Office for the Western Pacific)
33. *Scaling up antiretroviral therapy in resource-limited settings: treatment guidelines for a public health approach*

4. Number of partner organizations whose role in "3 by 5" is agreed and published

Partnerships, which WHO and UNAIDS identified and embraced early in the development of the "3 by 5" strategy, are indispensable for reaching the target.

In November 2003, a meeting of the "3 by 5" Global Partners Group attended by some 30 organizations, institutions, donors, nongovernmental organizations, advocates and people living with HIV/AIDS was held to build support for the "3 by 5" target and to solicit and receive partner input to the draft "3 by 5" strategy. Six months later, more than 90 individuals and groups participated in the second meeting of the "3 by 5" Global Partners Group. In December 2003, no formal agreements were in place to document the nature of the relationships and accompanying expectations. As of 1 June 2004, some 15 specific partnerships were defined by letters or memoranda of understanding. This is below the target of 90.

WHO has improved outreach to the faith-based community, with more than 20 organizations now identified as potential partners. In addition to infrastructure, financial resources and technical expertise, faith-based organizations also offer a vast corps of volunteers and communities of caregivers.

Although clearly documenting the respective roles and responsibilities WHO and its partners will assume in scaling up antiretroviral therapy will continue to be desirable, acknowledging what such partnerships are providing will also be important in the future. Thus, in future progress reports, in addition to documenting the partnerships that have been clearly agreed in writing, WHO will also report what various partner organizations are doing, and – as country-level experience becomes clearer – define more focused measures of the impact of these partnerships.

5. Number of countries appealing to WHO for support for "3 by 5"

Since 1 December 2003, 56 countries have appealed to WHO for support in scaling up national antiretroviral therapy programmes. This is well above the target of 40. The actual expressed demand reflects the considerable need for technical assistance countries require. WHO will be placing priority on strengthening WHO country offices to provide direct assistance, emphasizing developing and implementing plans for scaling up treatment.

6. Number of countries establishing antiretroviral therapy targets in accordance with "3 by 5"

One of the compelling reasons for setting a time-limited and ambitious target for the number of people accessing antiretroviral therapy by the end of 2005 was to challenge countries and the donor community to address global treatment needs. The most visible manifestation of any new approach would be the speed with which countries faced up to their own treatment needs and committed to addressing them by adopting antiretroviral therapy targets in accordance with "3 by 5". WHO predicted that 35 countries would commit to treatment targets in accordance with "3 by 5" by June 2004 – slightly less than those appealing for support for scale-up activities. So far, only 12 countries have antiretroviral therapy targets equal to or greater than the "3 by 5" target. Some countries are in the process of setting national targets; others remain conservative and will need appropriate national success models for inspiration. WHO will continue to vigorously advocate that national governments adopt targets that would allow 50% of the people in need to receive treatment by the end of 2005.

7. Number of countries with a plan for implementing scale-up in accordance with the "3 by 5" target

National implementation plans for scaling up antiretroviral therapy, which outline how national programmes and proposals for the Global Fund to Fight AIDS, Tuberculosis and Malaria will actually be put into operation, are a prerequisite for achieving "3 by 5". In establishing process milestones for activities for scaling up antiretroviral therapy within countries, it was assumed that action planning would usually follow on after a commitment had been made for national targets in line with "3 by 5". Based on 40 countries appealing for help in scaling up antiretroviral therapy, and 35 countries having targets in line with "3 by 5", WHO expected that slightly more than half would have national plans for implementation by June 2004. Such predictions of national preparedness have been too optimistic, and so far only three countries have published these plans.

More encouragingly, as of 30 June 2004, WHO was aware of 20 additional countries currently in the process of developing their national plans for scaling up antiretroviral therapy. WHO is now giving priority assistance for the development of national scale-up plans to many of these countries that have already adopted or are planning to adopt ambitious targets for scaling up.

8. Average price per person per year for the first-line treatment regimen

In April 2004, the lowest price of quality-assured first-line treatment in low-income developing countries that includes fixed-dose combinations of antiretroviral drugs where possible ranged from US\$ 285 (for generically sourced stavudine + lamivudine + nevirapine) to US\$ 675 (for (zidovudine + lamivudine) and nevirapine, sourced from the research-based pharmaceutical industry).⁴ The average price was US\$ 484, which is above the target of US\$ 100–350.

