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## **Foreword**

On World AIDS Day 2003, WHO and UNAIDS set an ambitious target that 3 million people living with HIV/AIDS in developing and transitional countries would be receiving antiretroviral therapy by 2005. This "3 by 5" target was received with understandable scepticism.

It was a necessary risk.

Based on the right to treatment and building on years of work by governments, donors, and civil society, "3 by 5" aims to help infuse hope and energy into communities that have been largely immobilized by the devastating toll of the epidemic. Further, we were convinced that the entire United Nations System, and especially WHO, could do much more to help countries provide treatment to the poorest, most affected communities.

As we present our second progress report, we are witnessing incredible synergy arising from strategic partnerships across a variety of sectors. The global effort to achieve "3 by 5" is gaining momentum and has clearly shifted from vision to reality.

Progress in the second half of 2004 has been dramatic, reaching the December milestone of 700 000 people receiving antiretroviral therapy. A remarkable international movement has now gathered behind the "3 by 5" target. Most importantly, many countries have shown leadership by increasing their own political and financial commitments, mobilizing human resources and effectively engaging partners to scale up treatment. It is clear that that the success of "3 by 5" will ultimately depend on continued strong commitment and follow-through by governments.

Partnerships have become one of the main engines of HIV/AIDS treatment scale-up. At the country level, unprecedented responses are being made by both the public and private sectors, caregivers, activists, faith-based communities and the mass media. Internationally, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief, the World Bank, the Clinton Foundation, Médecins sans Frontières and many other partners have all played a critical role.

We are also pleased to report that initial data show that adherence and treatment success rates in developing countries are similar to if not higher than those obtained in affluent, industrialized countries. As the health of people living with HIV/AIDS improves with treatment, we are beginning to see the rejuvenating impact on families, communities and economies. As access to treatment increases, more opportunities emerge to promote prevention. Only through effective prevention services will treatment be sustainable.

As this report reflects, many real challenges must still be overcome, but they are not insurmountable. With billions of dollars available, a surge of political will and a groundswell of public demand for antiretroviral therapy, the "3 by 5" target can play a critical role in focusing attention and galvanizing action. A sustained commitment to the wellbeing of people living with HIV/AIDS is crucial if we are to meet and exceed the target of 3 million together.

LEE Jong-wook
Director-General

World Health Organization

Executive Director
Joint United Nations Programme

on HIV/AIDS (UNAIDS)

# **Executive summary**

#### Statistical overview

In the second half of 2004, the number of people on antiretroviral (ARV) therapy in developing and transitional countries increased dramatically from 440 000 to an estimated 700 000. This figure represents about 12% of the approximately 5.8 million people currently needing treatment in developing and transitional countries and includes people receiving ARV therapy supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief, the World Bank and other partners.

In sub-Saharan Africa, the number of people on treatment doubled from 150 000 to 310 000 in just six months. In Botswana, Kenya, South Africa, Uganda and Zambia the number of people receiving treatment increased by more than 10 000 in each country. Botswana, Namibia and Uganda now have an estimated ARV therapy coverage that exceeds one quarter of all people needing treatment, and 13 countries in the region have exceeded 10% coverage. This region now has well over 700 sites that can deliver ARV therapy.

In East, South and South-East Asia, 100 000 people were on treatment by the end of 2004, twice the number reported six months previously. Thailand is leading the way, expanding treatment access to all districts with more than 900 ARV therapy facilities and starting more than 3000 people on treatment every month.

In Latin America and the Caribbean, access to ARV therapy continued to improve. Brazil has led the way by providing access to ARV therapy for its entire population, but nine more countries also have estimated coverage rates exceeding 50%. Progress in Eastern Europe, Central Asia, North Africa and the Middle East has generally been much slower.

Initial data show that treatment success rates in developing countries are just as good as those in affluent industrialized countries. Adherence to regimens is as high as 90% and treatment benefits to individuals are dramatic, with survival rates exceeding 90% after one year and 80% after two years of ARV therapy.

#### **National Achievements**

Crucial to the rapid expansion has been the courageous public commitment by governments in affected countries, making HIV/AIDS interventions a fiscal priority and a consistent theme of public outreach. Led by effective and energetic national AIDS councils, many countries are exceeding their individual targets, showing that the global "3 by 5" target can be attained if countries lead the way, make the most of their own resources and engage partners effectively.

In several countries, dramatic improvements in treatment access have followed an increase in the number of locations for delivering ARV therapy. Generally, the numbers of women on therapy have increased as rapidly as those for men, but treatment for children is still a neglected issue.

#### Close collaboration

Over the past 12 months, a strong international movement has gathered behind the "3 by 5" target. Partnerships, both within countries and globally, are among the main engines of HIV/AIDS treatment scale-up. At the country level, the response has been unprecedented from both the public and the private sectors. Building on ongoing work in many affected countries, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief and the World Bank have all played a critical role in making scale-up possible. Their large new financial commitments have greatly facilitated activities at the country level, augmented responses by other donors and in general boosted advocacy efforts.



#### The building blocks of ARV therapy scale-up

In many locations, several key building blocks of ARV therapy programmes have been put into place. These include expanding access to HIV testing and counselling; integrating ARV therapy and tuberculosis programmes; improving access and integrating care and support services; preventing mother-to-child HIV transmission; providing drugs and diagnostics; training for professionals, community members and people living with HIV/AIDS; developing systems for tracking and monitoring the people receiving treatment; and institutionalizing operational research to translate hard-won experience into evidence-based programme design adapted to local conditions. The scaling up of ARV therapy, if managed wisely, can lead to the strengthening of both HIV prevention programmes and the broader health system.

During the second half of 2004, an additional 40 000 to 50 000 people initiated treatment each month worldwide. Nevertheless, there are enormous barriers to reaching the target in 2005. Many of the advances have been geographically uneven: critical building blocks are still missing in far too many areas of high-burden countries.

The success of "3 by 5" will ultimately be determined by the action taken in countries, by governments, civil society, health care providers and partner organizations. Political will demonstrated at the highest possible level in any individual country will be decisive in determining whether it reaches its target. Governments can also be encouraged by the flexibility and creativity already displayed by major donors in making money move to where it is needed most, but their efforts must now be taken to the next level. Given present system costs, at least US\$ 2 billion in sustained additional funding from national governments and external funders will be necessary to provide access to ARV therapy for approximately 2.3 million people.

The resource gap is only one of many difficult obstacles that confront us. Cost of ARV medicines to countries and individuals is an area of particular concern, as is the geographical distribution of services related to HIV/AIDS and human resources. There is still a critical need to improve the infrastructure for delivery of care and treatment. Organizations working in the field of HIV/AIDS must ensure that their efforts offer real solutions to the very real problems countries will face. However, progress in 2004 has laid the foundations for an extraordinary push to reach the "3 by 5" target by the end of 2005.

## Introduction

In an effort to keep abreast of rapid changes in the landscape of the HIV pandemic, WHO and UNAIDS report semiannually on progress toward "3 by 5". The first update was presented at the XV International AIDS Conference in Bangkok, Thailand, in July 2004.

This second report measures progress made by countries and describes how international partners are supporting their efforts. In addition, it summarizes how the building blocks of antiretroviral (ARV) therapy programmes are being put into place and how issues beyond treatment are being addressed.

It provides examples of country progress and a global estimate of the number of people receiving ARV therapy, and it assesses how well the therapy is working. It also identifies some of the challenges faced in resource-constrained settings and how these are being met by improving health care systems, links between prevention and treatment and providing equal access to quality care.

This report is based on reports and updates provided by dozens of international, national and community organizations involved in scaling up ARV therapy. We thank everyone who has contributed to this progress report. WHO departments at the headquarters, regional and country levels worked with national governments and nongovernmental organizations to gather the latest information on the scaling up of ARV therapy. The UNAIDS Secretariat and the UNAIDS Cosponsors gathered information on how United Nations agencies and international nongovernmental organizations are translating the rapidly expanding commitment to "3 by 5" into action.

Many partners in scaling up ARV therapy have shared their experiences on the ground. WHO, UNAIDS, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief and the World Bank participated in special meetings to share data and reports so that this consensus report could present the most accurate estimates.

Reporting the results of the intensive effort to collect information could easily require hundreds of pages. In the context of the semiannual "3 by 5" progress reports, we have chosen to focus on the most common and important themes that emerged from the reports, illustrated by examples provided by countries and partner organizations. The data presented in this report either originated in their entirety with health ministries or, where country documentation did not include all treatment projects, was supplemented by approved figures from externally funded aid programmes.

# Progress in numbers

The last six months have seen dramatic progress toward the "3 by 5" target. Between June and December 2004, the number of people receiving antiretroviral (ARV) therapy in developing and transitional countries increased to approximately 700 000 (low estimate 630 000, high estimate 780 000) (Fig. 1). The upward trend was driven especially by countries in sub-Saharan Africa, where the number of people receiving ARV therapy doubled.

The figure of 700 000 represents about 12% of the estimated 5.8 million adults who currently need ARV therapy in developing and transitional countries. It includes people receiving ARV therapy supported by national programmes, nongovernmental organizations, the private sector, the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States President's Emergency Plan for AIDS Relief, the World Bank and other partners.

Fig. 1. Number of people receiving ARV therapy in developing and transitional countries by region, 2002–2004

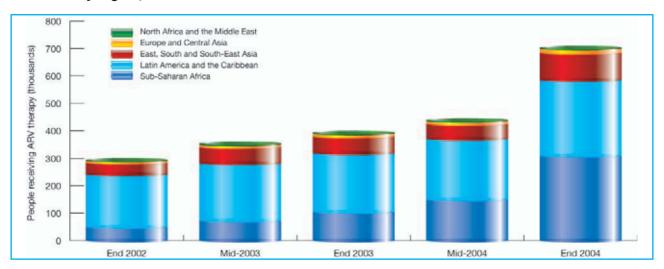


Table 1. Estimated number of people receiving ARV therapy, people needing ARV and percentage coverage in developing and transitional countries by region, December 2004<sup>a,b</sup>

| Geographical region               | Estimated number of people<br>receiving ARV therapy,<br>December 2004 (low<br>estimate-high estimate)° | Estimated number<br>of people 15–49<br>years old needing<br>ARV therapy,<br>2004 <sup>d</sup> | ARV therapy<br>coverage,<br>December<br>2004 (%)° | Estimated<br>number of people<br>receiving ARV<br>therapy, June<br>2004 |
|-----------------------------------|--|---|---|---|
| Sub-Saharan Africa                | 310 000 [270 000–350 000]  | 4 000 000   | 8%  | 150 000   |
| Latin America and the Caribbean   | 275 000 [260 000–290 000]  | 425 000   | 65%   | 220 000   |
| East, South and South-East Asia   | 100 000 [85 000–115 000]   | 1 200 000   | 8%  | 55 000  |
| Europe and Central Asia           | 15 000 [13 000–17 000]   | 150 000   | 10%   | 11 000  |
| North Africa and the Middle Eastf | 4 000 [2 000–6 000]  | 55 000  | 7%  | 4 000   |
| Total                             | 700 000 [630 000–780 000]  | 5.8 million   | 12%   | 440 000   |

Note: numbers do not add up due to rounding.

<sup>&</sup>lt;sup>a</sup> Annex 1 explains the methods used and also includes a table with the same data according to WHO region. Annex 2 includes the country-level data.

<sup>&</sup>lt;sup>b</sup> 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.

<sup>&</sup>lt;sup>c</sup> A few countries report the number of children younger than 15 years of age receiving ARV therapy, and they have been included in this table. Preliminary data show that, overall, less than 5% of the total number receiving ARV therapy are children younger than 15 years of age.

<sup>&</sup>lt;sup>d</sup>The figure presented is the midpoint of the low and high estimates of the number of AIDS deaths and the number of AIDS cases. The needs estimates are based on the methods described in Annex 1. Estimates for individual countries may differ according to the local methods used.

This is a best coverage estimate based on the midpoints of the number of people receiving ARV therapy and the estimated need for ARV therapy.

<sup>&</sup>lt;sup>f</sup> Except for Turkey, no updates have been received from this region since June 2004.

Several African countries have made enormous progress during the second half of 2004. The number of service delivery points for ARV therapy has increased to well over 700, leading to a sharp rise in the numbers of people starting treatment. The number of people receiving treatment in Botswana, Kenya, South Africa, Uganda and Zambia increased by more than 10 000 in each country. Botswana, Namibia and Uganda now have an estimated ARV therapy coverage that exceeds one quarter of all people needing treatment, and 13 countries in the region have exceeded 10% coverage. Nevertheless, overall coverage in sub-Saharan Africa remains low, at about 8% (Table 1, for WHO Regions see Annex 1).

In East, South and South-East Asia, the numbers of people receiving treatment also increased rapidly, from about 50 000 in June 2004 to 100 000 in December 2004 (Table 1). Thailand accounts for most of the increase. The numbers of people receiving treatment in Latin America and the Caribbean continued to increase steadily to 275 000, which is estimated to be about two thirds of all people in need. Brazil alone reported 154 000 people receiving treatment by December 2004.

Countries in Europe and Central Asia reported modest increases to reach 15 000 people receiving treatment. Countries in North Africa and the Middle East reported little new information (Table 1). The numbers for these countries were therefore kept at the June 2004 level in the global totals, although efforts to enhance access to treatment are increasing.

#### Estimating the numbers of people receiving ARV therapy

The global figures are powerful and reassuring indicators of progress. We are confident that the current figures are of much greater quality than any previous data on ARV therapy, but they must be read against a backdrop of systems for monitoring the people receiving ARV therapy that are still being adapted to local conditions in many places. The numbers are based on data reported by countries in written reports or through personal communication with key informants. The data have been checked against other sources, such as reports by donors or nongovernmental organizations, and all efforts have been made to avoid double counting.

Ideally, country reports should distinguish between people initiating ARV therapy, people who do not adhere to treatment and those who have died. For instance, Botswana reported that 21 267 people had initiated treatment in public clinics between January 2002 and September 2004 but 1761 (8%) of these had died. This level of detail has been difficult to achieve in some countries that are still in the process of building their monitoring systems.

Measuring the ARV therapy provided in the private sector is difficult. Many people receive their drugs through local pharmacies and private clinics that seldom report their activities to the government. Many private companies have programmes supporting ARV therapy for workers with advanced HIV infection that are not included in the estimates. An example of good practice is again Botswana, where it is reported that nearly one quarter of the people receiving ARV therapy get it through the private sector. In many instances however, people attending health facilities outside the public sector are not recorded in official statistics.

There is also a time lag between global reporting, which is for the end of 2004, and country reporting, which usually relates to an earlier point in time. Given the current rapid expansion in numbers, trends must be estimated and projected to a standard time period. Thus, the estimates for the end of 2004 are based on simple linear projections of reported numbers using the current trend as an indicator of growth and taking mortality into account.

Consequently, the global estimate is likely to be lower than the actual number on treatment because all the evidence indicates very rapid scaling up of both the numbers of sites and the numbers receiving treatment. Because the overall estimates by country are uncertain, Annex 1 and 2 indicate low estimates and high estimates. The number of people receiving ARV therapy is estimated to lie between 630 000 and 780 000. The Annexes also explain in detail how the numbers of people on treatment and those needing treatment were derived.

#### Treatment works

Overwhelming evidence from several national programmes and individual treatment centres indicates that highly active triple-drug therapy for HIV/AIDS can be delivered effectively. For years, most of the examples of successful treatment programmes came from industrialized countries. Brazil has clearly shown that a

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middle-income country can also deliver ARV therapy through the public sector and thereby achieve universal access to treatment with excellent results. These precedents offer inspiration to people around the globe that political will can make treatment a reality in developing and transitional countries.

Many have questioned whether such treatment effectiveness can be achieved in resource-constrained regions with a far higher burden of HIV/AIDS, that require a less physician-oriented and more standardized public health approach. New data now show, however, that a public health approach to ARV therapy can yield exceptional results in many developing countries.

Adherence rates have been consistently high in the vast majority of demonstration projects and start-up services. For example, self-reported adherence to treatment in a community-based ARV therapy programme initiated by Médecins Sans Frontières (MSF) in Khayelitsha township in Cape Town, South Africa demonstrated that 90% of those receiving therapy take more than 95% of their medication<sup>2</sup> (Fig. 2). An initiative sponsored by the Government of Senegal has maintained good (80–90%) adherence over two to three years.<sup>3</sup>

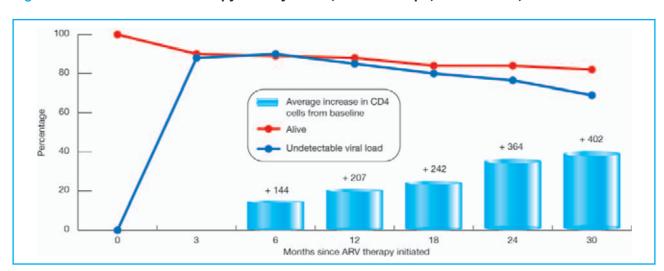


Fig. 2. Success of ARV therapy in Khayelitsha, Western Cape, South Africa, 2002–2004

More importantly, empirical data show that treatment works to the same degree observed in Europe and the United States when triple combination therapy was first used. In Entebbe, Uganda, more than 90% of those with CD4 counts below 200 are alive after 15 months of ARV therapy.<sup>4</sup> Only 50% of a group of adults with similar levels of immune suppression without access to ARV therapy were alive after 15 months (Box 1). Botswana has reported similar survival rates (91%) after 15 months of treatment.

In Khayelitsha and in Senegal, 80% of the people receiving ARV therapy are alive after 30 months of follow-up.<sup>5</sup> The overall probability of survival of almost 7000 people receiving ARV therapy in clinics supported by MSF in several countries after 24 months of treatment was 85%.<sup>6</sup> The effects of treatment on immunity and viral load are comparable to those of treatment programmes in industrialized countries. Botswana, for example, reported that 85% of the people receiving ARV therapy had complete viral load suppression at six months. At 15 months, their average weight increased 10 kg and their average CD4 count increased by 220.<sup>7</sup>

<sup>&</sup>lt;sup>1</sup> Marins JRP et al. Dramatic improvement in survival among adult Brazilian AIDS patients. *AIDS*, 2003, 17:1675–1682.

Coetzee D et al. Outcomes after two years of providing antiretroviral treatment in Khayelitsha, South Africa. AIDS, 2004, 18:887–895. Goemaere E et al. Evolving experience after three years of ART in Khayelitsha. *MedGenMed*, 2004, 6(3) [eJIAS, 2004, 11(1): ThPeB7249] (http://www.iasociety.org/ejias/show.asp?abstract\_id=2169310, accessed 31 December 2004).

Laurent C et al. Long-term benefits of highly active antiretroviral therapy in Senegalese HIV-1 infected adults. *Journal of AIDS*, 2005, 38:14–17.

Data provided by the Development of Antiretroviral Therapy in Africa (DART) team in Uganda.

<sup>&</sup>lt;sup>5</sup> See notes 2 and 3.

Data provided by MSF office in Geneva, Switzerland, combining the data reported for sites in 27 countries.

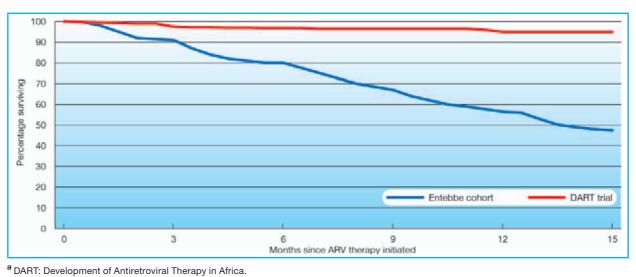
De Korte D et al. Introducing ARV therapy in the public sector in Botswana. Case study. Geneva, World Health Organization, 2004 (http://www.who.int/hiv/pub/prev\_care/botswana/en, accessed 31 December 2004).

