



Progress on Global Access to HIV Antiretroviral Therapy

An update on "3 by 5"

June 2005

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Joint United Nations Programme on HIV/AIDS
UNAIDS
UNHCR-UNICEF-WFP-UNDP-UNFPA
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**World Health
Organization**



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Table of Contents

Foreword	5
Executive Summary	7
Global Progress in Scaling Up Treatment	11
The evolution of “3 by 5”	11
Progress in numbers	12
Overcoming Obstacles to Progress	15
Moving ahead in the highest-burden countries.....	15
Political commitment.....	15
Financial sustainability	16
Equitable access.....	17
Integration of prevention and treatment	19
Expanding human resource capacity	21
Strengthening procurement and supply management systems.....	23
Overcoming and improving limited health infrastructure	24
Coordinating technical partnerships	26
Conclusion and Recommendations	27
Annexures	29
1. Estimating the number of people on antiretroviral treatment	29
2. The “3 by 5” focus countries	31



June 2005

Foreword

Over the past two decades, the HIV/AIDS epidemic has continued to illuminate obstacles to progress in the global development agenda. Of eight key areas covered by the Millennium Development Goals, six – reduced poverty and child mortality, increased access to education, gender equality, improved maternal health and efforts to combat major infectious diseases – are being undermined by high rates of HIV in many low- and middle-income countries.

Since the cause of AIDS was identified in the early 1980s, standards of treatment and care have evolved considerably, primarily in high-income countries. Yet, the human immunodeficiency virus (HIV) has spread across political, economic and social boundaries much more quickly than have clinical and public health responses. Until recently, antiretroviral therapy (ART) was accessible only to the fortunate few, while millions were denied their fundamental right to benefit from the advances of science.

In recent years an international consensus has emerged on the need to fight HIV/AIDS with a comprehensive response, including treatment, care, prevention and impact mitigation. There has been a sharp increase in available funding for HIV/AIDS in low- and middle-income countries, which has marked a new era in international public health, focused on providing access to treatment, care and prevention for the people most in need, despite poverty and other daunting obstacles. In response to the opportunity presented by these new resources, WHO and the UNAIDS Secretariat set an urgent challenge for the UN system and the global community as a whole: the "3 by 5" target of providing ART to 3 million people living with HIV/AIDS in low- and middle-income countries by the end of 2005. This corresponds to treating just half of those in need.

The collective efforts of many countries and their international partners have generated real momentum in scaling up HIV treatment and prevention. "3 by 5" has helped to show how targets can shift debates, helping us to move from "if" ART can be provided in resource-limited countries, to "when", and now, to "how" it can be done most effectively. As documented in this report, many countries are showing the world how. From crowded metropolis to isolated village, structures are being put into place that allow hundreds of thousands of people to access a level of medical care that, just a short time ago, was unimaginable.

Understanding current bottlenecks to rapid scale up of HIV treatment and prevention is of critical importance, not only in efforts to meet interim national targets but also in ensuring universal access in the long term. This interim progress report therefore highlights not only the progress to date, but also the major obstacles that remain. A detailed report to be published at the end of 2005 will provide in-depth data and analysis on progress made at country level.

The lessons learnt so far confirm that success in the global fight against HIV/AIDS does not come without great effort. Nor does it depend on any single country, organization or individual.

We must continue working towards it together.



LEE Jong-wook
Director-General
World Health Organization



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



Executive Summary

Since late 2003, when WHO and UNAIDS launched a strategy for ensuring treatment for 3 million people living with HIV/AIDS in low- and middle-income countries by the end of 2005 (the "3 by 5" target), coverage of antiretroviral therapy (ART) in these countries has more than doubled – increasing from 400 000 to approximately 1 million people receiving treatment at the end of June 2005. To date, 14 of these countries are providing ART to at least 50 per cent of those who need it, consistent with the "3 by 5" target.

The current momentum in expanding treatment access in sub-Saharan Africa, where the burden of disease is greatest, is especially encouraging. Approximately 500 000 people in the region are receiving treatment, a three-fold increase in the last 12 months. Overall, scale-up appears to be accelerating, with about 150 000 and then about 200 000 more people on treatment in successive six-month periods. Most African countries report that demand for treatment is outstripping their capacity to supply it, and stress their urgent need for increased resources and technical support in order to maintain their momentum in scaling up.

Progress in Asia, the region with the second highest need for treatment, has also been significant, with the number of people receiving treatment increasing nearly three-fold – from 55 000 to 155 000 – in the last 12 months.