Regimen	Sourced from	Lowest price (US dollars)	Average price (US dollars)
(Stavudine 30 mg + lamivudine + nevirapine)	Ranbaxy Laboratories Limited	285	420
Stavudine 30 mg + lamivudine + nevirapine	Bristol-Myers Squibb Company + GlaxoSmithKline + Boehringer Ingelheim	555	
(Stavudine 30 mg + lamivudine) + efavirenz	Ranbaxy Laboratories Limited + Merck & Co., Inc.	472	472
(Zidovudine + lamivudine) + nevirapine	(Ranbaxy Laboratories Limited or Hetero Drugs Limited) + Hetero Drugs Limited	287	481
(Zidovudine + lamivudine) + nevirapine	(GlaxoSmithKline) + Boehringer Ingelheim	675	
(Zidovudine + lamivudine) + efavirenz	(Ranbaxy Laboratories Limited or Hetero Drugs Limited) + Merck & Co., Inc.	544	564
(Zidovudine + lamivudine) + efavirenz	(GlaxoSmithKline) + Merck & Co., Inc.	584	
Total average			484

The price of first-line treatment with the fixed-dose combination formulation stavudine + lamivudine + nevirapine, sourced from the generic pharmaceutical industry, continues to decline, with the mass media often quoting benchmark prices of US\$ 140–168 per person per year. Nevertheless, the reality is that many countries cannot or do not use this combination or pay more for it. In addition, many people cannot use this combination, either because they need concomitant treatment for tuberculosis (TB) or because they develop side-effects from the drugs contained in it. Consequently, representing these benchmarks as the average price for first-line antiretroviral therapy would not be accurate.

Based on experience from Uganda, the average cost of first-line treatment was calculated assuming that 25% of the people eligible for treatment would use each of the four WHO-recommended first-line treatment regimens. This brings the average price of first-line treatment, weighted for the share of different treatment regimens, to US\$ 484 per person per year. Reaching the December 2005 target of US\$ 50–200 per person per year will require substantial effort to reduce the cost of efavirenz and brand-name nevirapine.

⁴ *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries*. 6th ed. Geneva, Campaign for Access to Essential Medicines, Médecins Sans Frontières, 19 April 2004 (<http://www.accessmed-msf.org/prod/publications.asp?scntid=22420041625454&contenttype=PARA&>, accessed 28 June 2004).

The benchmark of US\$ 140, announced by the William J. Clinton Foundation, requires countries or programmers to provide significant guarantees that are difficult to provide given the relatively small size of their antiretroviral therapy programmes and uncertainty about long-term funding. Consequently, to the best of WHO's knowledge, only a few small transactions of antiretroviral drugs have taken place at this price so far. The other benchmark of US\$ 168 per person per year is a recent one. Prequalified fixed-dose combinations of stavudine + lamivudine + nevirapine were sold at this price to programmes in April 2004 and were publicly offered to WHO at the meeting of the "3 by 5" Global Partners Group in May 2004 by a consultant speaking for Cipla Ltd. Before April 2004, most countries that used generic fixed-dose combinations paid more – between US\$ 200 and US\$ 300 per person per year.

Even in programmes that begin with stavudine + lamivudine + nevirapine as their preferred first-line treatment, about 20% of the people receiving therapy experience severe adverse events and treatment-limiting toxicity related to some components of the regimen. Further, in programmes that enrol significant numbers of TB patients, nevirapine cannot be used because of interactions with the TB drug rifampicin. The most reasonable way to report on the average cost of first-line treatment is therefore to calculate the value of the basket of drugs needed, weighted for their relative share in the basket.

Finally, the benchmarks for stavudine + lamivudine + nevirapine are for generic antiretroviral drugs only. In many countries, generic antiretroviral drugs are either not registered or cannot or will not be used for fear of litigation as a consequence of potential patent infringement. Consequently, the average price of antiretroviral drugs needs to take into account the proportion of first-line drugs originating from the research-based pharmaceutical industry.

Reaching the December 2005 target will require further price reduction among all antiretroviral drugs included in first-line treatment regimens. The various options available include reducing the prices of the drugs that are currently most expensive. However, the most powerful tool for lowering prices is competition. WHO will continue to develop normative and policy guidance to enable countries to buy antiretroviral drugs from an increasing number of manufacturers. Countries can ensure the presence of an enabling legal environment for competition, for example, by changing their patent laws so that they can use the flexibility of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, and some could invest in the local production of antiretroviral drugs so that more competitors enter the market. AMDS will also assist countries in pooling demand for antiretroviral drugs for large tenders to drive down prices by leveraging collective scale.