#### Box 1. Successful treatment in Entebbe, Uganda

In Entebbe, Uganda, many adults with HIV/AIDS have given consent and participated in trials of interventions to reduce morbidity and mortality. Some interventions such as isoniazid and co-trimoxazole prophylaxis were effective. Others, such as vaccination against *Pneumococcus* spp., the commonest cause of bacterial pneumonia, were not. The overall survival of the people in the Entebbe cohort who had a CD4 count below 200 was poor and similar to that seen in the early days of the HIV/AIDS epidemic in the United States.

Since January 2003, ARV therapy has been available through the DART (Development of Antiretroviral Therapy in Africa) trial – and more than 1050 people with CD4 counts below 200 have commenced triple-drug therapy. Survival has improved dramatically. Instead of 50% mortality after 15 months of follow-up, more than 90% of trial participants on ARV therapy are still alive, and most have resumed normal activities (Fig. 3).

Fig. 3. Survival of people receiving ARV therapy through the DART trial versus the people in the Entebbe cohort receiving other interventions, Entebbe, Uganda, 2004<sup>a</sup>



#### The challenges of ensuring access

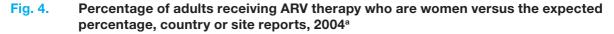
Ensuring access to care and treatment is the cornerstone of "3 by 5". This presents enormous challenges, and one of the first steps is to develop information systems that adequately monitor gender equity and resources to serve poor and marginalized people.

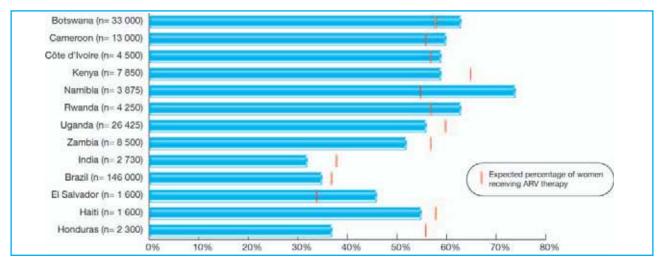
The AIDS epidemic update 2004 by UNAIDS and WHO<sup>8</sup> highlights the need to address issues related to women and girls, in terms of both prevention and treatment. In developing countries, 17.2 million women are living with HIV/AIDS; 48% of the adults living with HIV/AIDS are women. In sub-Saharan Africa, women account for 57% of the adults living with HIV/AIDS. Treatment needs may differ, depending on the epidemic stage and course, but those receiving ARV therapy should ultimately reflect these same proportions.

Although many countries do not report treatment figures by gender, data are available from a number of countries or sites in Latin America, the Caribbean and sub-Saharan Africa. Fig. 4 compares the proportion of adults receiving treatment who are women with the expected proportion based on the HIV prevalence.

The figures indicate that women and men are about equally represented in treatment populations in most countries. In Namibia, however, more women are benefiting, whereas in Honduras, and to a lesser extent India, women are underrepresented. It is critical to step up the monitoring of access and utilization to ARV therapy programmes by gender.







<sup>&</sup>lt;sup>a</sup> The expected percentage of women receiving ARV therapy is based on the percentage of people living with HIV/AIDS who are women.

Other dimensions of equity also need to be monitored, and access for poor people is of particular concern. Initially, new treatment programmes will be rolled out in urban areas where human resources and infrastructure are in place. It is important to ensure that rural populations can access care while care and treatment systems are being developed and implemented in their communities. The expansion of ARV therapy programmes to rural areas will present special challenges, but there are examples of successful rural programmes where community health workers play a key role, such as in Haiti.

Meanwhile, even where services exist they must be within reach for all members of the community. Uptake of ARV therapy increased rapidly after user fees were abolished in Zambia, especially among women, indicating the importance of reducing economic barriers to access.

Another area of concern is access to treatment for marginalized groups, such as sex workers and injecting drug users, men who have sex with men, prisoners and, in some settings, migrants or ethnic minority groups. Brazil and the triangular clinics in Kermanshah, Islamic Republic of Iran<sup>9</sup> provide good examples of how to address the special needs of injecting drug users. Nevertheless, much more needs to be done to reach this population.

Oppenheimer E, Hernandez Aceijas C, Stimson G. Treatment and care for drug users living with HIV/AIDS. London, Centre for Research on Drugs and Health Behaviour, Imperial College, 2003 (http://www.ahrn.net/img/document/Treatment\_care\_for\_DUs.pdf, accessed 31 December 2004).

# Progress in countries

For highly affected countries, response to the global health emergency has been a joint project of governments, civil society and the private sector. Courageous effort has led in several instances to remarkable progress, often in very difficult fiscal, political and social circumstances. A significant proportion of the funding for scale-up has come from countries themselves, despite a host of competing and urgent priorities. National AIDS councils and other coordinating bodies have developed rapidly in recent months, in some cases almost from the ground up. Many countries have set specific numerical targets for people on ARV therapy by the end of 2005.

#### Botswana: political leadership shows the way

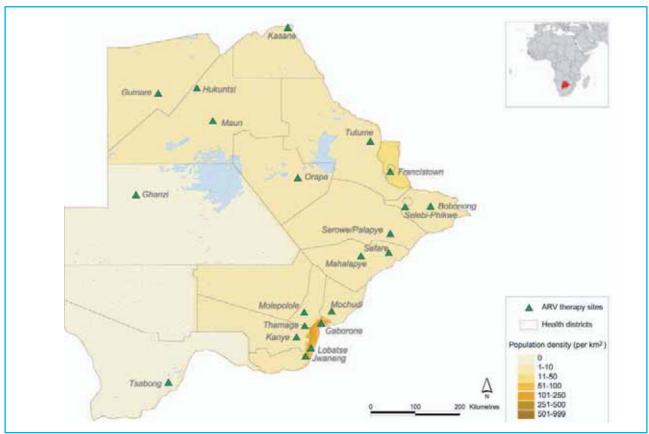
In Botswana, where one in three pregnant women tests HIV positive, political leadership and public-private partnerships are making a significant difference.

Faced with the second highest HIV prevalence in the world, the Government of Botswana has made HIV/AIDS a priority and has adopted a compelling, long-term vision to have no new HIV infections by 2016, when Botswana will celebrate 50 years of independence.

One of the first steps was creating a public-private partnership, the African Comprehensive HIV/AIDS Partnerships, with the Bill & Melinda Gates Foundation, The Merck Company Foundation and the pharmaceutical company Merck & Co., Inc.

ARV therapy programmes were first implemented in January 2002 with the Princess Marina Referral Hospital in the capital, Gaborone. Twelve facilities were offering ARV therapy by 2003 and 23 sites in 2004, covering all but two districts (Fig. 5). The programme is also being extended from hospitals to clinics.

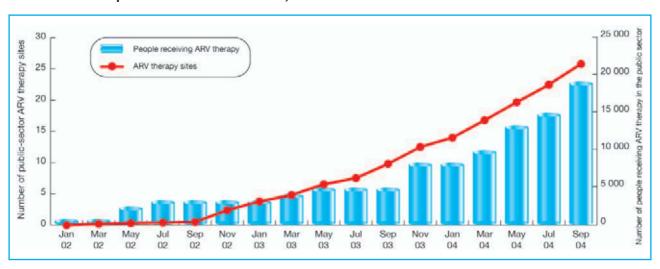
Fig. 5. Location of sites providing ARV therapy in Botswana, September 2004



By March 2004, 2212 health workers had been trained including physicians, nurses, pharmacists, counsellors and other health workers. Of these, 536 were recruited specifically to support ARV therapy and to implement programmes for preventing mother-to-child transmission of HIV.

The number of adults receiving treatment in Botswana rose gradually during the first years of the public-private partnership and much more rapidly in 2004. About one quarter receive treatment through private facilities. In the public sector (Fig. 6), ARV therapy is provided free of charge to citizens of Botswana. Adherence in terms of self-reporting, pill counts and attending scheduled appointments is good (85%) and is confirmed by complete viral load suppression every six months.

Fig. 6. Number of public-sector ARV therapy sites and number of people receiving ARV therapy in the public sector in Botswana, 2002-2004



A social mobilization campaign designed to increase public awareness of the availability and outcomes of ARV therapy has helped to reduce stigma and increased the involvement of people living with HIV/AIDS in promoting a supportive environment. A comprehensive approach to the entire family of the person initially diagnosed substantially increases public awareness and support for the programme. A routine offer of HIV testing was introduced in hospitals in January 2004. 10 Pregnant women are told that HIV tests are standard and are asked whether they want to opt out - an approach often used for other standard medical tests. During the first four months, 18 hospitals offered HIV testing to 6384 people, of whom one in seven opted out.

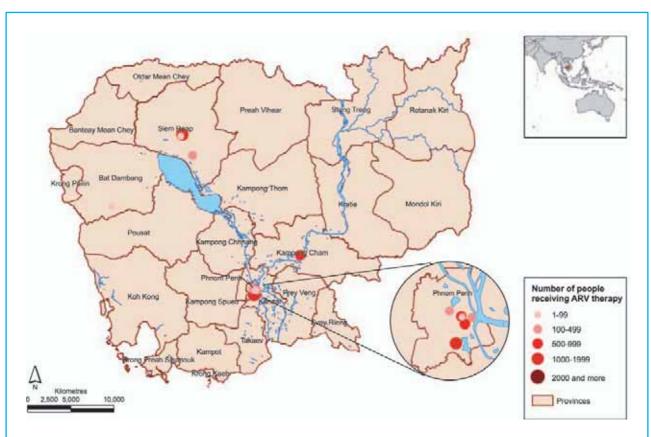
#### Cambodia: coordination at the country level

At the end of 2002, access to comprehensive HIV care and support services was limited, concentrated in urban areas and almost entirely supported by international nongovernmental organizations. Availability of treatment for opportunistic infections and ARV therapy was limited to three hospitals in the capital, Phnom Penh, and the major provincial city of Siem Reap.

Significant progress has been made in the past two years. The National Center for HIV/AIDS, Dermatology and Sexually Transmitted Infections of the Ministry of Health has successfully established a broad partnership around a national framework for prevention and care that includes increasing access to ARV therapy and focuses on decentralizing services to districts beyond the main cities.

By the end of 2004, 75 accredited sites were offering testing and counselling. These included 61 supported directly by government, 13 by nongovernmental organizations and one private centre established in Phnom Penh. Care services, including access to ARV drugs, are currently being expanded to seven sites in Phnom Penh and a further seven sites in other districts. At the end of October 2004, 4527 people were receiving ARV therapy (Fig. 7). This corresponds to about one in five adults who need treatment. About 7% of those receiving treatment were children.

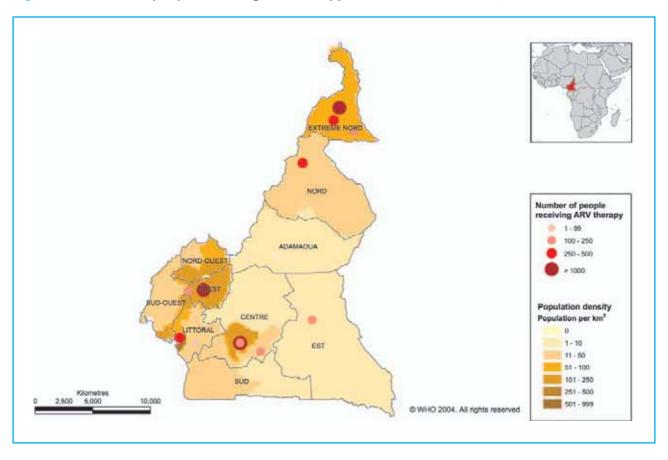
Fig. 7. Number of people receiving ARV therapy at 14 sites in Cambodia, December 2004



#### Cameroon: rolling out testing and counselling

As of 2003, UNAIDS and WHO estimated that 560 000 people in Cameroon were living with HIV/AIDS, which accounts for about 49 000 annual deaths. Cameroon has set a national target of providing ARV therapy to 36 000 people living with HIV/AIDS by the end of 2005. By November 2004, more than 12 000 people were receiving treatment (Fig. 8). Strong political commitment over the past five years and a dramatic decrease in cost from US\$ 600 to US\$ 30 per month of treatment in four years have been the indispensable prerequisites for scale-up. Counselling has also become less costly, and more people are requesting HIV testing. Provincial centres now assess eligibility for treatment at entry points such as the 14 voluntary counselling and prevention centres, 160 sites for preventing mother-to-child HIV transmission, 21 certified treatment centres and 140 tuberculosis screening centres.

Fig. 8. Number of people receiving ARV therapy at 21 sites in Cameroon, October 2004



#### Haiti: Global Fund helping to turn the tide

Haiti is the poorest country in the Americas and also, not coincidentally, the country most burdened by HIV. Political strife and natural disasters have also made work in Haiti extremely difficult in 2004. Nevertheless, remarkable strides have been made in the struggle against AIDS, and one reason is that Haiti was one of the first countries to receive funding from the Global Fund to Fight Aids, Tuberculosis and Malaria. Haiti was able to respond quickly to the first funding round because of a broad-based country coordinating mechanism under the activist leadership of former First Lady Mildred Trouillot Aristide, who had also led the Haitian delegation to the United Nations General Assembly Special Session on HIV/AIDS in 2001. A broad range of missions working to improve health in Haiti offered technical assistance. A group of AIDS-focused nongovernmental organizations worked with both officials of the Ministry of Health and groups of people living with HIV/AIDS to propose an integrated prevention-and-care model that also stressed the importance of community-based efforts in both rural and urban Haiti.

One of the chief challenges for many of those implementing the projects are low rates of literacy and numeracy, especially in rural Haiti. The Global Fund proved responsive to requests for simplified reporting, and the Global Fund's local fund agents also provided technical assistance in accounting and reporting. The Global Fund provided the first large grants that many smaller organizations had received. Nevertheless, with broad technical assistance and the hard work of those on the front lines of prevention and care, Haiti was among the countries meeting or exceeding all the goals of the initial proposal.

The Global Fund also provided Haiti with its first substantial funding for care for people living with advanced HIV disease. Tens of thousands sought voluntary counselling and testing. Support from the President's Emergency Plan for AIDS Relief, working closely with the Global Fund, between February and September 2004 provided ARV therapy to 2800 people in urban and central Haiti. The advent of proper AIDS care has led to a sustained interest in voluntary counselling and testing, which has also provided new opportunities for both primary and secondary prevention. The safety of transfusion has improved, with at least one new blood bank established in central Haiti under the auspices of the Haitian Red Cross.

These successes are due in great part to the ability of the Global Fund to respond quickly and flexibly to the great need registered in poor countries, which are also those that often have inadequate infrastructure for managing and reporting. Global Fund experience in Haiti suggests that improving such capacity should be a part of projects rather than a reason to avoid funding small and administratively weak organizations in areas without electricity, adequate roads or land telephone lines.

#### Mozambique: first steps towards an ambitious goal

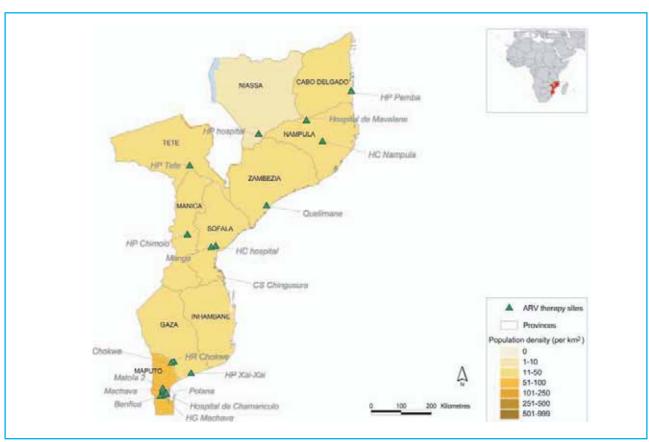
Ravaged by decades of civil war, a slowly recovering Mozambique is another example of what can be achieved in extremely difficult circumstances.

With about 200 000 adults needing ARV therapy, the country's major challenges include a scarcity of resources, shortages of trained health care workers and poor coordination among several partners working in the country. Nevertheless, there is strong political commitment, and the National Health Sector Strategic Plan to Combat Sexually Transmitted Infections and HIV/AIDS calls for scaling up ARV therapy to 132 000 people by the end of 2008.

Mozambique has a specific plan to train 2000 intermediate-level health care professionals, and a new drug management and logistics system is being developed in anticipation of a massive increase in ARV therapy coverage.

Given the scale of the challenges, the increased availability of ARV therapy during 2004 is encouraging, with the Ministry of Health reporting almost 6300 people receiving treatment in November 2004 versus 2800 in June 2004. Twenty-three sites offer ARV therapy in the public sector through collaboration between the government and nongovernmental organizations such as the Community of Sant'Egidio, MSF and Health Alliance International (Fig. 9).

Fig. 9. Location of sites providing ARV therapy in Mozambique, October 2004



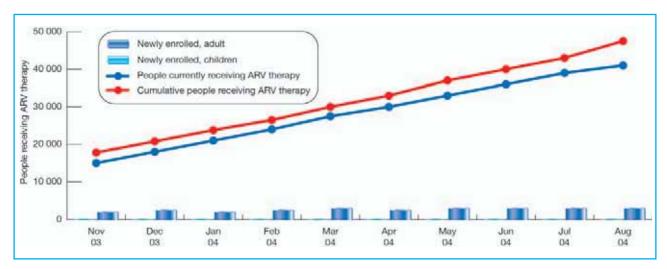
#### Thailand: rolling out in all districts

In 2003, UNAIDS and WHO estimated the number of people living with HIV/AIDS in Thailand to be 570 000 and that 58 000 deaths were related to AIDS. The national ARV therapy programme includes extensive training of health personnel, a standardized national ARV therapy protocol, a computerized central procurement and supply system with regional centres, the formation of a laboratory network and a well-functioning monitoring and evaluation system. An electronic system for data transmission is being put in place. The Government of Thailand increased its budget for ARV therapy from 300 million baht (US\$ 7.7 million) in 2003 to 800 million baht (US\$ 20.5 million) in 2004.

The programme was rolled out from specialist centres to 914 hospitals in three years. Patient groups and nongovernmental organizations have been working to provide people living with HIV/AIDS with enough knowledge to make informed decisions on treatment and to play a central role as partners in providing care. The number of people receiving ARV therapy has been increasing linearly, with more than 3000 new adults and an additional 200–300 children enrolled every month between January and August 2004 (Fig. 10). Since there were 40 000 people on treatment in August 2004, Thailand is projected to have reached more than 50 000 by the end of 2004.

Thailand has also made a major effort to enhance prevention and treatment of opportunistic infections, including co-trimoxazole prophylaxis, the treatment of TB and secondary prophylaxis for cryptococcal meningitis among people living with HIV/AIDS.





<sup>11</sup> Kumphitak A et al. *Involvement of people living with HIV/AIDS in treatment preparedness in Thailand*. Geneva, World Health Organization, 2004 (http://www.who.int/hiv/pub/prev\_care/thailand/en, accessed 31 December 2004).