In eastern Europe and central Asia, the number of people on treatment has almost doubled in the last 12 months, from 11 000 to 20 000 people. The majority of countries in this region aim to be providing universal access by the end of 2005, but this does not include the two countries with the largest unmet treatment need, the Russian Federation and Ukraine.

In Latin America and the Caribbean, WHO estimates that the total number of people on treatment grew from 275 000 to 290 000 in low- and middle-income countries during the first half of 2005, which indicates that about two out of three people who need treatment in this region are receiving it. The most populous countries in the region - including Argentina, Brazil and Mexico - already have relatively high coverage, but several other countries are lagging behind. In north Africa and the Middle East, coverage remains low at about 5 per cent with little change in the number of people on treatment, currently estimated at about 4 000.

The momentum achieved to date in scaling up HIV treatment access has been the result of a broad range of local, national, regional and international efforts, including, first and foremost, those of many of the most highly affected countries. These efforts have been supported by resources from the Global Fund to Fight AIDS, TB and Malaria (the Global Fund), the United States President's Emergency Plan for AIDS Relief and other bilateral donors, the World Bank, international non-governmental organizations (NGOs) and the private sector, with technical support from United Nations agencies and many other organizations.

The estimate of approximately 1 million people now on treatment falls short of the milestone of 1.6 million set in the WHO/UNAIDS "3 by 5" strategy for June 2005. Current data and trends indicate that providing ART to 3 million people by the end of 2005 will be unlikely. However, there is reason to be hopeful that growth rates will continue to increase in the remainder of 2005 and beyond. Although less than what is needed, an estimated US\$27 billion are available or have been pledged for HIV/AIDS globally from all sources for the three-year period 2005-2007. At the same time, substantial political commitment to moving forward is evident in the many countries that have translated the global "3 by 5" target into ambitious but feasible national treatment targets.

This interim report on global efforts to increase access to ART focuses primarily on understanding the reasons for the successes and failures of scaling up HIV/AIDS interventions in different settings. The report also makes recommendations concerning the approaches needed to overcome major bottlenecks, as well as the need for sustainable financing mechanisms and greater harmonization of effort by technical and financing partners at country level. A comprehensive report and country-specific analysis of access efforts and obstacles that remain will be released at the end of 2005.

Progress and challenges in countries

The “3 by 5” target has been an important element in the overall international effort to build momentum for expanded access to ART. Progress at the country level is encouraging. Invaluable experience has been gained, and the need for both increased financial and technical assistance has become evident in order to keep moving forward.

The governments of many of the most highly affected countries have risen to the challenge of “3 by 5”. Of a total of 49 focus countries, 40 have set national treatment targets, up from only four in December 2003. Thirty-four of these countries are developing, or have completed, national treatment scale-up plans, up from only three countries 18 months ago. Many have committed their own resources to scale-up and are rapidly expanding the number of HIV testing, treatment and care sites.

The experience of these countries provides further evidence that large-scale HIV treatment access is achievable, effective and increasingly affordable, even in the poorest and most challenging settings. At the same time, the challenges of expanding coverage beyond current levels and building sustainable systems to support it remain significant. In particular, the need to build consistent high-level political commitment and the necessary sense of urgency remains in several countries where these prerequisites of a successful response are needed most.

Even where strong commitment exists and treatment programmes are now in place, obstacles to scaling up persist. These include concerns about financial sustainability and the need for more and better coordinated technical support; insufficient availability of simple dosing formulations and a lack of easy-to-administer, palatable drugs for children; weak procurement and supply management systems for medicines and diagnostics; and the need to implement service models that standardize and streamline health care delivery, build sustainable human resources capacity, and integrate HIV treatment and prevention with reproductive health and other disease control programmes at the different levels of the health system. Accelerating prevention efforts remains an important challenge for all countries, including in low-prevalence settings.

Experience to date provides models for improving the response in each of these critical areas, much of which is detailed in this report.

Data collected to date suggest that access to ART is relatively equitable for men and women. However, monitoring systems need to be strengthened in all regions to ensure that treatment is being provided in an equitable manner. Despite some progress, significant barriers persist in ensuring access to treatment and care for marginalized groups, such as injecting drug users and sex workers.

Presenting data for the first time on the number of children in need of ART, this report highlights the urgency of scaling up access to HIV care and ART for HIV-infected children – half of whom will die before their second birthday in the absence of treatment. An estimated 660 000 children – mainly in sub-Saharan Africa – are currently in need of ART and an estimated 4 million in need of cotrimoxazole prophylaxis.