9. Number of countries using AMDS for procurement and/or distribution of drugs and/or diagnostics

AMDS is a network of units and departments in the United Nations and technical partner organizations that work together to improve access to antiretroviral drugs and HIV diagnostics. Although new procurement partners might join the AMDS network, UNICEF is currently the main procurement partner in AMDS. As of June 2004, 50 projects in 29 countries had used UNICEF supply services for procuring antiretroviral drugs. In addition, one country procured antiretroviral drugs through the WHO supply service for its national programme. This is above the target of 20 countries. At present the volume in each of these supply transactions is small, but it is growing rapidly.

In future, the AMDS secretariat will provide a comprehensive clearing house for information on access to antiretroviral therapy and HIV diagnostics, with information at the global, regional and national levels and easy access to guidance on how to procure and manage these commodities. It will also provide access to an expanding network of partner organizations (such as UNICEF, the World Bank, UNDP, Management Sciences for Health, John Snow Inc., Médecins Sans Frontières and the International Development Association) that already provide technical assistance in procurement and supply management and will broker between these providers and the programmes that need technical assistance. With its partners, AMDS will also create new services. Among these is creating a strategic stockpile of antiretroviral drugs that country programmes can use to overcome stock-outs or to place small start-up orders. This initiative is in urgent need of funding. In addition, AMDS will support the creation of an emergency funding mechanism to deal with short-term cash flow problems in treatment programmes.

10. Number of countries that have introduced training using WHO-supported certification of competence

In June 2004, WHO convened an International Consultation on Antiretroviral Therapy Training and Certification, bringing together partners from more than 46 organizations representing 17 countries. Recommendations will be published soon on establishing in-country certification for health workers involved in antiretroviral therapy. Once these are published, countries will be able to begin using WHO-supported certification of competence.

Delays in establishing a formal framework for certification at the international level and in many countries reflect a situation in which scarce resources have been channelled into meeting urgent training needs at the expense of investing in the development of more formal regulatory mechanisms (see below for an assessment of training activities).

However, the positive response to the WHO Consultation suggests that countries and organizations that have been occupied with rapidly introducing the training of programmers are now keen to consolidate their training efforts and to start developing certification and quality control mechanisms. A significant number of countries are expected to investigate the WHO-supported certification of competence in the next six months.

11. Number of health care providers and community treatment supporters trained to deliver antiretroviral therapy services in accordance with national standards

By June 2004, reports submitted to WHO indicated that more than 15 000 health care workers from 32 focus countries had been trained in antiretroviral therapy since early 2001.⁵ At least 3000 of these people were trained in the first half of 2004, indicating that training efforts are gaining momentum. The number of 15 000 trainees may be somewhat understated, as reports from countries are incomplete.

More than one third of the people trained were physicians, followed by nurses and counsellors. Smaller numbers of community treatment supporters and other people involved in antiretroviral therapy delivery – such as laboratory technicians and pharmacy staff – were also trained.

The clear emphasis on training physicians mirrors the fact that the initial models of antiretroviral therapy service delivery have been largely physician-driven. However, this is unlikely to be sustainable, and newer models of antiretroviral therapy provision need to emphasize the necessity of shifting tasks towards nurses, health care workers and community treatment supporters.

Progress in training now depends critically on countries' ability to closely link existing training efforts with coordinated scale-up and human resources plans and to expand training towards the health workers who are carrying the bulk of the treatment burden at first-level facilities. UNDP's assistance in addressing social and community issues will also be important.

12. Number of service outlets providing antiretroviral therapy services according to national standards

When the WHO "3 by 5" strategy was published in December 2003, some service outlets were already providing antiretroviral therapy in countries targeted by the strategy. However, the number of these outlets was nowhere near sufficient to achieve the global "3 by 5" target, and most were not operating under standardized national frameworks. Since December 2003, WHO and key partners have supported the development of both international and national standards for antiretroviral therapy provision and provided the technical support necessary to scale up the number of health outlets providing antiretroviral therapy services.

At the end of May 2004, the total number of antiretroviral therapy outlets in 20 countries for which these data were available was 498. It is therefore reasonable to assume that the total number of antiretroviral therapy sites existing in June 2004 is likely to be more than the 500 set as a target. The reported figure does not include private outlets in most cases. In many countries, private providers are thought to account for a sizeable proportion of the sites where antiretroviral therapy can be obtained.

⁵ Reports included information provided by national AIDS coordination mechanisms, WHO country offices and WHO mission reports and reports provided by training institutions. Reporting on training prior to 2001 was excluded since many people who were trained never had the opportunity to apply these skills because antiretroviral drugs were not available.