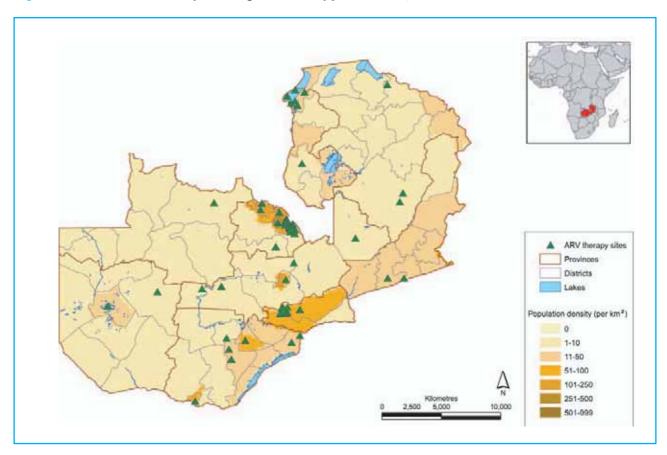
#### Zambia: a rapidly expanding programme

With a national HIV prevalence of 15% and growing numbers of people with advanced HIV infection, the demand for treatment and care in Zambia increased rapidly during the 1990s. Until November 2002, a single drug through the private sector was the only available treatment. In January 2003, the government decided to purchase sufficient drugs to treat 10 000 people but within a year its target increased to 100 000, which is well over 50% of the estimated number of people needing ARV therapy.

The public sector began providing ARV therapy with two pilot sites at the University Teaching Hospital Lusaka and at Ndola Central Hospital. The second phase extended to the remaining seven provincial hospitals plus Kitwe Central Hospital. The final phase involved roll-out at the district level. By the end of 2004, ARV therapy was available at 53 centres (Fig. 11). Twenty-four of 72 districts had at least one site offering ARV therapy and 11 districts had two or more sites. The distribution of sites closely mirrors Zambia's population distribution, with most sites concentrated in Lusaka and in the Copperbelt.

By September 2004, more than 11 000 people were receiving ARV therapy through the public sector versus just over 7000 in July, an increase of 57% in less than three months. The government decision to make ARV therapy free of charge is likely to have played a major role in this rapid increase. An additional 2400 people receive ARV therapy through the private sector, mainly through the mining industry. The increase in provision of ARV therapy to children has been equally rapid, although children on treatment still accounted for only 2.6% of all those receiving treatment.

Fig. 11. Location of sites providing ARV therapy in Zambia, November 2004



# Sharing the task

During 2004, the mobilization around the "3 by 5" target has grown into a mature partnership. At least 136 partners are formally involved as advocates, donors, advisers, collaborators and providers of funding and technical and other services (Table 2). As relationships continue to evolve, new synergies develop, and each new partner brings skills and networks that greatly enhance the scope of "3 by 5". Further, these partners extend and deepen their relationships beyond the early discussions. Although the partnership focuses especially on scaling up treatment, it also addresses key issues such as equity, prevention and health systems.

Table 2. Nature and focus of the 136 partners of the "3 by 5" Initiative

| Nature of partnership <sup>a</sup> |    | Focus of partnership <sup>a</sup>       |    |
|------------------------------------|----|---|----|
| Technical                          | 86 | ARV therapy                             | 69 |
| Collaborative                      | 54 | Advocacy                                | 63 |
| Networking                         | 32 | Prevention                              | 27 |
| Financial                          | 14 | Donors                                  | 22 |
| Political                          | 8  | Voluntary counselling and testing       | 21 |
|                                    |    | Preventing mother-to-child transmission | 17 |
|                                    |    | Procurement                             | 11 |

<sup>&</sup>lt;sup>a</sup> Each partner could choose multiple partners.

#### Partnership highlights

Highly affected countries are the fulcrum of "3 by 5" partnership activities. In recent months, governments have devoted unprecedented time, energy and money to combating the pandemic, visible not only in the expansion of infrastructure at the local and district level, but also in coordination and planning through national HIV/AIDS programmes. Community-based organizations and nongovernmental organizations have been at the forefront of providing prevention, care and treatment services (Box 2). Some nongovernmental organizations support large numbers of people on treatment in multiple countries. For instance, MSF reported 23 000 people receiving treatment in 27 countries by September 2004.

Most business leaders in severely affected countries expect AIDS to seriously affect future business. Mining companies such as Anglo American (aiming to have 3000 people receiving ARV therapy in 2004) and a handful of other multinational companies have taken responsibility for treating and preventing AIDS among their own employees in Asia and Africa. In most instances, treatment programmes are still small, the uptake of counselling and testing has been modest and stigma and discrimination are still major stumbling blocks. The Global Business Coalition on HIV/AIDS, dedicated to combating the AIDS epidemic through the business sector's unique skills and expertise, has expanded its membership to more than 170 international companies.

#### Box 2. Community-based organizations show the way

A survey of community-based organizations in early 2004 by SIDACTION provides many examples of the pivotal role they play in HIV/AIDS treatment and care in Africa.<sup>12</sup>

In Burkina Faso, two organizations began importing generic drugs before anyone else. The Oasis Centre, opened by Association African Solidarité in 1998 in Ouagadougou, has been supplied with generic ARV drugs through the financial support of European nongovernmental organizations. More than 100 people, who contribute through a community trust, have been receiving treatment. The Centre supplies many other care and support services to families affected by HIV/AIDS.

In Burundi, most people receive ARV drugs through community-based organizations. This is chiefly implemented through the Association Nationale de Soutien aux Séropositifs et Sidéens (ANSS), the main organization for people living with HIV/AIDS. In 2003, ANSS provided medical follow-up for 1700 people, including 1000 people receiving ARV therapy. It provides comprehensive care and is the largest service provider in Burundi.

In Mali, ARV drugs were brought into the country long before any government programme, and people receiving ARV therapy and health professionals have since lobbied for increased access. Three years ago, Espoir Vie-Togo was a "small support group". Today there are 100 clients, with 70 taking ARV drugs.

The efforts of the Treatment Access Campaign in South Africa to lobby for access to treatment and bring about political changes are well known. Today, there are similar organizations in such countries as Burkina Faso, Kenya and Nigeria. African AIDS activism is now a reality.

The Partnership for Access to Antiretrovirals (PAARV) was launched in 2002 for a number of African community-based organizations financially supported by SIDACTION. The programme facilitates access to ARV drugs for the organizations' staff, which includes active volunteers, elected representatives and salaried staff. In other words, these are the people that keep the organization up and running. By September 2004, PAARV was active in eight African countries.

Since the "3 by 5" strategy was released in December 2003, international commitment to scaling up HIV treatment, care and prevention has dramatically increased (Annex 3). The entire UNAIDS Secretariat and the 10 UNAIDS Cosponsors have participated in promoting this encouraging development. For its part, WHO substantially altered its staffing patterns to support "3 by 5," relocating a number of technical positions from Geneva to highly affected countries. WHO is also providing leadership in developing normative standards and guidelines and operational research related to scaling up ARV therapy and accelerating prevention efforts. WHO has taken a lead role in developing and adapting training modules suitable for implementation in underserved locations.

The UNAIDS Secretariat has made significant contributions to overall leadership and advocacy of global efforts to combat HIV/AIDS, directing harmonization of policies and guidelines and directly supporting countries and regional structures to build critical capacity. The nine other UNAIDS Cosponsors have increasingly incorporated "3 by 5" into their respective areas of work.

In recent months, the World Bank has stepped up its already substantial investment for HIV/AIDS programmes by providing financial and technical support for improving national health systems in 100 countries. It has also provided direct support to ARV therapy programmes in the Caribbean, 13 African countries, three Asian countries and one country in eastern Europe, and it has announced the Treatment Acceleration Project in three African countries.

By December 2004, the Global Fund to Fight AIDS, Tuberculosis and Malaria had received pledges for US\$ 5.9 billion and payments of US\$ 3.3 billion against those pledges. In four rounds, it had approved proposals with a two-year value of US\$ 3.1 billion and disbursed US\$ 860 million. With these four first rounds, the Global Fund is projected to reach 52 million people with voluntary counselling and testing for HIV and 1.6 million people with ARV therapy over the five-year lifetime of the individual grants.

de Cenival M, Prunier-Duparge C. Accés commun. Paris, SIDACTION, 2004 (http://www.sidaction.org/accescommun/index\_en.php, accessed 31 December 2004).

#### December 2004

Since its establishment in 2003, the United States President's Emergency Plan for AIDS Relief has created an unprecedented dynamic, making a major contribution to scaling up responses to HIV/AIDS with a 5-year commitment of \$15 billion and a mission to treat 2 million people, prevent 7 million new infections, and provide care and support to 10 million people infected and affected by HIV/AIDS, including orphans and vulnerable children. Beginning in 2004, the United States President's Emergency Plan for AIDS Relief spent US\$ 2.4 billion on AIDS worldwide. The 2005 budget requests US\$ 2.8 billion for AIDS globally, which more than triples the investment since 2001.

A number of other bilateral donors have made critical contributions to the "3 by 5" effort. The Government of Canada, for example, underwrote much of the recent expansion of WHO activity at the country level. Canada's contribution to support efforts related to "3 by 5" was the largest single donation to WHO in its history. The Government of the United Kingdom, UNAIDS and the World Bank have also strongly supported technical and operational support to countries, as have Sweden, Italy, Norway, Belgium, Spain, Luxembourg and the OPEC Fund for International Development. More than two thirds of the resources for "3 by 5" will go directly to WHO country offices, which are being strengthened to offer technical support for country efforts. Progress towards the "3 by 5" milestones is summarized in Annex 4.

With the encouraging increase in attention to HIV came several new challenges, including the emergence of multiple coordinating mechanisms and initiatives with multiple procedures and requirements for funding, monitoring and reporting at the country and programme level. Harmonizing efforts within the HIV/AIDS response community is ever more essential.

Recognizing the new contours of the playing field, activists, providers, officials and people living with HIV/AIDS in affected countries, along with donors and stakeholders, have developed a series of principles known as the "three ones". The principles are **one** agreed HIV/AIDS action framework that drives the alignment of all partners, **one** national HIV/AIDS coordinating authority with a broadly based multisectoral mandate and **one** agreed HIV/AIDS monitoring and evaluation system at the country level. The "three ones" concept for country-level responses to HIV/AIDS provides a framework for ensuring that resources and effort are harmonized, sustainable and based on results. Monitoring and Evaluation (M&E) has been simplified and harmonized by all major partners agreeing on common reporting frameworks, like the joint partner M&E toolkit. This toolkit has already been successful in harmonizing and simplifying M&E and reporting back to donors, providing a basis to support common global estimates in this report.

# The building blocks of "3 by 5"

As national responses to the pandemic accelerate, the most critical elements are becoming easier to identify. First and foremost is ARV therapy, which must be regarded as part of a continuum of care for adults and children infected with HIV. It is initiated only at the point where the course of opportunistic infection and related illnesses – diagnosed via CD4 counts and/or clinical staging – indicates the need for ARV drugs.

To qualify for ARV therapy, an individual must test HIV-positive. Whatever the results of tests, they must be accompanied by pre-test and post-test counselling. For many individuals, the point of entry will be a counselling and testing site at which the client voluntarily opts into the process. However, WHO and UNAIDS recommend that, particularly in key health care settings such as antenatal clinics and TB treatment facilities, counselling and testing be offered routinely.

Testing and counselling underlie many other important processes. If a person is clinically well when first diagnosed with HIV infection, it may be possible to postpone ARV therapy by prompt diagnosis and treatment of opportunistic infections such as TB; and by prophylaxis using simple and safe drugs such as co-trimoxazole to prevent opportunistic infections. In such cases, all that is required are monitoring and basic medical interventions. The individual needs to adopt a healthy lifestyle and be empowered to make informed decisions. This, in turn, requires education.

Early testing has another critically important spin-off, as many people who voluntarily test are found not to be infected and immediately become a prime target for prevention. Many centres are now monitoring people who have been referred from entry points, such as clinics treating sexually transmitted infections and antenatal clinic services rolling out prevention of mother-to-child transmission, or harm-reduction centres for injecting drug users.

The vast majority of people are diagnosed with HIV infection when they are already sick. In many countries, TB is the most common opportunistic infection. This makes TB services an important entry point for ARV therapy programmes. Inpatient hospital wards are another important entry point.

All programmes need an uninterrupted supply of quality medicines and diagnostics, which are essential to identify HIV and to monitor clinical progress. Staff must be trained and the capacity developed to implement ARV therapy. From the outset, an integrated approach is best, because once ARV therapy is initiated, it must be continued for the person's entire life. Training should involve all relevant types of health care workers: at tertiary and referral centres, district hospitals and health centres. It should also include community workers and adherence supporters.

Standard systems for monitoring the progress of people receiving ARV therapy are critical and should be linked at the facility level to drug supplies, dispensing cards and laboratory records. Regular cohort analysis of registers of people receiving therapy becomes possible as information is extracted for reporting to regional centres and the national programme. From these data, countries can report progress to civil society, all national stakeholders and donors. The data also facilitate regular updates for global reporting, including the impact of treatment on mortality.

## HIV testing and counselling

As access to ARV therapy is scaled up, HIV testing and counselling are increasingly recognized by national programmes as the gateway to prevention, care, treatment and support interventions. A key theme being promoted in many countries is "know your status". Published information and community mobilization programmes, along with toolkits for testing and counselling, have been developed to spread this message.

In June 2004, UNAIDS and WHO issued a joint policy statement on HIV testing and produced guidelines for rapid testing in resource-constrained settings. <sup>13</sup> They also cosponsored, with the United States Government, a consultative meeting on the scaling up of testing and counselling for 18 African countries in Johannesburg,

<sup>13</sup> WHO and UNAIDS, UNAIDS/WHO Policy Statement on HIV Testing (http://www.who.int/hiv/pub/vct/en/hivtestingpolicy04.pdf)

South Africa during November 2004. WHO worked with the International HIV/AIDS Alliance to produce a toolkit for testing and counselling and teamed up with the Global Business Coalition on HIV/AIDS to advocate for scaling up the use of "know your status" toolkits.

There has been considerable progress, with countries such as Botswana, Kenya (Fig. 12) and Lesotho routinely offering this service. Key to this issue is a need to identify how many people have been tested and counselled. This information is not yet available, and highlights the need for standardized reporting systems.

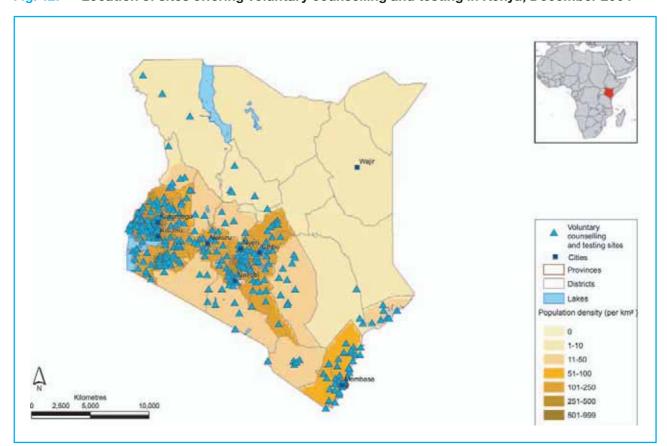


Fig. 12. Location of sites offering voluntary counselling and testing in Kenya, December 2004

#### **Tuberculosis and HIV/AIDS**

TB programmes are emerging as an important partner in HIV prevention, treatment and care in resource-constrained settings. Although TB is one of the most common causes of morbidity and mortality among people living with HIV/AIDS, TB is far more than part of the problem, TB programmes can be an important part of the solution.

Many countries have well-established TB control programmes that could, with additional resources, contribute to systems for delivering ARV therapy (Box 3). Both TB and ARV therapy programmes require political commitment, community mobilization to enhance early detection, standard case definitions, quality diagnostic services, standard treatment regimens with adherence support, reliable drug supplies and standardized monitoring systems.

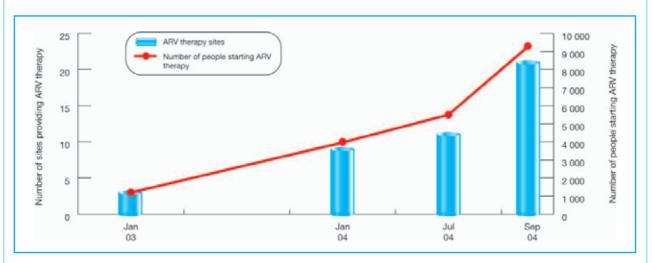
In countries with a high prevalence of HIV infection, up to 80% of people living with TB test positive for HIV, and these TB programmes are increasingly taking responsibility for reducing the impact of HIV and in collaboration with HIV/AIDS programmes are becoming an important partner in the "3 by 5" movement.

#### Box 3. Building on experience from TB control: Malawi

In Malawi, an estimated 900 000 people are living with HIV/AIDS, and 170 000 need ARV therapy. Malawi's plan for expanding ARV therapy aims to provide ARV therapy free of user charges to 80 000 people by the end of 2005, exceeding their "3 by 5" target of 68 000, despite annual per capita spending on health of only US\$ 12 and a huge human resources deficit (Fig. 13).

How will Malawi meet its ambitious target? For many years, the country has followed the DOTS strategy for effective TB control. Now, it is applying the lessons learned to accelerate access to ARV therapy. This means standard definitions of who is eligible, simple treatment regimens, reliable drug supplies, treatment supporters to ensure adherence and regular monitoring and evaluation through standardized recording and quarterly reporting. Thus, Malawi intends to maximize uptake and adherence to ARV therapy and minimize drug resistance.

Fig. 13. Number of sites providing ARV therapy and number of people starting ARV therapy in Malawi, January 2003–September 2004

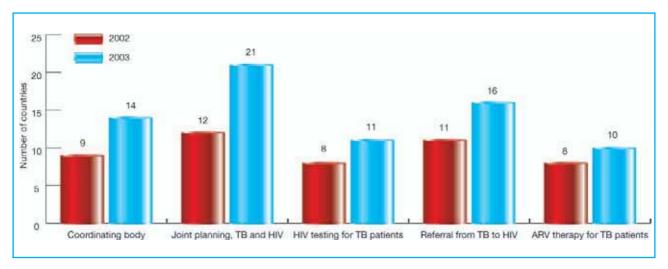


Collaboration between TB clinics and HIV counselling and testing clinics has led to more than 70% of people being treated for TB accepting the offer of HIV testing. Lay counsellors relieve nurses of counselling duties and help to compensate for an acute shortage of nurses. By January 2005, all 44 hospitals in Malawi's 28 districts will be providing routine HIV counselling and testing for people being treated for TB. As of December 2004, 23 of 59 earmarked sites in the public sector are providing ARV therapy and more than 9000 people are receiving ARV therapy. Regional TB officers have been trained in ARV therapy and are recording, reporting, monitoring and evaluating for both TB and ARV therapy. New monitoring and evaluation tools for ARV therapy build on the cohort analysis approach also used for TB. Central units of the national TB and HIV/AIDS programmes will work together on analyzing the data collected by the regional officers.<sup>14</sup>

A survey of collaborative TB and HIV/AIDS activities of 45 countries with a high burden of HIV-related TB elicited responses from 32 countries (Fig. 14). There was progress in almost every policy area. Ten of the 32 countries now have a policy to provide ARV therapy to people living with TB.

Harries A et al. Monitoring the responses to antiretroviral therapy in resource-poor settings: the Malawi model. Transactions of the Royal Society of Tropical Medicine and Hygiene, 2004, 98:695–701. Harries A et al. Expanding antiretroviral therapy in Malawi: drawing on the country's experience with tuberculosis. British Medical Journal, 2004, 329:1163–1166.