Despite initial concerns that HIV treatment could divert both resources and attention away from prevention, it is now clear that treatment scale-up actually increases opportunities to undertake effective prevention. Evidence is emerging that the availability of ART leads to an upsurge in demand for HIV counselling and testing services. New approaches to testing and counselling, including family and couples testing and counselling, the more routine offer of testing in health settings – as recommended by WHO and UNAIDS since 2004 – and home-visit testing and counselling, are gaining increasing acceptance. As more people become aware of their HIV status and access treatment and care, new opportunities are also arising to provide prevention counselling and commodities, including for people living with HIV/AIDS, as an essential part of the continuum of care. Regardless of the setting, protecting the human rights of those taking the HIV test remains crucial as access to testing expands.

"3 by 5" and beyond

The "3 by 5" target emerged along with the upsurge in commitment and new resources that accompanied the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in July 2001. An analysis of resource needs completed at that time indicated that a coverage target of 3 million on ART in low- and middle-income countries would be feasible by 2005 if global treatment access efforts were supported by full political commitment and increased resources, and if countries successfully undertook a range of activities to rapidly expand services and build health systems capacity. The "3 by 5" strategy was published in December 2003 and thereafter was endorsed by all 192 Member States of WHO.

While the ideal envisaged in 2001 has not yet been achieved, momentum and commitment in many countries are yielding solid results which provide the basis for continued expansion of access to treatment, care and prevention. Several obstacles must still be overcome. Increased attention is now being given to improving coordination among the technical and financial partners working at country level, notably through the Global Task Team process being convened by UNAIDS, which is working to improve coordination among multilateral institutions and international donors, and to help secure sustainable global financing for HIV/AIDS. Innovative mechanisms for meeting technical support needs have been established and rapid harmonization of financing, monitoring and evaluation mechanisms has become a top priority.

This report highlights a number of the major obstacles to scaling up antiretroviral treatment and accelerating HIV/AIDS prevention efforts. Based on their assessment of progress and obstacles to date, WHO and UNAIDS make the following recommendations:

Political Commitment

- Countries must continue to increase their high-level political commitment for a comprehensive response to HIV/AIDS, including ART scale-up. In particular, "3 by 5" focus countries that do not have national treatment targets and ART scale-up plans should put these in place as quickly as possible.

Financial Sustainability

- UNAIDS estimates that at least an additional US\$18 billion above what is currently pledged is needed for global HIV/AIDS efforts over the next three years, including treatment, care and prevention. Donors should continue to increase their financial commitments, and work with countries to develop long-term funding arrangements that assure sustained and predictable support.
- Countries should continue to increase their own financial commitments to HIV efforts. The 10 "3 by 5" focus countries that are immediately eligible for debt relief under the new G8 debt relief proposal should quickly reallocate resources from debt payment to HIV/AIDS efforts.
- Countries and donors should finance ART programmes at a level that does not require poor patients to pay any fees at the point of service delivery.

Human Resources and Supply Management

- Countries and partners should implement simplified and standardized ART regimens and clinical monitoring procedures that maximize the number of people who can receive quality HIV treatment.
- In many countries, a lack of doctors and nurses to deliver ART is a major bottleneck to scaling up treatment access. Countries and partners should shift from a physician-centred model of delivering ART and increase the number of non-physician health workers who are trained in simplified and standardized approaches for safely and effectively administering ART.
- Countries and partners should invest in improved medicines supply management, including systems to reliably forecast the need for supplies at each treatment site, and systems to store adequate quantities of supplies at central locations from which they can be efficiently transported.

Integrating Treatment and Prevention

- Whenever possible, HIV treatment should be scaled up alongside prevention, so that health workers and service sites are equipped to deliver an essential package of HIV treatment and prevention interventions. These include offering HIV treatment, testing, and counselling at the same sites, and training health workers to deliver both ART and prevention messages and interventions.

Equitable Access

- To ensure that ART access is equitable by sex, age, location and other factors, countries and partners should improve their systems for monitoring ART coverage.
- To increase the number of children receiving ART, new medicine formulations for children are urgently needed, and current costs must be reduced. In many countries, greater on-the-ground expertise in managing ART in children needs to be built up.
- Countries and partners should work to develop and implement innovative programmes for delivering ART to hard-to-reach populations, including injecting drug users and sex workers, and people living in areas where there is major conflict or social instability.

Coordinating Support and Evaluation

- Donors and partners should better coordinate their financial and technical support to countries, by establishing a rational process for determining support needs on a country-by-country basis and then establishing mechanisms to facilitate rapidly-delivered support. Donors and partners should also better coordinate their monitoring and evaluation of the programmes that they support. One forum for promoting better coordination is the UNAIDS Global Task Team, which has made bold and innovative recommendations to address these needs.