13. Number of partnerships between formal antiretroviral therapy service outlets and community-based groups

From the outset, the "3 by 5" Initiative assumed that effective partnerships between local community-based groups and the providers of antiretroviral therapy services, usually a government-supported entity, were essential to the successful scaling up of antiretroviral therapy. An appropriate measure of the uptake of antiretroviral therapy was considered to be a simple count of such partnerships between organizations of people living with HIV/AIDS and local service outlets. Experience has demonstrated that this approach is not currently generating useful data. More important are the potentially multiple actions and interactions that enable an entire community to participate in and accept the scaling up of antiretroviral therapy.

WHO has already convened community-based groups, including organizations of people living with HIV/AIDS, treatment activists and others dedicated to improving treatment access, and will continue to do so from July to December 2004. The objective of these sessions is to assist in developing appropriate measures and guidelines for community involvement in areas such as programme communication, treatment preparedness and the training of community health workers and other adherence supporters. Clearer qualitative and quantitative measures will be developed to replace the initial indicator that can better measure and monitor the effective involvement of communities in scaling up antiretroviral therapy.

14. Number of public and nongovernmental organization service outlets providing testing and counselling services

The data on service outlets providing testing and counselling are from 18 countries and suggest important preliminary conclusions.

- Many of the countries in which antiretroviral therapy scale-up is planned already have a substantial number of sites for testing and counselling.
- This information has not previously been consolidated, so it remains unclear how many testing and counselling services currently operate in all focus countries and where they are sited: for example, are they integrated within clinical in- and outpatient settings or antenatal care services? What proportion are operated by government? What proportion are nongovernmental organization services? Are they located in areas where the need is greatest?
- Because the "3 by 5" milestone activity constitutes a baseline assessment in many of the countries from which data were requested, the proportion of these services implemented since "3 by 5" was declared as a global target cannot be determined yet. Based on the figures available for this review, at least 173 of the sites were specifically identified as new since December 2003.

Identifying 3 million people needing treatment requires identifying 20 million people living with HIV, assuming that 15% need treatment at any one time.

If the overall HIV prevalence across the focus countries is 10%, 200 million people would need to be tested to identify the 20 million with HIV. However, this number could be very substantially reduced and most likely halved if services targeted the settings in which people living with HIV/AIDS and related diseases are more likely to present. The target of 20 000 testing and counselling service outlets was based on the assumption that reaching sufficient numbers to enable the "3 by 5" target to be achieved would require each site to see an average of 20 people daily and to provide testing and counselling for 5000 people by 31 December 2005.

As part of planning for "3 by 5", WHO advocates integrating decentralized testing and counselling services in all clinical settings where people at greater risk of HIV infection are likely to present, such as sites for services for tuberculosis, sexually transmitted infections, injecting drug users and other sites, including those linked to family planning and antenatal care services.

15. Number of children, women and men with advanced HIV infection receiving antiretroviral therapy

Since December 2003, the number of people receiving antiretroviral therapy in developing and transitional countries has increased from 400 000 to 440 000. Although the number of people receiving antiretroviral therapy is below the original target for June 2004, important groundwork has been laid during the first six months of the “3 by 5” process. Countries with a high burden of HIV/AIDS are working to establish the foundation and crucial mechanisms to prepare an enabling environment for scaling up antiretroviral therapy, including improving technical capacity, drug supply logistics, financial viability and monitoring and evaluation schemes as well as monitoring drug resistance and strengthening health systems overall. With increased funding for scaling up treatment now becoming available, many countries will start scaling up antiretroviral therapy programmes on a wide scale during the next six months.

For the future, WHO technical guidance requests countries to disaggregate their monitoring and evaluation by gender and age to obtain more detailed information about the people receiving treatment. This is critical to understanding the gender equity dimensions of treatment access efforts.

Note on methods

The Department of HIV/AIDS of WHO has been collecting data in the past six months from countries on their estimates of the number of people receiving antiretroviral therapy. This has been done through surveys of key country specialists and informants, reports by national authorities and WHO and UNAIDS staff in the countries, including recently deployed WHO staff. The numbers obtained mostly include estimates for the public health sector and, in some cases, private-sector provision of antiretroviral therapy. After the data were collected, the country-specific estimates were made and rounded to accommodate potential underestimation of those receiving treatment in the private sector. Regional totals were generated from country data when available and by extrapolation when no data were available to give regional estimates of people being treated and antiretroviral therapy coverage.

An external consultant’s report was used in these extrapolations, and this process provided an additional source for estimating the antiretroviral therapy coverage. These estimates were compared with those derived from the approach of the Department of HIV/AIDS. In almost all cases, the numbers were essentially the same. In a few cases, substantial differences were found and additional data were sought to resolve the inconsistencies. When the difference could not be resolved, the average of the two estimates was used.

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