Fig. 14. Results of a survey of 32 countries with a high burden of HIV-related TB on national policies on collaborative TB and HIV/AIDS activities, 2002 and 2003



#### Preventing and treating opportunistic infections

HIV weakens people's immune systems and makes them susceptible to infections that can normally be controlled when the immune system is healthy. Prophylaxis with co-trimoxazole, a readily available, low-cost drug, can help prevent many such infections and is recommended for people with HIV infection or AIDS. Prophylaxis with isoniazid, a cheap and safe anti-TB drug, can help prevent active TB from developing. Cryptococcal infection can be prevented and prevented from recurring following initial therapy (secondary prophylaxis) by fluconazole, a widely available antifungal drug.

Some countries, such as Thailand, have made a concerted effort to improve the coverage of co-trimoxazole prophylaxis, the treatment of TB and secondary prophylaxis for cryptococcal meningitis among people living with HIV/AIDS.

In Africa, co-trimoxazole prophylaxis is rarely used. A 2003 survey estimated that 3% of adults and 1% of children living with HIV/AIDS received co-trimoxazole. The results of two recent studies in Uganda (on adults on adults on children on children on the United Nations Children Fund (UNICEF) to modify the current recommendations for co-trimoxazole prophylaxis in children. According to the new recommendations, prophylaxis should be given to all HIV-exposed children from 4–6 weeks of age and to any child identified as HIV-infected with clinical signs or symptoms suggestive of HIV. A follow-up review meeting is planned for early 2005.

## Preventing HIV infection among infants

Also high on the priority list is the need to prevent HIV infection among infants, especially preventing mother-to-child transmission. Nevertheless, in 2003 only an estimated 5% of pregnant women in sub-Saharan Africa and 8% globally were offered services for preventing mother-to-child transmission.

Just as TB presents a model for delivery systems, antenatal programmes are key to accelerating access to treatment for preventing mother-to-child transmission. One measure that is proving successful is the choice to routinely offer HIV testing and counselling. Pregnant women are told that HIV tests are standard and are asked if they want to opt out – an approach often used for other standard medical tests.

Primary prevention services, testing and counselling, treatment and support to women living with HIV and their families also need to be expanded.

USAID, UNAIDS, WHO, UNICEF and the Policy Project. Coverage of selected services for HIV/AIDS prevention, care and support in low and middle income countries in 2003. Washington, DC, Policy Project, 2004 (http://www.who.int/hiv/pub/prev\_care/coverage/en, accessed 31 December 2004).

Mermin J et al. Effect of co-trimoxazole prophylaxis on morbidity, mortality, CD4-cell count, and viral load in HIV infection in rural Uganda. *Lancet*, 2004, 364: 1428–1434.

Chintu C et al. Co-trimoxazole as prophylaxis against opportunistic infections as HIV-infected Zambian children (CHAP): a double-blind randomized placebo-controlled trial. *Lancet*, 2004;364:1865–1871.

#### December 2004

Ukraine has shown that the prevention of mother-to-child transmission can be scaled up. The Ministry of Health has a well-developed infrastructure for maternal and child health services that looks set to eliminate new HIV infections in infants by 2010. Using the "routine offer" approach to testing and counselling and with nearly all women consenting to be tested, Ukraine reduced mother-to-child transmission from 28% in 2000 to 10% in 2002.

By June 2004, the Elizabeth Glaser Pediatric AIDS Foundation was supporting programmes for preventing mother-to-child transmission in 17 countries worldwide. Of the more than 90 000 women living with HIV/AIDS who had been identified through the programmes, over two thirds received ARV prophylaxis to prevent transmission to their infants. By December 2004, the Foundation had also provided ARV therapy to nearly 9500 adults and 785 children through its care programmes in four countries.

Columbia University in New York City operates the MTCT-Plus initiative at 13 sites in nine countries: eight in sub-Saharan Africa and one in Thailand. The initiative supports the prevention of mother-to-child transmission and the provision of care, including ARV therapy for women, their partners and their children. Between January 2002 and August 2004, 5540 women and their families had benefited, and 1142 had received ARV therapy. Both the Glaser Foundation and Columbia University programs receive significant funding from the United States President's Emergency Plan for AIDS Relief.

#### Prevention and treatment go together

Prevention and treatment must be synergistic, and achieving the "3 by 5" target involves scaling up both. Effective treatment is a form of prevention, albeit imperfect, because it lowers viral loads and decreases the chances of transmitting HIV, even in unprotected sex. In scaling up treatment, the concomitant need to rapidly scale up counselling and testing is a critical entry point for expanding all prevention activities. The more people learn about HIV and AIDS, the better able they are to prevent transmission and to protect themselves from opportunistic infections. If they test negative, they can take measures to protect themselves and their families from getting infected.

As people become better informed, stigma and discrimination decline, making it easier for others to determine their status and thus break the chain of transmission.

There has been relatively little information on how treatment affects prevention in developing countries. In affluent industrialized countries, a recent meta-analysis concluded that people living with HIV/AIDS receiving ARV therapy did not exhibit increased sexual risk behaviour, even when therapy achieved an undetectable viral load. However, people's beliefs about ARV therapy and viral load may promote unprotected sex. Prevention messages should address these issues.<sup>18</sup>

## Preparing for treatment

People living with HIV/AIDS and affected communities both have a key role to play in preparing people to begin and stay on HIV treatment over the long term. As the intended beneficiaries of treatment, care and prevention programmes they need to be heard, to be involved in their own health care decisions and to be active participants in developing and implementing long-term programmes. They also need to be supported in their advocacy efforts. Treatment preparedness – encompassing advocacy, literacy and community mobilization for people living with HIV/AIDS and affected communities – is therefore central to the potential impact of any plans, resources and delivery systems for HIV/AIDS treatment. The WHO Preparing for Treatment Programme has therefore made a major financial contribution to the Collaborative Fund for HIV Treatment Preparedness. The Collaborative Fund is structured as a global partnership between the Tides Foundation, the International Treatment Preparedness Coalition, WHO, more than 15 other donors and numerous providers of technical assistance. Its core activity is providing peer-reviewed grants to support HIV/AIDS treatment literacy, advocacy and community mobilization projects in developing countries. Community review panels comprising people living with HIV/AIDS and community-based treatment advocates and educators in each funding region or subregion determine funding priorities, review applications and decide about disbursement.

In addition, the Collaborative Fund undertakes capacity-building efforts in relation to treatment access and preparedness among regional networks of people living with HIV/AIDS, community-based HIV treatment

<sup>18</sup> Crepaz N, Hart TA, Marks G. Highly active antiretroviral therapy and sexual risk behavior: a meta-analytic review. JAMA, 2004, 292:224–236

advocates and educators. The type of support provided varies in each region, depending on the respective needs, capacity and established infrastructure. In addition to providing financial support to the Fund, WHO is supporting a participatory evaluation of the programme's effectiveness which will assist in the design and implementation of future community-driven initiatives.

The Collaborative Fund is a leading example of the principles of the Greater Involvement of People Living with HIV/AIDS (GIPA) applied to a global public health initiative.

#### AIDS medicines and diagnostics

A reliable source of medicines and diagnostics related to HIV/AIDS is critical to programmes in developing countries. The costs of drugs and diagnostics to people and to countries are still an impediment to scaling up and need to be addressed. The quality of drugs and diagnostics also needs to be assured. Moreover, it is important to ensure an adequate supply of treatments that can make them easier to take and lower their cost, increasing adherence to ARV therapy.

An important part of this effort is WHO's prequalification programme. Prequalification is not a drug regulatory system. WHO does not approve drugs for use in any particular country. That is the role of national regulatory authorities based on the national legal requirements. WHO simply lists those drugs that have been proven to meet existing international standards for quality, safety and efficacy – making them suitable, first and foremost, for procurement by United Nations agencies (see http://mednet3.who.int/prequal and http://www.who.int/medicines/organization/qsm/expert\_committee/expertcomm.shtml). WHO prequalification is transparent (all relevant information is available in the public domain) and is conducted by highly qualified assessors and inspectors from well-established regulatory authorities including European Union countries, Canada and Switzerland (Box 4). The programme also facilitates training for regulators from developing countries.

The AIDS Medicines and Diagnostics Service (AMDS) has expanded to 16 members and has redefined itself as a network of organizations providing support in procuring and managing supplies of HIV/AIDS drugs and diagnostics. WHO acts as the secretariat, and other partners provide much of the technical support and actually supply the ARV drugs.

AMDS has pursued dialogue and negotiations with the research-based pharmaceutical industry with a view to ensuring adequate supplies of affordable, high-quality HIV/AIDS treatments. One focus is on the tiered pricing system and expanding the lists of countries eligible for low and intermediate prices. Another is on tracking sales to help determine the numbers of people receiving treatment in each country and to help assess needs for accelerating access to treatment.

A clearinghouse for information on ARV drugs and diagnostics, AMDS provides partners with the latest data on patents, registration status and prices and on the discovery, manufacture, availability and cost of new drugs.

The AMDS partners involved in procurement have seen sharp rises in their sales of ARV drugs and diagnostics. The International Dispensary Association has provided ARV drugs worth US\$ 105 million to 21 countries in 2004 – a dramatic increase from only three countries in 2003. UNICEF has provided ARV drugs to 37 countries in the past 18 months. The value of procurement is rapidly increasing from less than US\$ 2 million in 2003 to US\$ 7.5 million in the first three quarters of 2004. UNICEF has been stockpiling ARV drugs since October 2004 to help meet shortages. It has agreements with 22 countries and a stockpile worth US\$ 500 000 to deal with emergencies. The Bill & Melinda Gates Foundation has donated an additional US\$ 250 000 to increase the stockpile. The William J. Clinton Presidential Foundation has negotiated preferential prices for some generic ARV drugs and for some diagnostics and concluded agreements with the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNICEF, the International Dispensary Association and WHO that ensure that the countries and organizations with which they work can access these drugs and diagnostics at preferential prices.

AMDS partners, including WHO and UNICEF, also support the development of principles for national drug regulatory authorities to help guide them through reviewing applications for approval of fixed-dose combination products. WHO has prequalified generic fixed-dose combinations to treat people living with HIV/AIDS in resource-constrained countries. A small multiple-site clinical trial in Cameroon showed very encouraging effectiveness, safety and quality of a generic fixed-dose combination of nevirapine, stavudine and lamivudine. Such studies are vital for continuing to assess the drugs that WHO recommends and that numerous donor agencies purchase.

Laurent C et al. Effectiveness and safety of a generic fixed-dose combination of nevirapine, stavudine, and lamivudine in HIV-1 infected adults in Cameroon: open-label multicentre trial. *Lancet*, 2004, 364:29–34.

#### Box 4. Ensuring high standards

In late May 2004, WHO removed two of Cipla Ltd's prequalified antiretroviral products from the list of prequalified products. On 9 November 2004, India-based Ranbaxy Laboratories Ltd voluntarily withdrew seven ARV drugs (plus all ARV product dossiers under assessment) from the WHO prequalification list. The following week, another generic antiretroviral manufacturer based in India, Hetero Drugs Limited, also withdrew six of its ARV drugs from the WHO prequalification list.

These de-listings were spurred by WHO inspections of contract research organizations that had carried out bioequivalence studies. In subsequent inspections, the companies found discrepancies in the documentation relating to proof of the products' bioequivalence with originator medicines. The companies also found that the contract research organizations they had used for studies of bioequivalence were not working in compliance with the international guidelines on good clinical practices and good laboratory practices.

WHO has advised its Member States that, in principle, the irregularities found at the contract research organizations do not undermine the proven pharmaceutical quality of the medicines, including their purity and stability, but users should – where possible – suspend the use of the de-listed medicines and switch to other prequalified products. WHO, however, has also recommended the continued use of de-listed products if obtaining alternative prequalified products immediately is difficult. The risk of withholding treatment is higher than that of providing medicines that may or may not be bioequivalent but that have demonstrated quality and safety. A switch to non-prequalified products is not recommended, as WHO has not documented their quality.

On 30 November, WHO reinstated two ARV drugs manufactured by Cipla Ltd on its list of prequalified medicines. Cipla has carried out new bioequivalence studies to confirm that its two ARV drugs are therapeutically equivalent to their brand-name counterparts.

Ongoing WHO inspections of contract research organizations conducting tests on ARV drugs are part of the continuing monitoring process and an integral component of the prequalification project. This work reflects WHO's responsibility to assist countries in promoting safe and effective medicines and improving their quality assurance mechanisms. The current WHO list of prequalified medicines contains 50 ARV drugs, including three double and two triple fixed-dose combination (two or three ARV drugs in one pill) manufactured by Abbott Laboratories, GlaxoSmithKline and Cipla. A number of new ARV drugs – including fixed-dose combinations – are currently in the pipeline for WHO assessment.

AMDS brokers technical support, helping countries build capacity into their supply chains, so supplies move efficiently from central purchase to treatment centres. One way of supplying this support is through regional workshops in procurement and supply management. In December, for example, workshops in Kenya and Cambodia provided training to dozens of participants from almost 20 countries. Another way is to help countries develop procurement and supply management plans. Many countries have developed such plans and expect to have 120 supply managers trained by mid-2005.

## ARV drug prices in developing countries

The high cost of ARV drugs remains a barrier to scaling up HIV treatment and care. For first-line treatments, the lowest price available to countries is around US\$ 140 per person per year, but average prices are still at least US\$ 300. Reaching the December 2005 milestone of US\$ 50–200 per person per year will require substantial collaboration by all "3 by 5" partners. Meanwhile, second-line treatments remain prohibitively expensive throughout much of the world. As the contours of the epidemic change, this situation could pose an increasingly serious public health hazard. It is critical that the international community acts now to ensure that the cost of drugs does not pose a barrier to continued improvement in the uptake of and adherence to HIV-related services.

#### Pricing in Europe and central Asia

Meanwhile, pricing of first-line and second-line treatment remains a concern in eastern Europe and central Asia. Countries that are members of the Commonwealth of Independent States have secured reductions in the prices of ARV drugs. In the Republic of Moldova and Ukraine, for example, governments are buying generic ARV drugs via the International Dispensary Association through their grant from the Global Fund to Fight Aids, Tuberculosis and Malaria. In the Russian Federation, direct negotiations with the research-based industry are ongoing, and at the same time generic ARV drugs are in the process of being registered.

In other countries, prices remain high, severely limiting treatment access. As the number of people with AIDS is relatively low, except for Romania, most people currently receive ARV drugs through the official public health care system. As their numbers grow, the financial burden for purchasing ARV drugs starts weighing heavily.

A meeting of activist organizations in Warsaw established a working group that aims to urge the Health and Consumer Protection Directorate-General of the European Commission to take action. Reducing prices for the 10 countries that joined the European Union in May 2004 is complicated because the provisions of the single market of the European Union have resulted in prices being raised to the levels prevailing in the 15 countries that were members before May 2004. Several meetings have been held to address this issue, and more are planned.

#### Procurement and supply management

Countries and programmes are rapidly accumulating first-hand experience in procuring ARV medicines. Challenges and potential bottlenecks in procurement and supply management are therefore shifting. During 2005, officials will struggle less with selecting products, identifying suppliers and placing orders than with funding repeat purchases, preserving operational and legal flexibility in the procurement process, forecasting demand based on the uptake of ARV therapy and implementing a robust system for supply management to ensure that health facilities are (re)-supplied in a timely manner. Helping countries to develop an efficient and effective system for procurement and supply management is not only critical to scaling up ARV therapy but also facilitates the treatment of other chronic diseases such as diabetes and hypertension.

## Training health workers

As access to ARV therapy expands, a major constraint is the lack of skilled health care workers, ranging from specialized physicians to aides. As many as 100 000 trained health workers may be needed to realize the "3 by 5" targets. WHO's Integrated Management of Adult and Adolescent Illness (IMAI) training modules provide a technically sound approach to shifting essential skills, transferring knowledge and expanding health care teams to embrace laypeople, including people living with HIV/AIDS.

The IMAI modules provide simple guidelines, training materials and educational tools and addresses clinical care, counselling and monitoring of people receiving treatment as well as district coordination of ARV therapy.

Pioneered in Uganda, the IMAI approach fosters new partnerships within and between countries. Workshops and the creation of knowledge hubs nurture local buy-in and exponential growth in the number of professional and lay health care workers (Box 5). This also strengthens the whole health system, as limited human resources are used optimally and care is integrated.

# Box 5. A regional knowledge hub in Ukraine

Training for ARV therapy was virtually nonexistent in central and eastern Europe before 2003. In 2003, a grant from the German Gesellschaft für Technische Zusammenarbeit (GTZ) supported WHO and the American International Health Alliance in working with Ukraine's Ministry of Health, the National AIDS Centre, the Kiev Medical Academy of Postgraduate Education, MSF and AIDS Foundation East-West on planning a regional knowledge hub. In January 2004, the Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia was established in Kiev, Ukraine. The Knowledge Hub:

- helps develop national HIV/AIDS plans that address needs for human capacity-building;
- develops and implements training programmes with knowledge-based components in educational and clinical settings and skills-based components through on-site mentoring;
- · develops online information resources for health care professionals; and
- translates and adapts guidelines, protocols and best practice materials.

The Knowledge Hub was instrumental in building a consensus for Ukraine's national plan for scaling up ARV therapy, with targets of providing ARV therapy to 2000 adults and 100 children in six regions by 2005. The approach is to start by building care teams consisting of a physician, a nurse and a social worker or counsellor. Knowledge-based training will be followed by skills-based training. Since June 2004, the Knowledge Hub has trained 66 caregivers with a grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria and support from the International HIV/AIDS Alliance.

The Knowledge Hub has developed a system for measuring and evaluating the results of the training that includes regular on-site follow-up. Knowledge Hub staff also visit sites to assist with ARV therapy as the first groups of people receiving therapy come through.

The Knowledge Hub is now working towards nationally and internationally recognized certification for physicians, nurses and social workers that take its courses. It plans to extend its training programmes into the Russian Federation in 2006 and is engaged in discussions with other countries.

Because people living with HIV/AIDS tend to become experts in their own illness, they are encouraged to become expert patient trainers in courses for clinicians and aides and to become aides themselves. Those with the aptitude can also assume administrative duties, thus freeing up professional staff.

In Swaziland, for example, eight expert trainers and 12 other IMAI trainers are in place. By August 2004, 32 health professionals from Swaziland's four regions had been trained. IMAI training is also well underway in Eritrea, in the Province of the Eastern Cape in South Africa and in Sudan. Clinical guidelines have been rapidly adapted in Burundi and Senegal, where training is underway. Guidelines are being adapted in Burkina Faso and other French-speaking countries in Africa.

# Quality assurance and accreditation

A lack of physical infrastructure and services that meet satisfactory standards remains a problem in most developing countries. The Joint Commission International sets the standards by which health care quality is measured for more than 15 000 health care organizations worldwide. Accreditation includes on-site reviews by teams of Joint Commission International health care professionals at least once every three years.

Some countries already have systems of accreditation but there is no system pertaining specifically to the treatment of HIV/AIDS. Practical, adaptable guidelines for developing accreditation systems are expected to be available by August 2005.

Standard-setting is in no way intended to penalize countries or individual health facilities. Rather, the objective is to introduce a framework for continuously improving quality. This in turn can help to structure a country's approach to scaling up treatment. WHO and the Joint Commission International are developing practical, adaptable guidelines to be used as tools for introducing accreditation systems for HIV/AIDS service delivery. They will also provide technical support to countries or institutions wishing to set up accreditation systems. They will promote and support the development of in-country, regional and international partnerships to encourage the acceptance of and compliance with accreditation standards, to monitor and evaluate application of the standards and to improve them.