WHO, UNAIDS, and other UN agencies are in the process of assigning additional financial resources and staff to provide countries and other partners with increased technical assistance in each of the above priority areas. WHO is focusing in particular on helping implement simplified and standardized treatment and prevention approaches, training health workers, ensuring equitable treatment access, expanding testing and counselling, improving procurement and supply management at the global and country levels, and improving monitoring of access to ART and other essential health services.

The fight against AIDS is not an isolated struggle, but sits at the core of the development agenda. “3 by 5” needs to be seen not as an end in itself, but as an important milestone in the long-term global effort to achieve the collective goal of universal access to a comprehensive package of essential HIV/AIDS prevention and treatment interventions. Ultimately, the response to HIV/AIDS must also continue to drive a global agenda that sustains and increases momentum towards attaining the broader health and development objectives set out in the Millennium Development Goals.

Global Progress in Scaling Up Treatment

The evolution of "3 by 5"

The movement to expand access to antiretroviral therapy (ART) in low- and middle-income countries did not begin, and will not end, with "3 by 5". Brazil has been providing triple combination ART in the public health sector since 1996, and Thailand since 2000. The UNAIDS Drug Access Initiative piloted the concept of providing ART in the public sector in four low- and middle-income countries in the late 1990s. Partners in Health began delivering community-based HIV treatment in 1998 and Médecins Sans Frontières established its first treatment programme in Cameroon in 2001. These and other pioneers have shown that treating people with HIV/AIDS is possible in these environments. However, until recently, limited resources and political commitment have impeded the replication and expansion of such programmes globally.

At the International AIDS Conference in Durban in 2000, activists demanded that more serious attention be paid to the HIV treatment needs of low- and middle-income countries. Attention, political commitment and new resources began to materialize at the time of the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS in July 2001. An analysis of resource needs for reaching the UNGASS goals estimated that a major injection of new resources could finance an expanded global response to the HIV/AIDS epidemic - including key prevention, care and support interventions - and enable scale-up of ART coverage to approximately 3 million people globally by 2005¹. This optimal scenario was based on the assumption that, in addition to resources, other prerequisites for implementing such an expanded response - including political will, treatment protocols, trained health personnel and mobilized communities - would by then need to be in place.

"3 by 5" - the target of providing ART to 3 million people in low- and middle-income countries by 2005 - has subsequently evolved as a driver of international treatment access efforts due to the combined resolve of many partners working at international, regional and local levels to put these necessary elements in place. In December 2003, WHO and UNAIDS published the "3 by 5" strategy to clearly define their own contributions to reaching the target, focusing on: 1) leadership, partnership and advocacy; 2) urgent, sustained country support; 3) simplified, standardized tools for delivering ART; 4) effective, reliable supplies of medicines and diagnostics; and 5) mechanisms to rapidly identify and re-apply new knowledge and successes. The strategy was subsequently endorsed by all 192 Member States of WHO.

Over the last 18 months, some 180 partner organizations have worked with WHO and UNAIDS in these five areas. Important new tools and guidelines developed during this period include simplified and standardized treatment guidelines, patient tracking systems and training modules for health workers. Common indicators for monitoring and evaluating national ART programmes have been agreed between major partners². Procurement and supply management systems are being strengthened in countries with the assistance of partners in the AIDS Medicines and Diagnostics Service (AMDS)³, and a global surveillance network is being established to monitor antiretroviral drug resistance. Significantly, WHO's capacity to provide guidance and rapid technical support at country level has been greatly enhanced with the recruitment of prevention and treatment scale-up officers or teams in 34 countries, with a corresponding realignment of resources to strengthen regional and country offices.

¹ Resource Needs for AIDS, Schwärzlander B. et al, Science, Vol 292, Issue 5526, 2434-2436, 29 June 2001.

² WHO, UNAIDS, the Global Fund, the US Agency for International Development, Family Health International and Measure Evaluation.

³ AMDS partners include The Clinton Foundation, Commonwealth Pharmaceutical Association, Crown Agents, Ecumenical Pharmaceutical Network, the Global Fund to Fight AIDS, TB and Malaria, ESTHER, International Pharmaceutical Federation, International Dispensary Association, John Snow Incorporated, Management Sciences for Health, UNAIDS, UNDP, UNICEF, UNFPA and WHO. Refer to <http://www.who.int/3by5/amds/en/> for more information on the AMDS.