# Monitoring treatment

Successful ARV therapy can transform HIV/AIDS from a death sentence to a chronic disease. Chronic disease management to keep the person healthy and productive requires regular monitoring and evaluation of clinical condition and adherence to medication.

Ideally, the history of a person living with HIV/AIDS is recorded and available whenever a clinic visit is made. The patient register is one critical component of the record-keeping and monitoring system. Most of the information is used for that person's own benefit; the remainder allows programmes to work properly and to produce the data used to evaluate and improve services at the institutional, national and global levels. Summaries of these data help, for example, with the timely procurement and distribution of drugs and supplies and with measuring progress towards national and global targets. Simplicity is the key to a robust monitoring system, so the system collects the minimum data needed for the care of the person living with HIV/AIDS, for managing the facility and the national system well and for international reporting.

In March 2004, WHO convened a meeting of representatives from the U.S. Government, other bilateral donors and many nongovernmental organizations to agree on a standardized minimum set of data to be collected.

In several countries the monitoring system is building on the TB experience with alterations to accommodate lifelong ARV therapy. Malawi has developed such a system (Box 3).

There are also examples of developing electronic monitoring systems. Brazil has more than 900 ARV therapy sites and uses an Internet-based system to manage the procurement and distribution of drugs and supplies to the sites. Other institutions and organizations have developed computer-based medical record systems, including the Mosoriot Hospital in Kenya, MSF (a software package called FUCHIA) and the United States Government (the CareWare system designed for use with U.S. HIV patients and now used in some clinics in Uganda). In Haiti, Partners In Health has developed an electronic medical record system that uses satellites to communicate with remote sites, track current stocks of drugs and other supplies and estimate future needs, thus proving the feasibility of bypassing weak infrastructure to solve a critical problem.

# Drug resistance

HIV mutates frequently during replication in human cells, and some mutations reduce the effectiveness of HIV drugs. If treatment adherence is poor, resistant HIV strains can emerge and lead to treatment failure. However, if ARV therapy regimens are properly designed and delivered and adherence is high, the emergence of HIV drug resistance will be minimized.

There is no evidence to indicate that scaling up ARV therapy in developing countries is making the spread of drug-resistant HIV strains more difficult to manage. The resistance to drugs is no higher than that reported by affluent industrialized countries. Primary HIV-1 drug resistance has remained low in Brazil, where triple therapy was introduced on a large scale in 1995–1996, and in Côte d'Ivoire and Uganda, which introduced ARV therapy in 1998 as part of the Accelerating Access Initiative.

WHO is now focusing on working with countries to set up HIV systems for the surveillance and monitoring of drug resistance. Threshold surveys are planned to determine the level of drug resistance transmission, mostly using specimens left over from HIV surveillance rounds or special studies at sentinel sites, in populations where ARV therapy has been in use informally for several years. The first study has been completed in Mexico. Monitoring of HIV drug resistance will start in populations commencing standardized treatment in two countries in the next few months. In addition, much attention is being paid to building a network of

laboratories that test for drug resistance. Laboratories in Botswana, Côte d'Ivoire, Senegal and South Africa are now involved in a programme for the quality assurance of laboratories involved in monitoring HIV drug resistance in the African Region of WHO.

# Operational research

There are no universal models for scaling up the provision of HIV treatment and optimizing prevention programmes at the necessary scale. An evidence-based approach is essential, but the urgency of the task requires innovative approaches. "Learning by doing", of which operational research is a key element, is essential to the process of scaling up. Incomplete evidence must not constrain efforts, and learning from the various initiatives underway requires assessing evidence in real time while treatment programmes are being launched and expanded.

Priority must be given to research that is directly relevant and can be applied widely. There are two core principles. First, research must be multidisciplinary, incorporating clinical, economic, health systems and sociobehavioural elements. Second, ownership of the process must rest with countries. Implementation of operational research studies should be embedded within routine programme activities, whether the initiative originates with local stakeholders or outside partners. WHO, UNICEF, the World Bank, the United Nations Development Programme (UNDP) and other partners have started to work with countries to set priorities for operational research and to develop research proposals.

#### Home based care

In many highly affected countries, the burden of HIV has fallen squarely on large health facilities. A study in Zambia reported that up to half of all patient-days in medical wards of a central hospital were accounted for by people with HIV-related illness. Home care programmes are therefore a critical component of scale-up efforts, and their expansion is a priority.

Where appropriate, home care can reduce the burden on health systems significantly; for the patient they also have clear advantages. After initiation of ARV therapy, long-term hospitalization is rarely needed. Most HIV-related infections, such as fever and diarrhoea, can be treated at home with support from trained health workers. In many cases, staying at home is the only option since hospital facilities are often remote, making transport and lodging prohibitively expensive.

Another advantage of home-based care is its contribution to the acceleration of prevention efforts. Experience from the TASO programme in Uganda and other locations suggests that counselling and education for people with HIV and their families is both easier and more effective in the home setting. Moreover, well designed home care programmes can reduce isolation and stigma, drawing on social and psychological resources offered by the local community.

# Treating children

Children have been tragically neglected in efforts to accelerate access to ARV therapy. Advocacy on behalf of children has been weak, monitoring is limited and, despite proof to the contrary, policy-makers and caregivers are offen unconvinced that ARV therapy works for children.

Globally, children under 15 years of age account for an estimated one-sixth of all HIV/AIDS deaths but account for a much smaller proportion of people getting ARV therapy. Few programmes have focused on treating children. An exception is Thailand's national programme, through which 200–300 children per month are enrolled in ARV therapy programmes and children constitute about 8% of the number of people in treatment. In Brazil, where women and children comprise a minority of infected people, about 5% of people being treated are children. MSF reports that 6% of the people it treats in all countries are children.

The exact number of children infected with AIDS is unknown. Rough global estimates are based on estimating the number of women living with HIV/AIDS delivering children and applying a mid-range rate of mother-to-child transmission, assuming breastfeeding is the norm. In 2004, more than half a million children are thought to have died globally from HIV/AIDS.

There is very limited surveillance of HIV status in children; this has not been a priority issue or a component of second-generation surveillance approaches. Surveillance is complicated by the fact that diagnosing infants is not easy. In children under the age of 18 months, HIV can only be diagnosed reliably by special tests. Most children who are born to infected mothers do not have access to these expensive and complex technologies. Standard, widely available HIV tests are based on detecting antibody, which transfers from mother to infant: a positive test under the age of 18 months may represent passive transfer of maternal (positive) antibody rather than true infection in the child. Over half of childhood HIV-related deaths occur in this period; they are largely undiagnosed and uncounted – and therefore invisible.

WHO is proposing the development of criteria for the presumptive diagnosis of HIV/AIDS that will lead to treatment even without definite confirmation. WHO, UNICEF and other partners are proposing a revised definition for HIV/AIDS in children, along with an improved clinical staging system that takes into account the rapid roll-out of programmes for preventing mother-to-child HIV transmission. Meanwhile, WHO is advocating for funding of research programmes to develop better methods of diagnosis.

The WHO clinical staging system for HIV infection and disease in children was developed several years ago and has never been evaluated. Many of the stage 2 and stage 3 clinical events are not specific to HIV infection and there is considerable overlap with HIV-uninfected children. Few laboratories are equipped to conduct CD4 assays, and most have equipment that can only report absolute counts rather than CD4 percentages (this requires much more expensive and complex machines). The recommendations appear too complex for widespread use in a public health approach. The treatment guidelines will be revised and simplified in accordance with new data on the safety and efficacy of different treatment regimens and drug resistance.

Besides improved clinical and diagnostic tools, there is an urgent need for affordable and appropriate paediatric drug formulations. There are very few specific paediatric formulations, and those that exist are often much more expensive than the adult formulations. Many providers break adult tablets into half or even quarters and accept that the drug dose in the broken-up pills may be relatively erratic. Dosing charts based on body weight are complex and not generally easy to use in facilities without specialized paediatric expertise.

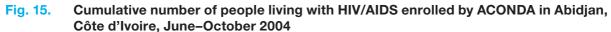
Dispensing complex dosing regimens is challenging for the guardian or caregiver, and the volume of drugs needed per month can be considerable. Simpler, more practical approaches to dosing need to be developed (Box 6). UNICEF and WHO have convened the first of a series of consultative meetings to develop new paediatric formulations consistent with the revised treatment guidelines. Better data on HIV/AIDS in children will improve the forecasting of demand for various formulations and assist the pharmaceutical industry in committing to making the necessary products.

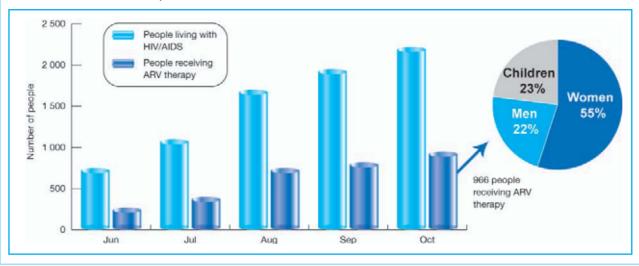
# Box 6. A family-centred approach towards HIV care: the ACONDA experience in Abidjan, Côte d'Ivoire<sup>20</sup>

Côte d'Ivoire has a decade of experience in clinical and therapeutic HIV research. It has become one of the leading countries developing pilot programmes to enhance access to care, including highly active ARV therapy. ACONDA is a nongovernmental organization created in Abidjan by physicians and other health professionals involved in these activities together with the Ministry of Health and the Agence Nationale de Recherches sur le Sida. In collaboration with its partners, ACONDA is now providing comprehensive care and treatment services for families affected by HIV/AIDS in the two most densely populated districts of Abidjan.

In two community-run maternal and child health clinics, 446 pregnant or delivering women living with HIV/AIDS have been enrolled since August 2003. Women of childbearing age are the entry point to build a family care HIV programme. Pregnant women who meet the WHO criteria for ARV therapy for themselves start ARV therapy prior to delivery in accordance with the 2004 WHO guidelines for preventing the mother-to-child transmission of HIV.<sup>21</sup> A total of 192 women and 27 children in the same families have started ARV therapy. Further, 116 male partners have already accepted being tested for HIV, 64 have been told their HIV-positive serostatus and 33 have started treatment.

In early 2004, the same team rolled out the comprehensive approach to a large government-run primary care hospital with a dedicated HIV clinic for adults and children offering voluntary counselling and testing and the full range of HIV services. Adults and children seeking regular care are the entry point to the HIV care programme. Within six months, 2217 people living with HIV/AIDS have been enrolled, including 1177 women and 338 children. Of these, 966 are now receiving ARV therapy, mostly women and children (Fig. 15). The programme is now being extended to 10 more sites in Greater Abidjan to provide the HIV primary care services and family approach with ARV therapy to at least 10 000 people living with HIV/AIDS by 2008. The initial treatment results are very good.





Reported by (alphabetical order): Xavier Anglaret, François Dabis, Bertin Kouadio, Valériane Leroy, Dominique Marchand, Thérèse Ndri-Yoman, Freddy Perez, Roger Salamon, Catherine Seyler, Besigin Tonwe-Gold and Siaka Touré for the ACONDA-ISPED Team. Fassinou P et al. Highly active antiretroviral therapies among HIV-1- infected children in Abidjan, Côte d'Ivoire. AIDS, 2004, 18:1905–1913.

Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. Geneva, World Health Organization, 2004 (http://www.who.int/hiv/pub/mtct/guidelines/en, accessed 31 December 2004).

# HIV/AIDS and health systems

Because HIV/AIDS is the first major chronic disease to which many developing countries are responding with large-scale ongoing treatment, it could strengthen many health systems, as a wide range of interventions need to be delivered through different points, public and private, on an ongoing basis. The challenges presented by the pandemic are shared with other health priorities such as TB, malaria and maternal and child health.

Achieving the "3 by 5" target requires a wide range of interventions to be delivered quickly through many public and private delivery points on an uninterrupted basis. Three questions are commonly raised:

- How can major health system constraints be overcome in the short term?
- How can results be sustained in the medium term?
- How can ARV therapy be scaled up not by diverting scarce resources from other health priorities but, instead, by enhancing the delivery of all health services?

Attention is being given to four critical elements that constitute what is known as the HIV/AIDS health system platform:

- a skilled workforce;
- information systems;
- a well-managed and regular supply of drugs and other supplies; and
- fair and sustainable financing systems.

# A skilled workforce

A report by the Joint Learning Initiative on Human Resources for Health and Development<sup>22</sup> – a consortium of more than 100 health leaders – shows that health workforce development in developing countries has suffered from years of neglect in national and international health policy circles. Nearly all resource-constrained settings are challenged by shortages of health workers, imbalances in skill mix, maldistribution of health workers, a negative working environment and a weak knowledge base. Especially in the poorest countries, the workforce is under assault by HIV/AIDS, emigration and inadequate investment. Mobilizing and strengthening human resources for health is critical to combating health crises.

# Information systems

An interim response to the lack of data in many of the countries with the highest burdens of HIV/AIDS is the application of a geographical information system to map the key services in districts: the Service Availability Mapping (SAM) tool. This captures district-level information on HIV/AIDS and other essential health services and on infrastructure, laboratories and human resources (Fig. 16). It can be used to monitor the scaling up of ARV therapy but simultaneously pays attention to the key health system indicators, including geographical equity.

Such short-term solutions need to be linked to more comprehensive efforts to improve health information systems in the poorest countries for the longer term. This is being pursued by the Health Metrics Network, a new international partnership underwritten by the Bill & Melinda Gates Foundation. The Network's goal is to catalyse the development of country health information systems, thus increasing the availability and use of timely and sound health information to support decision-making at the country and global levels.

# Procurement and supply

Even with the impressive reductions in drug prices, ARV therapy is still very costly. In 18 countries in Africa, total health spending is less than US\$ 10 per person per year, including external resources. Countries must have support in creating adequate, fair and sustainable funding mechanisms as well as obtaining additional funds for health. This requires action both on the ground, in the form of material and technical assistance to national, regional, and local health agencies; and internationally, in the form of advocacy and policy designed to increase competition in the markets for pharmaceuticals and other key inputs.

Joint Learning Initiative on Human Resources for Health and Development. Human resources for health: overcoming the crisis. Cambridge, Global Equity Initiative, Harvard University, 2004 (http://www.globalhealthtrust.org/Report.html, accessed 31 December 2004).

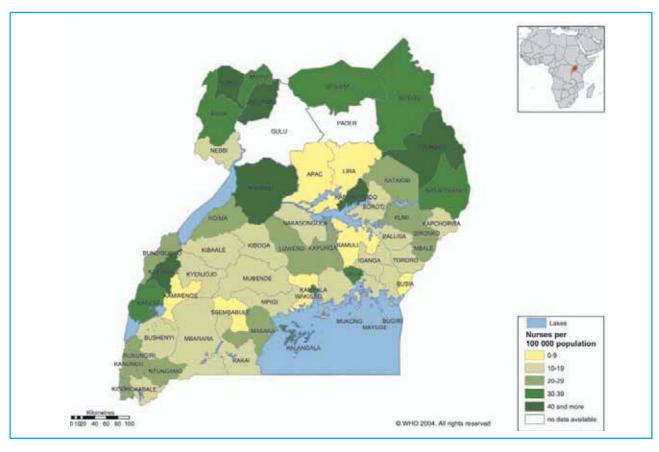


Fig. 16. Number of nurses per 100 000 population in Uganda, by district, March 2004

# Fair and sustainable financing systems

Countries need the capacity to estimate financial needs and to track the sources and uses of funds. They need to develop plans for financial sustainability that ensure that the health system can cope with extensive scale-up that incurs continuing costs – for the health system and for treatment. In doing so, a key issue under discussion by countries is whether to impose a direct user charge for ARV drugs. Donors need to acknowledge that external funds will remain a critical funding source in the poorest countries for some years to come.

Meanwhile, HIV/AIDS scale-up activities take place within a health and development landscape that includes health reforms, sector-wide approaches to health development, medium-term expenditure frameworks and poverty reduction strategies. Governments, having agreed to all of the Millennium Development Goals related to health, are trying to advance on several fronts at once. Oversight and dialogue are needed to reconcile the competing demands for resources, to avoid excluding vulnerable groups and to reduce duplication and waste. In the field of HIV/AIDS, this has already led to acceptance of the UNAIDS "three ones" approach (see above). Careful attention needs to be given to how HIV/AIDS strategies fit the overall sector strategies and to the potential and actual effects of scaling up on the rest of the health system.

Given the current level of financial scale-up, recipient countries are expected to meet high standards of fiscal accountability. On the other hand, many recipient countries want to tackle HIV/AIDS more effectively but are concerned about how major increases in funds will affect carefully negotiated health policies, expenditure frameworks and fiscal stability. Insistence on accountability and concerns about macroeconomic policy are two sides of the same coin – both hinge on a reciprocal, trusting and respectful relationship between highly affected countries and donors. The cornerstone of this relationship must be a commitment by all parties to the absolute priority of HIV treatment, care and prevention services.

# The way forward: challenges in 2005

Progress in 2004 has laid the foundation for the extraordinary effort needed to reach the "3 by 5" target by the end of 2005. Many countries need to accelerate their scale-up, and commit additional resources. International organizations need to become much faster in providing assistance. The second half of 2004 saw tremendous shifts, as political will translated into action. Although the level of commitment is encouraging, it must accelerate in 2005. Necessary innovations such as the routine offer of testing and counselling in many key health care settings and reducing or abolishing user fees at the point of service require significant energy and focus by providers, policy-makers and communities; meanwhile, policy changes by national governments, bilateral and multilateral funders and other stakeholders continue to be critical to maximize the funds available for scaling up treatment.

# Growing demand for treatment

Reaching the target of 3 million people by the end of 2005 requires having at least another 2.3 million people initiate treatment. A total of 5.1 million adults still need treatment in 2005 and are not receiving it; 72% live in sub-Saharan Africa and 22% in Asia. These two regions thus account for nine of ten people whose need for treatment has not yet been met (Fig. 17).

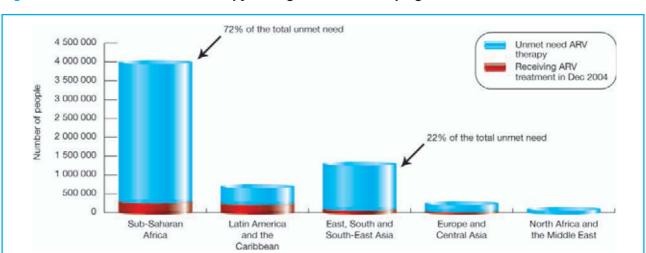


Fig. 17. Unmet need for ARV therapy among adults in developing and transitional countries in 2005

Twenty countries have at least 50 000 people each who still need treatment in addition to the people who are already on treatment (unmet need). Together these countries represent 84% of the unmet need for ARV therapy in developing and transitional countries in 2005 (Fig. 18). The top three, South Africa, India and Nigeria, account for 41% of the need. Thirteen countries in sub-Saharan Africa – Zimbabwe, United Republic of Tanzania, Ethiopia, Mozambique, Kenya, Democratic Republic of the Congo, Malawi, Zambia, Cameroon, Côte d'Ivoire, Uganda, Lesotho and Ghana – have 37% of the 5.1 million people who still need to initiate treatment. China, the Russian Federation, Thailand and Sudan add another 6%.

The figures speak for themselves. Global progress towards the "3 by 5" target can only be made if major progress is made in the countries with the greatest unmet need for treatment.

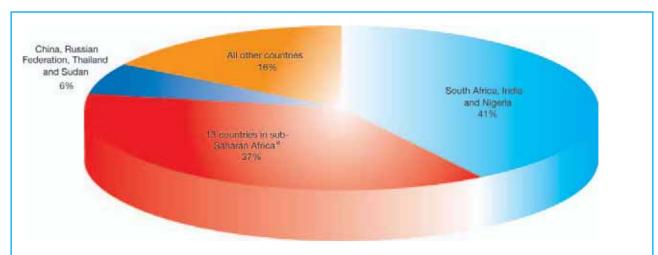


Fig. 18. Where do the 5.1 million people who need to start treatment in 2005 live?

# The resource gap

As of mid-2004, the costs of achieving "3 by 5" were estimated to be US\$ 3.1 billion to US\$ 3.8 billion for 2005 depending on drug costs and the rate of programme expansion in 2004.<sup>23</sup> ARV drug costs accounted for 43% of this amount in one of the higher drug cost scenarios.

More recently, using the Zambia treatment model with an average drug cost of US\$ 304 per person per year as a standard and applying it to 49 high burden and focus countries, it has been estimated that, to achieve "3 by 5", US\$ 3.55 billion to US\$ 3.80 billion is needed in 2005.<sup>24</sup> Based on commitments and pledges, about \$1.55 billion is available for 2005 from developing and transitional country sources, Global Fund to Fight AIDS, Tuberculosis and Malaria disbursements to countries, the United States President's Emergency Plan for AIDS Relief, World Bank and other donors. This would leave a shortfall of more than \$2 billion. The resource gap can be reduced by reductions in the costs of drugs or service delivery.

Clearly, the equation still does not balance. The level of international commitment to the "3 by 5" target must be matched by action on the ground. This will require, over the next 12 months, a concerted, collaborative effort to speed up the rate of disbursement and coordination between funders, country officials and providers to ensure that funds are swiftly absorbed and to ensure that oversight and urgent scale-up are complementary aims. Countries can also commit additional resources and make more effective use of new and existing health personnel.

# Ensuring equitable access

Access to ARV therapy services will need to be improved dramatically by increasing the numbers and distribution of service delivery points, especially in rural populations. More people need to come forward for testing and counselling. Stigma and discrimination issues will have to be addressed aggressively.

Strong uptake and reporting from programmes designed to prevent the mother-to-child transmission of HIV indicate that more women are receiving treatment in public facilities than men. This development, however, needs to be monitored closely. It is critical that testing, prevention and treatment access for children be improved, an effort that will include, among other things, widespread availability of affordable pediatric ARV formulations. Further, equitable access must be ensured for marginalized populations most affected by the epidemic such as prisoners, sex workers, injecting drug users and men who have sex with men. Drugs and diagnostics must become affordable for everyone in need.

<sup>&</sup>lt;sup>a</sup> Other than South-Africa and Nigeria.

Gutierrez JP et al. Achieving the WHO/UNAIDS antiretroviral treatment 3 by 5 goal: what will it cost? Lancet, 2004, 364: 63–64. Estimating funding gap to reach the target of 3 million with access to antiretroviral drugs by 2005 ("3 by 5"). Geneva, World Health Organization, Department of HIV/AIDS, unpublished document.

<sup>&</sup>lt;sup>24</sup> Estimating funding gap to reach the target of 3 million with access to antiretroviral drugs by 2005 ("3 by 5"). Geneva, World Health Organization, Department of HIV/AIDS, 2004, unpublished document.

# Efficient and effective treatment programmes

As HIV/AIDS evolves from a death sentence to a chronic disease, much needs to be done to further develop high-quality ARV therapy programmes. This includes management teams to coordinate the process of providing services, treatment preparedness and community engagement, reliable and efficient procurement and supply chains, training and capacity-building, standardized systems for monitoring the adherence of people receiving ARV therapy and treatment success, monitoring drug resistance, adherence support and operational research to learn by doing. Greater links between HIV and TB treatment and prevention programmes will greatly increase the scale-up of both services.

# Prevention - full speed ahead!

Treatment provides an opportunity to strengthen prevention, but investment in prevention is needed more than ever to turn around the epidemic. Salomon et al.<sup>25</sup> modelled the epidemic to try to predict the number of new infections and deaths in sub-Saharan Africa from now until 2020, depending on whether control efforts focused on prevention, treatment or both. By far the most effective way of decreasing new infections and deaths was to combine the two approaches. According to these estimates, more than 29 million fewer new infections and 10 fewer million deaths might be prevented by integrating prevention and care.

# Coordination

During 2004, coordination and collaboration among "3 by 5" partners and other organizations have improved significantly at the international and national levels. The "three ones" concept has gained momentum within countries and among donors and technical agencies. Harmonization of efforts to combat HIV/AIDS, including "3 by 5", is essential and must continue.

# Strengthening health systems

The year 2005 is an important opportunity to promote equitable and sustained development in poor countries. Weak health systems are a leading obstacle to achieving health-related Millennium Development Goals in many of the most needy countries. "3 by 5" presents an opportunity to address the core underlying issues: a skilled health sector workforce, sound information systems, a well-managed and regular supply of drugs and other supplies and fair and sustainable funding systems.

# Beyond "3 by 5"

The next 12 months will see unprecedented activity by many countries in the field of HIV/AIDS. They will also need to look forward and plan beyond 2005. Mid- and long-term strategies will have to be developed, new targets set and resource needs estimated. Most importantly, we must learn how to evaluate our efforts – and where necessary, change our approach "on the fly".

Assessing treatment scale-up and implementing lessons learned is a critical component of the "3 by 5" effort. Never before has so complex a public health campaign been implemented in such a short space of time. Effective operational research, knowledge management and training are critical and will offer significant benefits to all efforts to treat illness in developing and transitional countries.

Enrolling 2.3 million new people on ARV therapy in the next year is clearly the most difficult task the global public health community has ever faced. However, we should be encouraged by the rapid progress we have witnessed in the last six months. The most successful countries are and will continue to be those with strong political and financial commitment and effective partnerships.

"3 by 5" started as the declaration of an emergency. It is now evolving into a global movement for access to treatment, given life by governments, people living with HIV/AIDS and their communities, health care workers, NGO's, businesses, donors and international organizations. Working together, remarkable things have happened. Maintaining these partnerships may enable us to finally face down the most fearsome epidemic of our time.

<sup>&</sup>lt;sup>25</sup> Salomon JA et al. Integrating HIV prevention and treatment: from slogans to impact. *PLoS Medicine*, 2005, 2(1): e16.

# Annex 1. Data by WHO region and methods used in estimating the numbers of people receiving and needing ARV therapy

Estimated number of people receiving ARV therapy, people needing ARV and percentage coverage in developing and transitional countries by WHO region, December 2004<sup>a,b</sup>

| WHO region                   | Estimated number of people<br>receiving ARV therapy,<br>December 2004 (low<br>estimate-high estimate)° | Estimated number<br>of people 15–49<br>years old needing<br>ARV therapy,<br>2004 <sup>d</sup> | ARV therapy<br>coverage,<br>December<br>2004 (%)° | Estimated<br>number of people<br>receiving ARV<br>therapy, June<br>2004 |
|------------------------------|--|---|---|---|
| African Region               | 310 000 [270 000–350 000]  | 4 000 000   | 8%  | 150 000   |
| Region of the Americas       | 275 000 [260 000–290 000]  | 425 000   | 65%   | 220 000   |
| European Region              | 15 000 [13 000–17 000]   | 150 000   | 10%   | 11 000  |
| Eastern Mediterranean Region | 4 000 [2 000–6 000]  | 77 500  | 5%  | 4 000   |
| South-East Asia Region       | 85 000 [70 000–100 000]  | 950 000   | 9%  | 40 000  |
| Western Pacific Region       | 17 000 [15 000–19 000]   | 200 000   | 9%  | 15 000  |
| Total                        | 700 000 [630 000–780 000]  | 5.8 million   | 12%   | 440 000   |

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

### **Explanatory notes (also apply to Table 1 of the report)**

# Number of people 15–49 years old receiving ARV therapy, December 2004 (low estimate-high estimate)

The estimate of the number of people receiving ARV therapy is based on the most recent report received from the Ministry of Health, the WHO or UNAIDS office in the country or another reliable source in the country. Annex 2 provides details. The estimated numbers will be somewhat uncertain for countries that have not yet established systems for monitoring the people receiving therapy with regular reporting of numbers of new people receiving treatment, adherence, defaulters, loss to follow-up and deaths. One source of uncertainty is that country-reported figures often do not distinguish between those who have ever started ARV therapy and those who are still on treatment (that is, continuing to pick up and take their drugs). The difference between the two numbers reflects losses due to discontinuation of treatment or death.

<sup>&</sup>lt;sup>a</sup> See below for explanation of the methods used.

<sup>&</sup>lt;sup>b</sup> 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.

<sup>&</sup>lt;sup>c</sup> A few countries report the number of children younger than 15 years of age receiving ARV therapy, and they have been included in this table. Preliminary data show that, overall, less than 5% of the total number receiving ARV therapy are children younger than 15 years of age.

<sup>&</sup>lt;sup>d</sup> The figure presented is the midpoint of the low and high estimates of the number of AIDS deaths and the number of AIDS cases.

<sup>&</sup>lt;sup>e</sup> This is a best coverage estimate based on the midpoints of the number of people receiving ARV therapy and the estimated need for ARV therapy.

<sup>&</sup>lt;sup>f</sup> No updates have been received from the Eastern Mediterranean Region since June 2004.

Another source of uncertainty is the difficulty of measuring the extent of ARV therapy provided through the private sector. Many people are supplied with ARV drugs through local pharmacies and private clinics that do not report through the usual channels (this also applies to treatment for other diseases). Private companies may have programmes that support ARV therapy for workers with advanced HIV infection, but in many cases data are not easily accessible.

A third source of uncertainty arises from the time lag between global reporting, which is for the end of 2004, and country reporting, which usually relates to an earlier point in time. The current rapid expansion in numbers has required estimating the monthly increases and projecting these to December 2004. Thus, the estimates for end of 2004 are based on simple linear projections of reported numbers using the current trend as an indicator of growth.

Because of the uncertainty involved in making the overall estimates by country, the annex tables indicate uncertainty ranges for the December 2004 estimate of the number of people receiving treatment. For the country-reported data, public sector only or public and private sector combined, we used 0–10% uncertainty ranges depending on the strength of the monitoring system. For private sector numbers, which were separately reported for a limited number of countries, we used uncertainty ranges of 10–30%. For the numbers of people receiving ARV therapy, we used a 0.8% monthly attrition rate from dropping out of treatment or death (corresponding to an annual attrition of 10%).

# Estimated number of people 15-49 years old needing ARV therapy, 2004

UNAIDS and WHO have developed a standard method to estimate the size and course of the AIDS epidemic<sup>26</sup> that also generates estimates of the number of new HIV infections, AIDS cases and deaths. 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 HIV-infected people will need to start treatment than in a mature or declining epidemic.

WHO recommends that, in resource-constrained settings, HIV-infected adults and adolescents start ARV therapy when the infection has been confirmed and there are signs of clinically advanced disease (HIV disease stage IV, regardless of CD4 cell count or stage III with CD4 cell count below 350 cells per mm³) or laboratory evidence of severe immune suppression (CD4 cell count below 200 per mm³ or, if not available, lymphocyte count below 1200 per mm³ with symptomatic disease.<sup>27</sup>

Studies have shown that the median survival time for people with AIDS who are not receiving ARV therapy, in resource-constrained settings is just under one year.<sup>28</sup> Ideally, people should start receiving treatment before they develop AIDS: once they have advanced HIV infection. The number of adults 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 adults needing ARV therapy is calculated by adding the number of adults needing to start ARV therapy to the number of adults who were being treated in the previous year and survived into the current year. Since some of the adults who are projected to develop AIDS in these two years may already have started treatment in the previous year, the number needing to start ARV therapy is adjusted to subtract the adults who started treatment in the previous year. It is currently assumed that between 80% and 90% of adults receiving treatment will survive to the following year, depending on the time of treatment initiation, adherence to treatment, drug resistance patterns, the quality of clinical management and other factors.

Again, there is uncertainty around these estimates. This is related to uncertainty in the estimates of HIV prevalence, AIDS cases, AIDS deaths and treatment need. The better the surveillance system in place in the country, the smaller the uncertainty range. The greatest difficulty lies in estimating treatment needed, especially because of the uncertainty around death rates. If programme performance is good and increasing numbers of people begin treatment, coverage will increase but only slowly because need will be increasing at the same time. If programme performance is sluggish, people will die before receiving treatment, but

Ward H, Walker N, Ghys PD, eds. Methods and tools for HIV/AIDS estimates and projections. Sexually Transmitted Infections, 2004, 80(Suppl. 1):i1-i38.

<sup>27</sup> 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 31 December 2004).

Schneider M, Zwahlen M, Egger M. Natural history and mortality in HIV-positive individuals living in resource-poor settings: a literature review. London, UNAIDS Reference Group on Estimates, Modelling and Projections, 2004 (http://www.epidem.org/Publications/unaids%20HQ\_03\_463871%20final.pdf, accessed 31 December 2004).

coverage will decrease only slowly because the need also decreases. Survival rates may also improve if programmes expand, as more people will begin treatment earlier.

# ARV therapy coverage, December 2004

The coverage is the number of people receiving ARV therapy by the end of 2004 divided by the estimated number of people needing ARV therapy. The latter figure only includes adults 15–49 years old, as no good method to estimate need in children is currently available. Further, adults 50 years and older are not included, as no estimate of HIV prevalence is available. The numerator includes children and all adults, and coverage is therefore slightly overestimated. Children, however, are only a small proportion of the number of people receiving treatment, probably less than 5% (see also main text).

# Estimated number of people 15-49 years old receiving ARV therapy, June 2004

Estimates made for the first "3 by 5" progress report presented at the XV International AIDS Conference in Bangkok, Thailand.

Annex 2.

# Estimated number of people receiving ARV therapy, people needing ARV therapy and percentage coverage by country in developing and transitional countries, December 2004<sup>a</sup>

| -                       |             | ,                | :  | ( ,   | ( ( L   | 107    | (    | 1   |        | 0      | 1    |
|-------------------------|-------------|------------------|--|-------|---------|--------|------|-----|--------|--------|------|
| nigh burden             | pasic tocus | Λ,<br>4          |  | AFK   | 45 500  | 2 /34  | Sep  | 13/ | 3 000  | 3 200  | %/   |
| high burden             | basic focus | 1, 2, 4 MAP      | Burundi                                  | AFR   | 40 000  | 3 210  | Sep  | 101 | 3 000  | 4 000  | %6   |
| high burden             | basic focus | 1, 2, 4          | Cambodia                                 | WPR   | 22 000  | 4 527  | Oct  | 285 | 4 500  | 0009   | 23%  |
| high burden             | basic focus | 3, 4 MAP         | Cameroon                                 | AFR   | 95 000  | 12 896 | Oct  | 424 | 12 000 | 15 000 | 14%  |
|                         | basic focus | MAP              |  | AFR   | :       | :      |      | :   | :      | :      | ÷    |
| high burden             |             | 2, 4 MAP         | Central African<br>Republic              | AFR   | 40 500  | 525    | Dec  | 0   |        | <1 000 | 1%   |
|                         | basic focus | 2,3              | Chad                                     | AFR   | 30 000  | 300    | unr> | :   |        | <500   | :    |
|                         |             | -                | Chile                                    | AMR   | 5 750   | 7 413  | lnC  | 376 | 8 000  | 10 000 | 100% |
| high burden             | basic focus | 1, 3, 4          | China                                    | WPR   | 122 000 | 8 219  | nn   | 136 | 7 500  | 9 500  | %2   |
|                         |             | 2,3              | Colombia                                 | AMR   | 25 000  | 12 000 | Nov  | 0   | 11 000 | 13 000 | 47%  |
|                         |             | 2,3              | Comoros                                  | AFR   | :       | 200    | unr> | :   |        | <500   | :    |
|                         |             |                  | Congo                                    | AFR   | 14 500  | 464    | unr> | :   |        | <500   | :    |
|                         |             | 2                | Cook Islands                             | WPR   | :       | :      |      | :   | :      | :      | :    |
| regionally<br>strategic | basic focus | 2, 4             | Costa Rica                               | AMR   | 3 150   | 1 850  | lul  | 77  | 2 000  | 2 500  | %89  |
| high burden             | high focus  | 2,3              | Côte d'Ivoire                            | AFR   | 84 000  | 4 536  | Sep  | 36  | 4 000  | 2 000  | 2%   |
|                         | basic focus | 2                | Croatia                                  | EUR   | :       | 204    | Oct  | 2   |        | <500   | :    |
|                         |             | 2                | Cuba                                     | AMR   | 1 350   | 1 585  | Jul  | 42  | 1 500  | 2 000  | 100% |
|                         |             |                  | Czech Republic                           | EUR   | <200    | 270    | Oct  | 0   |        | <500   | 100% |
|                         |             | 1, 3             | Democratic People's<br>Republic of Korea | SEAR  | ÷       | :      | Dec  | ÷   | :      | ÷      | ŧ    |
| high burden             | basic focus | 2,3              | Democratic Republic of the Congo         | , AFR | 167 000 | 3 836  | Nov  | 203 | 3 500  | 4 500  | 2%   |
| regionally<br>strategic | basic focus | 4                | Djibouti                                 | EMR   | 1 350   | 200    | Dec  | 0   |        | <500   | 15%  |
|                         | basic focus | က                | Dominica                                 | AMR   | :       | 5      | Jul  | 0   |        | <200   | i    |
|                         | basic focus | 2-4              | Dominican Republic                       | AMR   | 15 500  | 1 011  | Dec  | 0   | 006    | 1 100  | 7%   |
|                         |             | 2-4              | Ecuador                                  | AMR   | 3 550   | 1 000  | Jul  | 20  | 1 000  | 1 500  | 34%  |
|                         | basic focus | 2                | Egypt                                    | EMR   | 2 050   | 28     | un(> | :   |        | <200   | :    |
| regionally<br>strategic | basic focus | 2, 4             | El Salvador                              | AMB   | 2 100   | 1 515  | Jul  | 43  | 1 500  | 2 000  | 32%  |
|                         |             | 4                | Equatorial Guinea                        | AFR   | 2 700   | 2      | unc> | :   |        | <200   | :    |
|                         | basic focus | 2, 3 MAP         | Eritrea                                  | AFR   | 10 500  | 20     | unر> | :   |        | <200   | i    |
|                         | basic focus | 2                | Estonia                                  | EUR   | <500    | 92     | Oct  | က   |        | <200   | 20%  |
| high burden             | high focus  | 1, 2, 4 MAP      | Ethiopia                                 | AFR   | 211 000 | 9 500  | Sep  | 743 | 10 000 | 13 000 | 2%   |
|                         |             | 2                | Fiji                                     | WPR   | <200    | :      |      | :   | :      | :      | :    |
|                         |             | 3, 4             | Gabon                                    | AFR   | 0369    | 2 000  | unc> | 20  | 2 000  | 2 500  | 29%  |
|                         | basic focus | 3 MAP            | Gambia                                   | AFR   | 1 100   | 150    | Dec  | 0   |        | <200   | 14%  |
|                         | basic focus | 2-4              | Georgia                                  | EUR   | <500    | 83     | Dec  | 13  |        | <200   | 20%  |
| high burden             | basic focus | 1, 2, 4 MAP, TAP | TAP Ghana                                | AFR   | 22 000  | 1 393  | Aug  | 153 | 1 500  | 2 000  | 4%   |

| Major                   | international s          | Major international support for countries | ries          |                                     |                            |   | Estimated  | antiretrovir     | Estimated antiretroviral therapy coverage and needs              | ge and need                          | <u>S</u>              |                       |
|-------------------------|--------------------------|---|---------------|-------------------------------------|----------------------------|---|--|------------------|--|--------------------------------------|-----------------------|-----------------------|
| "3 by 5"<br>Initiative  | United                   | Global Fund<br>to Fight AIDS.             | World<br>Bank | Country                             | WHO region                 | Estimated number of                       | Reported   | Month of report. | Average  | Estimated number of people receiving | d number<br>receiving | ARV                   |
|                         | President's<br>Emergency | Tuberculosis and Malaria,                 | 5             |                                     | -<br>5<br>5<br>5<br>7<br>7 | people 15–49<br>years old                 | of people<br>receiving                                 | 20049            | increase in<br>the number of                                     | ARV therapy,<br>December 2004        | erapy,<br>er 2004     | coverage,<br>December |
|                         | Plan for<br>AIDS Relief⁵ | approved<br>proposals, by<br>round        |               |                                     |                            | needing ARV<br>therapy, 2004 <sup>e</sup> | ARV therapy,<br>June–<br>December<br>2004 <sup>f</sup> |                  | people receiving<br>ARV therapy,<br>January–<br>December<br>2004 | Low                                  | High<br>estimate      | 2004                  |
| high burden             | basic focus              | 3, 4                                      |               | Guatemala                           | AMR                        | 13 500                                    | 3 617  | Jul              | 110  | 3 500                                | 4 500                 | 30%                   |
| high burden             |                          | 2   | MAP           | Guinea                              | AFR                        | 18 000                                    | 652  | Aug              | 19   |                                      | <1 000                | 4%                    |
|                         | basic focus              | 3, 4                                      |               | Guinea-Bissau                       | AFR                        | 3 650                                     | :  |                  |  | :                                    | :                     | ÷                     |
| regionally<br>strategic | high focus               | 3, 4                                      |               | Guyana                              | AMR                        | 1 900                                     | 469  | Sep              | 22   |                                      | <1 000                | 28%                   |
| high burden             | high focus               | 1, 3, 4                                   |               | Haiti                               | AMR                        | 42 500                                    | 2 829  | Sep              | 162  | 3 000                                | 4 000                 | 8%                    |
| regionally<br>strategic | basic focus              | -   |               | Honduras                            | AMR                        | 9 450                                     | 2 312  | lul              | 127  | 2 500                                | 3 000                 | 30%                   |
|                         |                          |   |               | Hungary                             | EUR                        | :   | 300  | Oct              | 0  |                                      | <200                  | ÷                     |
| high burden             | basic focus              | 1-4                                       |               | India                               | SEAR                       | 770 000                                   | 2 841  | Nov              | 200  | 20 000j                              | 36 000                | 4%                    |
| regionally<br>strategic | basic focus              | 1, 4                                      |               | Indonesia                           | SEAR                       | 11 500                                    | 2 500  | Oct              | 138  | 2 500                                | 3 000                 | 24%                   |
|                         |                          | 2, 3                                      |               | Iran, Islamic<br>Republic of        | EMR                        | 3 650                                     | 009  | unr>             | :  |                                      | <1 000                | ŧ                     |
|                         |                          |   |               | Iraq                                | EMR                        | :   | :  |                  | :  | ÷                                    | :                     | :                     |
|                         | basic focus              | 3, 4                                      |               | Jamaica                             | AMR                        | 2 600                                     | 200  | Jul              | 0  |                                      | <1 000                | 18%                   |
|                         | basic focus              | 2   |               | Jordan                              | EMR                        | :   | 40   | unر>             |  |                                      | <200                  | :                     |
| regionally<br>strategic | basic focus              | 0   |               | Kazakhstan                          | EUR                        | 1 050                                     | 7  | Oct              | 0  |                                      | <200                  | 1%                    |
| high burden             | high focus               | 1, 2, 4                                   | MAP           | Kenya                               | AFR                        | 220 000                                   | 16 952 <sup>k</sup>                                    | Sep              | 1 601  | 24 000 <sup>k</sup>                  | 33 000 <sup>k</sup>   | 13%                   |
|                         |                          | 2   |               | Kiribati                            | WPR                        | :   | :  |                  | :  | :                                    | :                     | :                     |
| regionally<br>strategic | basic focus              | 2   |               | Kyrgyzstan                          | EUR                        | <200                                      | 0  | Oct              | 0  |                                      | <200                  | ÷                     |
|                         | basic focus              | 1, 2, 4                                   |               | Lao People's<br>Democratic Republic | WPR                        | <200                                      | 104  | Aug              | 15   |                                      | <200                  | 64%                   |
|                         | basic focus              |   |               | Latvia                              | EUR                        | <1 000                                    | 202  | Oct              | 7  |                                      | <200                  | 22%                   |
|                         |                          |   |               | Lebanon                             | EMR                        | <500                                      | 353  | unر>             | 0  |                                      | <500                  | i                     |
| high burden             | basic focus              | 2   |               | Lesotho                             | AFR                        | 26 000                                    | 2 500  | Aug              | 50   | 2 500                                | 3 000                 | 2%                    |
|                         | basic focus              | 2, 3                                      |               | Liberia                             | AFR                        | 13 500                                    | :  |                  | :  | :                                    | :                     | :                     |
|                         |                          |   |               | Libyan Arab<br>Jamahiriya           | EMR                        | :   | 100  | nnر>             | :  |                                      | <200                  | ÷                     |
|                         | basic focus              |   |               | Lithuania                           | EUR                        | <200                                      | 37   | Oct              | က  |                                      | <200                  | 30%                   |
|                         | basic focus              | 1-4                                       | MAP           | Madagascar                          | AFR                        | 16 000                                    | :  |                  | 0  | :                                    | :                     | %0                    |

|                         |             | (           |                                    | (L   | 000     | 0.00               | (    | L   | 0      |        | , o o |
|-------------------------|-------------|-------------|------------------------------------|------|---------|--------------------|------|-----|--------|--------|-------|
| high burden             | basic tocus | 1, 2 MAP    | Malawi                             | AFK  | 140 000 | 9 240              | Sep  | 999 | 000 01 | 12 000 | %8    |
|                         |             |             | Malaysia                           | WPR  | 7 500   | 2 700              | unr> | 0   | 2 500  | 3 000  | :     |
|                         |             |             | Maldives                           | SEAR | :       | 0                  | Dec  | 0   | 0      | 0      | :     |
|                         | basic focus | 1, 4        | Mali                               | AFR  | 20 500  | 808                | -dun | 0   |        | <1 000 | Ξ     |
|                         |             |             | Marshall Islands                   | WPR  | :       | :                  |      | :   |        |        | ÷     |
|                         | basic focus | 2 MAP       | Mauritania                         | AFR  | 1 050   | 39                 | Oct  | 0   |        | <200   | 4%    |
|                         |             |             | Mauritius                          | AFR  | :       | 120                | Oct  | 0   |        | <200   | ÷     |
|                         | basic focus |             | Mexico                             | AMR  | 39 500  | 28 600             | Nov  | 646 | 26 000 | 32 000 | 74%   |
|                         |             | 2           | Micronesia,<br>Federated States of | WPR  | :       | :                  |      | ÷   |        |        | i     |
|                         |             | 1, 2, 4     | Mongolia                           | WPR  | <200    | :                  |      | :   |        |        | :     |
|                         |             | -           | Morocco                            | EMR  | :       | 465                | unr> | :   |        | <500   | :     |
| high burden             | high focus  | 2 MAP, TAP  |                                    | AFR  | 199 000 | 5 133              | Sep  | 764 | 6 500  | 8 000  | 4%    |
| high burden             | basic focus | 2, 3        | Myanmar                            | SEAR | 46 500  | 1 500              | Dec  | 0   | 1 500  | 2 000  | 3%    |
| high burden             | high focus  | 2           | Namibia                            | AFR  | 32 000  | 4 000              | Sep  | 844 | 7 500  | 11 000 | 28%   |
|                         |             |             | Nauru                              | WPR  | :       | :                  |      | :   | :      | :      | :     |
|                         | basic focus | 2, 4        | Nepal                              | SEAR | 7 800   | 75                 | Dec  | 0   |        | <200   | 1%    |
| regionally<br>strategic | basic focus | 2, 4        | Nicaragua                          | AMR  | 1 000   | 33                 | luľ  | 2   |        | <200   | 4%    |
|                         | basic focus | 3, 4 MAP    | Niger                              | AFR  | 8 700   | :                  |      | :   | ÷      | :      | ÷     |
| high burden             | high focus  | 1, 2, 4 MAP | Nigeria                            | AFR  | 558 000 | 13 579             | Sep  | 0   | 12 000 | 15 000 | 2%    |
|                         |             | 2           | Niue                               | WPR  | :       | :                  |      | :   | :      | :      | :     |
|                         |             |             | Oman                               | EMR  | <200    | 100                | nn(> | :   |        | <200   | :     |
|                         |             | 2, 3        | Pakistan                           | EMR  | 11 500  | 100                | un∫> | :   |        | <200   | ÷     |
|                         |             | 2           | Palau                              | WPR  | :       |                    |      |     | :      | :      | ij    |
| regionally<br>strategic | basic focus | 1, 4        | Panama                             | AMR  | 1 850   | 1 873              | Dec  | 14  | 1 500  | 2 000  | 100%  |
|                         | basic focus | 3, 4        | Papua New Guinea                   | WPR  | 1 750   | 09                 | -dun |     |        | <200   | Ξ     |
|                         |             | 3           | Paraguay                           | AMR  | 1 950   | 300                | Jul  | 0   |        | <200   | 15%   |
|                         | basic focus | 2, 3        | Peru                               | AMR  | 11 000  | 2 000              | lul  | 14  | 2 000  | 2 500  | 18%   |
|                         | basic focus | 2, 3        | Philippines                        | WPR  | 1 050   | 71                 | unc> | :   |        | <200   | :     |
|                         |             |             | Poland                             | EUR  | :       | 2 314              | Oct  | 101 | 2 000  | 2 500  | :     |
|                         | basic focus | -           | Republic of Moldova                | EUR  | :       | 120                | Dec  | 18  |        | <200   | :     |
|                         | basic focus | 2           | Romania                            | EUR  | :       | 0009               | Oct  | 125 | 2 500  | 2 000  | :     |
| high burden             | basic focus | 3, 4        | Russian Federation                 | EUR  | 92 000  | 3 000              | Oct  | 63  | 3 000  | 3 500  | 3%    |
| high burden             | high focus  | 1, 3, 4 MAP | Rwanda                             | AFR  | 39 000  | 5 165 <sup>m</sup> | Ang  | 418 | 0009   | 7 500  | 18%   |
|                         | basic focus | 3, 4        | Saint Kitts and Nevis              | AMR  | :       | 24                 | Jul  | 0   |        | <200   | :     |
|                         | basic focus | 3, 4        | Saint Lucia                        | AMR  | :       | 20                 | Jul  | 0   |        | <200   | :     |
|                         | basic focus | 3, 4        | Saint Vincent and the Grenadines   | AMR  | :       | 32                 | luC  | 0   |        | <200   | ŧ     |
|                         |             | 2           | Samoa                              | WPR  | :       | ÷                  |      | :   | ÷      | ÷      | ÷     |
|                         |             |             |                                    |      |         |                    |      |     |        |        |       |

| Major                   | international s  | Major international support for countries   | ries           |   |                         |  | Estimated  | antiretrovir   | Estimated antiretroviral therapy coverage and needs                              | le and neec  | S  |   |
|-------------------------|--|---|----------------|---|-------------------------|--|--|--|--|--|--|---|
| "3 by 5"<br>Initiative  | United<br>States<br>President's<br>Emergency<br>Plan for<br>AIDS Relief <sup>b</sup> | Global Fund<br>to Fight AIDS,<br>Tuberculosis<br>and Malaria,<br>approved<br>proposals, by<br>round | World<br>Bank° | Country   | WHO region <sup>d</sup> | Estimated<br>number of<br>people 15–49<br>years old<br>needing ARV<br>therapy, 2004° | Reported number of people receiving ARV therapy, June-December | Month of report, 20049   | Average monthly increase in the number of people receiving ARV therapy, January- | Estimated number of people receiving ARV therapy, December 2004' Low High estimate | d number<br>receiving<br>lerapy,<br>er 2004 <sup>f</sup><br>High<br>estimate | ARV<br>therapy<br>coverage,<br>December<br>2004 |
|                         |  | 4   |                | Sao Tome and                                    | AFR                     |  | 2004   |  | December<br>2004 <sup>n</sup>  |  |  |   |
|                         |  | 1   |                |   | ב                       | :  | i  |  | :  | :  | :  | :   |
|                         |  |   |                | Saudi Arabia                                    | EMR                     | :  | 100  | un∫>   | :  |  | <200   | ÷   |
|                         | basic focus  | 1,4   | MAP            | Senegal   | AFR                     | 7 850  | 1 600  | un∫>   | :  | 1 500  | 2 000  | :   |
|                         | basic focus  | 1,3   |                | Serbia and<br>Montenegro                        | EUR                     |  | 317  | Oct  | 0  |  | <500   | :   |
|                         |  |   |                | Seychelles                                      | AFR                     |  | 43   | Oct  | 0  | 20   | <200   | i   |
|                         | basic focus  | 2, 4  | MAP            | Sierra Leone                                    | AFR                     | 9 050  | 1 000  | unر>   | 0  | 1 000  | 1 500  | :   |
|                         |  |   |                | Slovakia  | EUR                     | :  | 65   | Oct  | 0  |  | <200   | :   |
|                         |  | 2   |                | Solomon Islands                                 | WPR                     |  | :  |  | 0  |  |  | :   |
| regionally<br>strategic | basic focus  | 2-4   |                | Somalia   | EMR                     | 7 000  | :  |  | 0  |  |  | %0  |
| high burden             | high focus   | 1–3   |                | South Africa                                    | AFR                     | 837 000  | 14 922   | Sep  | 2 697  | 37 000"  | 62 000"  | %2  |
|                         |  | 1, 4  |                | Sri Lanka                                       | SEAR                    | <500   | 25   | Dec  | 0  |  | <200   | 4%  |
| high burden             | basic focus  | 2–4   |                | Sudan   | EMR                     | 50 000   | 400  | unر>   | 0  |  | <500   | :   |
|                         | basic focus  | 3, 4  |                | Suriname  | AMR                     | <1 000   | 220  | Jul  | 0  |  | <200   | 25%   |
| high burden             | basic focus  | 2–4   |                | Swaziland                                       | AFR                     | 36 500   | 5 453  | Oct  | 210  | 2 000  | 6 500  | 16%   |
|                         |  |   |                | Syrian Arab<br>Republic                         | EMR                     | <500   | 468  | <du√< td=""><td>0</td><td></td><td>&lt;500</td><td>i</td></du√<> | 0  |  | <500   | i   |
| regionally<br>strategic | basic focus  | 1, 3, 4   |                | Tajikistan                                      | EUR                     |  | 0  | Oct  | 0  |  | 0  | i   |
|                         | basic focus  | 1–3   |                | Thailand  | SEAR                    | 114 000  | 41 000   | Aug  | 2 863  | 45 000   | 55 000   | 44%   |
|                         | basic focus  | Е   |                | The former Yugoslav<br>Republic of<br>Macedonia | EUR                     |  | 2  | Oct  | 0  |  | <200   | ij  |
|                         | basic focus  | 2-4   |                | Togo  | AFR                     | 17 500   | 1 500  | Ang  | 178  | 2 000  | 2 500  | 12%   |
|                         |  | 2   |                | Tonga   | WPR                     | :  | :  |  | :  | :  | :  | ÷   |
|                         | basic focus  | 3, 4  |                | Trinidad and Tobago                             | AMR                     | 4 700  | 784  | Jul  | 0  |  | <1 000   | 16%   |
|                         |  |   |                | Tunisia   | EMR                     | <500   | 437  | un∫>   | 0  |  | <500   | :   |
|                         |  | 4   |                | Turkey  | EUR                     | :  | 250  | Oct  | 0  |  | <500   | :   |
|                         | basic focus  |   |                | Turkmenistan                                    | EUR                     | i  | 0  | Oct  | 0  |  | 0  | :   |
|                         |  | 2   |                | Tuvalu  | WPR                     | :  | :  |  | :  | :  | :  | :   |
| high burden high focus  | high focus   | 1-4   | 1-4 MAP        | Uganda  | AFR                     | 114 000  | 35 000   | Sep  | 3 366  | 40 000   | 20 000   | 40%   |

| high burden             | high burden basic focus | 1    |          | Ukraine                        | EUR | 45 000° | 926     | Dec | 131   |        | <1 000 | 2%   |
|-------------------------|-------------------------|------|----------|--------------------------------|-----|---------|---------|-----|-------|--------|--------|------|
| high burden high focus  | high focus              | 1-4  | 1-4 MAP  | United Republic of<br>Tanzania | AFR | 263 000 | 2 880°  | Dec | 103   | 2 000  | 3 500  | 1%   |
|                         |                         |      |          | Uruguay                        | AMR | 1 450   | 1 400   | Jul | 70    | 1 500  | 2 000  | 100% |
| regionally<br>strategic | basic focus             | 2, 3 |          | Uzbekistan                     | EUR | 1 250   | 0       | Oct | 0     |        | 0      | %0   |
|                         |                         | 2    |          | Vanuatu                        | WPR |         | :       |     | 0     | :      | :      | ÷    |
|                         |                         | 3    |          | Venezuela                      | AMR | 18 000  | 9 525   | Jul | 0     | 8 500  | 10 000 | 51%  |
| high burden high focus  | high focus              | 1,3  |          | Viet Nam                       | WPR | 27 500  | 300     | Dec | 0     |        | <200   | 1%   |
| regionally<br>strategic |                         | 2-4  |          | Yemen                          | EMR |         |         |     | 0     | :      | :      |      |
| high burden             | high focus              | 1, 4 | 1, 4 MAP | Zambia                         | AFR | 149 000 | 13 636⁴ | Sep | 2 277 | 18 000 | 22 000 | 13%  |
| high burden             | high burden basic focus | 1    |          | Zimbabwe                       | AFR | 295 000 | 8 000   | Nov | 409   | 7 500  | 0006   | 3%   |
|                         |                         |      |          |                                |     |         |         |     |       |        |        |      |

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

This list includes bilateral and regional programmes from the United States Agency for International Development (USAID) and the United States Department of Health and Human Services (HHS)

" MAP: Multi-Country HIV/AIDS Program for Africa; TAP: HIV/AIDS Treatment Acceleration Project.

The figure presented is the midpoint of the low and high estimates of the number of AIDS deaths and the number of AIDS cases. The needs estimates are based on the methods described in Annex 1. "EMR: Eastern Mediterranean Region; EUR: European Region; AFR: African Region; AMR: Region of the Americas; SEAR: South-East Asia Region; WPR: Western Pacific Region

A few countries report the number of children younger than 15 years of age receiving ARV therapy, and they have been included in this table. Preliminary data show that, overall, less than 5% of the total Estimates for individual countries may differ according to the local methods used. number receiving ARV therapy are children younger than 15 years of age.

ereceive in the number of people receiving ARV therapy during the last twelve months of 2004, or, in some cases, the last 6 months, depends on the available data. The increase is calculated

using two recent data points in 2004 having the longest period between them and applying a linear projection for each month up to December 2004.

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

This is a best coverage estimate based on the midpoints of the number of people receiving ARV therapy and the estimated need for ARV therapy.

The government reported that 2841 people were receiving ARV therapy through the public sector by the end of November 2004. Overall, an estimated 28 000 people were receiving ARV therapy by the end of

indirect support from the United States Government (as of the end of September 2004). The estimated number of 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 2004 including people enrolled through private facilities.

\*A public-sector estimate of almost 17 000 people receiving ARV therapy is based on numbers reported by the Ministry of Health, nongovernmental organizations and mission facilities receiving direct or

The Ministry of Health and Social Services in Namibia estimated that almost 3000 people were receiving ARV therapy through private facilities by the end of August. The public sector was giving 4000 people equals the number shifting to public-sector providers of ARV therapy. ARV therapy in September 2004

"The Global Fund to Fight AIDS, Tuberculosis and Malaria reported a figure of 5165 people receiving ARV therapy through their principal recipient.

Includes a private-sector estimate of more than 35 000. The national health authorities reported a number of almost 15 000 for the public sector in September 2004

\*Almost 880 people were receiving ARV therapy through the public sector by the end of 2004. An estimated 2000 people are receiving ARV therapy from various private sources and donations and research Phe estimated number of people needing ARV therapy is currently under review and will be adjusted, if necessary, based on the best available evidence.

The Central Board of Health of Zambia reported that 13 555 people were receiving ARV therapy through the public sector in September 2004. By the end of September 2004, an additional 80 people were estimated to be receiving ARV therapy at a designated prevention of mother-to-child transmission (PMTCT-Plus) site.

# Annex 3.

# Progress by United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States President's Emergency Plan for AIDS Relief

#### **WHO**

WHO is structured to translate international knowledge into good health practice at the global, regional and country levels. WHO's role in the HIV/AIDS pandemic involves advocacy leadership, empowering and motivating stakeholders and providing technical support at the country level.

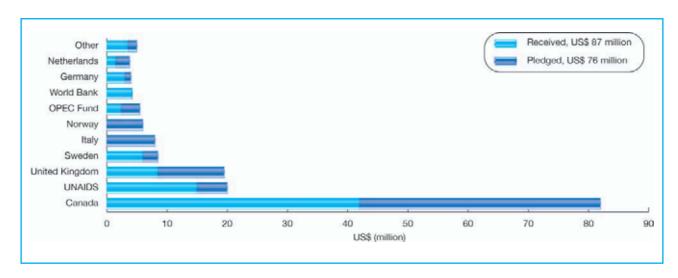
WHO, along with most other key actors, is caught up in a rapidly accelerating environment that has changed "3 by 5" from a simple numerical target to a sustainable global movement.

An indicator of across-the-board support for WHO's contribution to achieving the "3 by 5" target is that, by December 2004, WHO had received nearly US\$ 87 million in funding. An additional US\$ 76 million had been pledged (Fig. A1).

In May 2004, the Government of Canada announced a CAD 100 million contribution to WHO in support of the "3 by 5" Initiative. This shows Canada's ongoing commitment to the global efforts to respond to the HIV/ AIDS pandemic and its recognition that WHO has an invaluable role to play in developing and promulgating the normative standards and guidelines required to enable an accelerated response to providing access to HIV/AIDS care, treatment and support in resource-constrained settings.

More than two thirds of the resources will go directly to WHO country offices, which are being strengthened to offer technical support and backstopping to country efforts. From July to December 2004, WHO assigned 75 additional staff members to "3 by 5" activities in the WHO offices of 34 countries across WHO's six geographical regions. Of these, 32 were recruited as new full-time staff and 43 are refocusing their activities.

Fig. A1. Funds received by and pledged to WHO to support "3 by 5" according to donor, December 2004



Assistance to countries is the centrepiece of WHO's response. Since September 2003, WHO and its "3 by 5" partners have provided support to more than 75 countries in their efforts to scale up HIV/AIDS treatment, care and prevention. This has included support for advocacy, assessment of needs and assistance in planning as well as technical assistance for scaling up ARV therapy in specific areas including monitoring and evaluation, capacity-building, drug procurement and supply management.

With technical assistance from WHO, UNAIDS and their partners, 40 countries have developed or are developing national plans for prevention and accelerated access to ARV therapy.

WHO has stepped up its normative role to respond to the needs and requests for guidance from countries and partners. Recent publications have provided guidance on ethics and equitable access to treatment and care; nutrition counselling, care and support for women living with HIV/AIDS; and ARV therapy for pregnant women and for preventing HIV infection in infants.

Throughout 2004, an average of 5000 documents per month were distributed to 150 countries. Another 50 000 documents in multiple United Nations official languages were distributed at special events, including the XV International AIDS Conference in Bangkok.

In general, through headquarters and regional offices, WHO tries to ensure prompt and timely response to country requests for technical assistance. It maintains a "3 by 5" Help Desk in Geneva, which receives 80–100 requests for information or technical assistance from WHO regional and country offices each month and up to 60 information requests from the general public. The Help Desk also processes incoming information on the situation in countries and ongoing operations, which is used to update databases and archives, comprising about 450 e-mail messages per month.

#### **UNAIDS**

UNAIDS is the leading advocate for worldwide action against AIDS, bringing together 10 Cosponsors from the United Nations System. It recognized the critical need for HIV treatment early in the epidemic, and each cosponsor has pledged to support the rapid scaling up of treatment, care and support by focusing on their comparative advantages and working in a coordinated way to maximize efficiency.

The UNAIDS Secretariat operates out of Geneva and has offices in more than 60 countries. As it seeks to improve access to ARV therapy, its activities can be divided into three broad areas: leadership and advocacy; harmonizing policies and guidelines; and providing direct support to countries and regional structures to build critical capacity.

The Global Coalition on Women and AIDS, launched by UNAIDS in 2004, promotes gender equity and enhances women's access to prevention and treatment. UNAIDS has also worked with communities to address and overcome the barriers to women being tested for HIV, including the risk of violence and discrimination they may face if they are prove HIV-positive.

UNAIDS has also helped to facilitate relations between generic manufacturers of ARV drugs and civil society organizations, including those representing people living with HIV/AIDS. An example is the significant support for the Second World Community Advisory Board meeting between HIV treatment activists and generic manufacturers in India planned for Mumbai, India in early 2005.

This is in accordance with the emphasis of UNAIDS on helping to strengthen associations of people living with HIV/AIDS in educating and preparing their own communities with respect to HIV treatment and care – a process treatment activists have termed treatment preparedness.

Research has confirmed that community-based organizations are an important component of the scaling-up process, and UNAIDS has supported the first attempt to map the contributions of these organizations, including people living with HIV/AIDS. In Africa, many community organizations are already actively working to scale up treatment, and their public profile is growing rapidly.

Through collaboration with WHO and the World Bank, UNAIDS has laid the groundwork for developing policy guidance on whether out-of-pocket user fees are advisable or whether medicines and services should be free of user charges, in the context of achieving universal access to ARV therapy in developing and transitional countries.

UNAIDS mobilizes support within the United Nations System for "3 by 5" at the country level, through United Nations theme groups and its own country coordinators. By the end of 2004, the theme groups had developed joint United Nations System action plans for scaling up treatment in 33 high-burden countries where country offices have been strengthened. Since August 2004, UNAIDS has recruited 10 new United Nations country coordinator positions and nearly 30 technical specialists in monitoring and evaluation. They are expected to foster countries' ability to monitor the progress and effectiveness in preventing new infections and in providing HIV treatment, support and care services.

At the regional level, the UNAIDS Secretariat promotes the awareness and involvement of regional intergovernmental organizations in "3 by 5". It encourages the inclusion of "3 by 5" plans and programmes in agendas and promotes a unified approach to issues such as negotiating good prices and bulk purchasing of HIV medicines.

# **World Bank**

Since 1995, the World Bank has committed more than US\$ 1.7 billion through grants, loans and credits to support programmes to combat AIDS. More than US\$ 1 billion has gone to support the Multi-Country HIV/AIDS Program for Africa for 28 high-burden countries in Africa and another US\$ 155 million has gone to the Caribbean Multi-Country HIV/AIDS Prevention and Control Adaptable Program Lending. The overall goal of the World Bank multi-country HIV/AIDS programmes is to intensify action against AIDS in as many countries as possible and on all fronts, including prevention, testing, counselling, treatment, care and support.

Over the past six months, the Bank has supported accelerated access to treatment by providing ongoing financial and technical support for improving national health systems in 100 countries. It has also provided direct support to ARV therapy programmes in the Caribbean, 13 African countries, three Asian countries, and one country in eastern Europe.

In mid-2004, the World Bank announced the Treatment Acceleration Project with a US\$ 60 million International Development Association grant to support scaling up access to HIV treatment in three African countries: Burkina Faso, Ghana and Mozambique. Another US\$ 15 million grant has been given to Mali. Grassroots organizations, private companies such as the Private Enterprise Foundation/Pharma Access International in Ghana, faith-based groups such as the Community of Sant'Egidio in Mozambique, and a network of people living with HIV/AIDS in Burkina Faso, are directly involved in implementing the Treatment Acceleration Project, building on progress already achieved on a smaller scale in partnership with ministries of health.

# **Other UNAIDS Cosponsors**

The core strategies and initiatives of UNDP on HIV/AIDS – community capacity enhancement and leadership development – now include "3 by 5" components. The primary focus is on countries in southern Africa, where the leadership development programmes have identified parliamentarians, programme planners and implementers, trade union workers, community treatment supporters and chiefs for training. UNDP also co-hosted a workshop in Ghana at which officials from the health and trade ministries of several countries examined ways of developing legislation to maximize access to treatment.

UNICEF aims to raise the profile of children in the "3 by 5" Initiative, both in preventing mother-to-child HIV transmission and in treating children living with HIV/AIDS. Although successfully treating the parents will benefit their children, community-based government and nongovernmental organizations also urgently need to provide better pre-emptive support for children who are soon to become orphaned. In November 2004, UNICEF and WHO convened a first-ever consultation to review strategies for integrating child care into home-based care programmes.

Since becoming a cosponsor of UNAIDS in 2001, the International Labour Organization (ILO) has promoted the workplace as an ideal setting for delivering prevention, counselling, testing, treatment, care and support.

The ILO recently worked closely with WHO on mapping workplace capacity to provide HIV treatment in Guyana, Uganda, Zambia and Zimbabwe.

The World Food Programme (WFP) has a strong presence in most countries severely affected by the AIDS epidemic and is committed to providing nutritional support to people living with HIV/AIDS. WFP has been working with WHO and the UNAIDS Secretariat to develop a mechanism for exchanging the health and food security information needed to support the roll-out of "3 by 5". One of WFP's major strengths is its ability to target vulnerable groups through its Vulnerability Analysis & Mapping and WHO's HealthMapper. The information will be used to enhance the targeting and delivery of HIV support services.

The United Nations Office on Drugs and Crime (UNODC) focuses on the needs of people who are trafficked or live in situations of forced labour, especially in the sex industry, and injecting drug users, both within and outside prisons. ARV therapy is rarely available to injecting drug users, and UNODC advocates for its availability. All the drug dependence treatment projects UNODC supports now have a component of accelerated access to treatment.

The United Nations Educational, Scientific and Cultural Organization (UNESCO) works in close collaboration with UNAIDS, its Cosponsors and civil society partners on developing practical educational and communication strategies on all matters related to HIV/AIDS, including "3 by 5". Ongoing activities include training workshops for mass-media professionals on the science of HIV/AIDS, promoting a global network of young television producers focusing on HIV and AIDS and developing multimedia training kits.

The United Nations Population Fund (UNFPA) has galvanized support for "3 by 5" by spearheading, in 2004, the New York Call to Commitment: Linking HIV/AIDS and Sexual and Reproductive Health and the Glion Call to Action on Family Planning and HIV/AIDS in Women and Children. These calls for action underscore how sexual and reproductive health services can be used to deliver ARV drugs and to enhance efforts to prevent HIV transmission. In collaboration with nongovernmental organizations, including groups of people living with HIV/AIDS, UNFPA began to develop a framework for meeting the special sexual and reproductive health needs of women living with HIV/AIDS in 2004. In addition, their 2004 report – *Women and AIDS: confronting the crisis*<sup>29</sup> – draws attention to the need for ensuring equitable access to ARV therapy, especially for young people, women and pregnant women living with HIV/AIDS.

# Global Fund to Fight AIDS, Tuberculosis and Malaria

Reaching the Millennium Development Goal of reversing the HIV/AIDS epidemic by 2015 will require an estimated annual expenditure of US\$ 12 billion in developing and transitional countries by 2005. <sup>30</sup> Existing commitments and trends indicate that only US\$ 6 billion will actually be spent in 2005. <sup>31</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria is one of the mechanisms helping to close the gap between needs and real commitments. Established in January 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria now has about 750 partners (including donor countries, charitable foundations and industry) and aims to dramatically increase resources to fight three of the world's most devastating diseases and to direct resources to the areas of greatest need.

By December 2004, the Fund had received pledges for US\$ 5.9 billion and payments of US\$ 3.3 billion against those pledges. In four rounds of disbursements, it had approved proposals with a two-year value of US\$3.1 billion and had already disbursed US\$ 860 million. Of the US\$3. 1 billion approved, US\$ 1.7 billion (55%) has been allocated to AIDS, 70% to low-income countries and 30% to middle-income countries and 58% to sub-Saharan Africa. In total, 127 countries are benefiting.

So far, more than half the grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria are going to national governments, 25% to nongovernmental and community-based organizations, 4% to associations of people living with HIV/AIDS and 5% each to academic institutions, the private sector, faith-based organizations and others.

<sup>29</sup> Women and AIDS: confronting the crisis. New York, United Nations Population Fund, 2004 (http://www.unfpa.org/hiv/women, accessed 31 December 2004).

<sup>30 2004</sup> report on the global AIDS epidemic. Geneva, UNAIDS, 2004 (http://www.unaids.org/bangkok2004/GAR2004\_html/GAR2004\_00\_en.htm, accessed 31 December 2004).

Report on the state of HIV/AIDS financing. Geneva, UNAIDS, 2003 (http://www.data.org/pdf/attachment9.pdf, accessed 31 December 2004).

Expenditure targets are 49% for drugs and related supplies, 20% for human resources training, 13% for physical infrastructure, 6% for monitoring and evaluation, 7% for administration and 5% for other purposes.

With the money pledged so far, the Global Fund to Fight AIDS, Tuberculosis and Malaria is projected to reach 52 million people with voluntary counselling and testing for HIV and 1.6 million people with ARV therapy over the five-year lifetime of the individual grants (Table A1).

Table A1. Global Fund to Fight AIDS, Tuberculosis and Malaria spending (in millions of US dollars) on "3 by 5" by round of funding

| Round   | 1       | 2       | 3       | 4       | Total     |
|---|---------|---------|---------|---------|-----------|
| Amount approved for HIV/<br>AIDS grants <sup>b</sup>                        | 358     | 491     | 382     | 468     | 1 699     |
| Amount for grants with ARV therapy component                                | 309     | 429     | 361     | 443     | 1 542     |
| Number of new countries with ARV therapy component <sup>c</sup>             | 21      | 32      | 25      | 9       | 87        |
| Number of grants with ARV therapy components                                | 21      | 34      | 30      | 23      | 108       |
| Target number of people to receive ARV therapy – two years                  | 86 400  | 100 800 | 82 700  | 485 400 | 755 300   |
| Target number of people<br>to receive ARV therapy<br>– maximum <sup>d</sup> | 231 100 | 284 800 | 184 400 | 932 200 | 1 632 500 |

<sup>&</sup>lt;sup>a</sup>The numbers are based on four rounds of approved proposals and/or grant agreement targets.

No assumptions are made concerning eventual prolongation, extension or renewal of grants.

# U.S. President's Emergency Plan for AIDS Relief

Under President George W. Bush's \$15 billion Emergency Plan for AIDS Relief, the United States is preventing new infections, supporting lifesaving treatment to people with AIDS, and caring for those infected and affected by the disease, including orphaned and vulnerable children. The U.S. approach is characterized by swift action and an extraordinary financial commitment of US\$15 billion over 5 years. In Fiscal Year 2004, the U.S. committed a total of \$2.4 billion to the fight against HIV/AIDS, and this figure will increase to \$2.8 billion in Fiscal Year 2005.

The President's Emergency Plan directly provides HIV/AIDS treatment, prevention and care in more than 100 nations. This includes an intense focus on 15 of the world's hardest hit countries, which are collectively burdened with half of the world's infections: Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Viet Nam and Zambia.

In each of these countries, the Emergency Plan is working to support national response strategies. U.S. personnel have collaborated with host governments, local community-based and faith-based organizations, people living with HIV/AIDS, other donors, and other stakeholders to design a Country Operational Plan that responds to the nation's particular needs. They have also worked with these nations to determine annual and five-year target numbers of persons to be reached by U.S.-funded prevention, care and treatment programs.

In these countries over these five years, this Emergency Plan for AIDS Relief is aiming to support the provision of lifesaving drug treatment to 2 million HIV-infected people; the prevention of 7 million new HIV infections; and the care for 10 million people infected and/or affected by HIV/AIDS.

<sup>&</sup>lt;sup>b</sup>The amount approved for HIV/AIDS grants is the two-year total for HIV/AIDS plus 50% of the two-year total for HIV/TB grants.

<sup>&</sup>lt;sup>c</sup> Does not count countries receiving three multi-country Americas (MESO, CRN+ and OECS) grants.

<sup>&</sup>lt;sup>d</sup> Maximum number of people receiving treatment over the lifetime of proposals (up to five years).

The single greatest obstacle is a desperate lack of infrastructure and health care workers in the hardest hit nations. It is essential to build the health care capacity of the highest-risk regions. For this reason, a substantial portion of the U.S. funds is being invested in training health care workers, and in upgrading national and local public-health infrastructure under national strategies.

Cooperation with other international donors in pursuing these objectives is a key element of the President's Emergency Plan. The U.S. co-sponsored the UNAIDS-led "Three Ones" agreement for cooperation among donors in support of one national strategy, one national coordinating mechanism, and one monitoring and evaluation system in each host country. Implementation of this agreement is ensuring that donors work together with the clear recognition that the host nations must own the fight against AIDS in their countries. U.S. support of international efforts to fight HIV/AIDS, such as UNAIDS, WHO, and the Global Fund, is another key element of the Emergency Plan.

# Annex 4. Progress in results versus objectives for "3 by 5"

| Input  | Published<br>milestones<br>for<br>December<br>2004 | Result as<br>of<br>December<br>2004 |
|--|--|-------------------------------------|
| Amount of additional financial resources allocated to "3 by 5" within WHO overall budget (in millions of US dollars) | 174  | 163                                 |
| Number of additional WHO staff deployed and/or realigned to WHO country offices for "3 by 5"                         | 400  | 112ª                                |
| Number of partner organizations whose role in "3 by 5" is agreed and published                                       | 150  | 136                                 |
| Process  |  |                                     |
| Number of countries appealing to WHO for support for "3 by 5"  | 50   | 78                                  |
| Number of countries establishing antiretroviral therapy targets in accordance with "3 by 5"                          | 50   | 30                                  |
| Number of countries with a national plan for implementing scale-up in accordance with "3 by 5"                       | 35   | 40                                  |
| Number of service outlets providing antiretroviral therapy services according to national standards                  | 1 000  | >3 000                              |
| Outcome  |  |                                     |
| Number of men, women and children with advanced HIV infection receiving antiretroviral therapy                       | 700 000  | 700 00                              |



Milestone not achieved but solid progress being made

<sup>&</sup>lt;sup>a</sup> This is the total number of WHO staff engaged in "3 by 5" activities in country offices and includes 34 newly recruited staff members, 41 realigned existing staff, plus 37 staff from headquarters and regional offices who undertook interim deployments to country offices for "3 by 5".