The global effort to expand treatment access

The “3 by 5” target has been widely embraced by the international community, and many governments, agencies, organizations and individuals are contributing to the global effort to expand access to ART and to scale up HIV/AIDS prevention.

Major new resources for bilateral and multilateral HIV/AIDS initiatives are being provided by Canada, the European Union, France, Germany, Ireland, Italy, Japan, the Netherlands, Norway, Spain, Sweden, the United Kingdom and the United States. Low- and middle-income countries are also increasing their own domestic spending on HIV/AIDS, as well as making financial contributions to multilateral initiatives such as the Global Fund. The Global Fund has now committed more than US\$3 billion to the fight against the three major infectious diseases in 128 countries, while the World Bank’s Multi-Country AIDS Program (MAP) and Treatment Acceleration Program (TAP) have allocated more than US\$1 billion to HIV/AIDS projects in 28 countries, with projects now being planned for a further 10 countries. The United States is the single largest contributor to the global AIDS effort, having pledged more than US\$15 billion over five years to 15 countries in Africa, Asia and the Caribbean, as well as other programming, through the President’s Emergency Plan for AIDS Relief. UNICEF has made a critical contribution to the procurement of antiretroviral medicines (ARVs) at country level.

A large number of technical agencies are working to support the implementation of these new resources, including all 10 UNAIDS cosponsoring agencies, which are currently working with major donors to more effectively coordinate the technical support they provide for “3 by 5” activities at country level. Numerous community-based, faith-based, international non-governmental and philanthropic organizations are involved in efforts to scale up treatment and prevention through advocacy, education, community mobilization and direct service provision.

The estimate of approximately 1 million people now on treatment falls short of the milestone of 1.6 million set in the WHO/UNAIDS “3 by 5” strategy for June 2005. As more data are collected and trends in scale-up become clearer, it is evident that the task of providing ART to 3 million people by the end of 2005 will be difficult. However, there is reason to be hopeful that growth rates will continue to increase in the remainder of 2005 and beyond. Resources are flowing from major donors and political commitment is evident in the many countries that have established ambitious but feasible national treatment targets.

Progress in numbers

From a baseline of approximately 400 000 people on ART in low- and middle-income countries at the launch of the “3 by 5” strategy in December 2003, WHO estimates that approximately 1 million people were on ART in low- and middle-income countries at the end of June 2005 (range 840 000 – 1 100 000)⁴. To date, 14 of these countries are providing treatment to half or more of people living with HIV/AIDS that need it, consistent with the “3 by 5” target⁵.

⁴ The data collection methods are described in detail in Annex 1.

⁵ Argentina, Barbados, Botswana, Brazil, Chile, Costa Rica, Cuba, El Salvador, Mexico, Panama, Poland, Thailand, Uruguay, Venezuela.

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

Geographical region	Estimated number of people receiving ARV therapy, June 2005 (low estimate–high estimate) ^b	Estimated number of people 0–49 years old needing ARV therapy, 2005 ^c	ARV therapy coverage, June 2005 (%) ^d	Estimated number of people receiving ARV therapy, December 2004 (low estimate–high estimate) ^b
Sub-Saharan Africa	500 000 [425 000–575 000]	4 700 000	11%	310 000 [270 000–350 000]
Latin America and the Caribbean	290 000 [270 000–310 000]	465 000	62%	275 000 [260 000–290 000]
East, South and South-East Asia	155 000 [125 000–185 000]	1 100 000	14%	100 000 [85 000–115 000]
Europe and Central Asia	20 000 [18 000–22 000]	160 000	13%	15 000 [13 000–17 000]
North Africa and the Middle East	4 000 [2 000–6 000]	75 000	5%	4 000 [2 000–6 000]
Total	970 000 [840 000–1 100 000]	6.5 million	15%	700 000 [630 000–780 000]

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

^a See Annex 1 for an explanation of the methods used.

^b 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.

^c The figure presented is the midpoint of the low and high estimates of the number of people needing ARV therapy. The needs estimates are based on the methods described on Annex 1.

^d 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 current momentum in expanding treatment access in sub-Saharan Africa, where the burden of disease is greatest, is especially encouraging. Approximately 500 000 people in the region are receiving treatment, a three-fold increase in the last 12 months. Overall, scale-up appears to be accelerating, with about 150 000 and then about 200 000 more people on treatment in successive six-month periods. Most African countries report that demand for treatment is outstripping their capacity to supply it, and stress their urgent need for increased resources and technical support in order to maintain their momentum in scaling up.

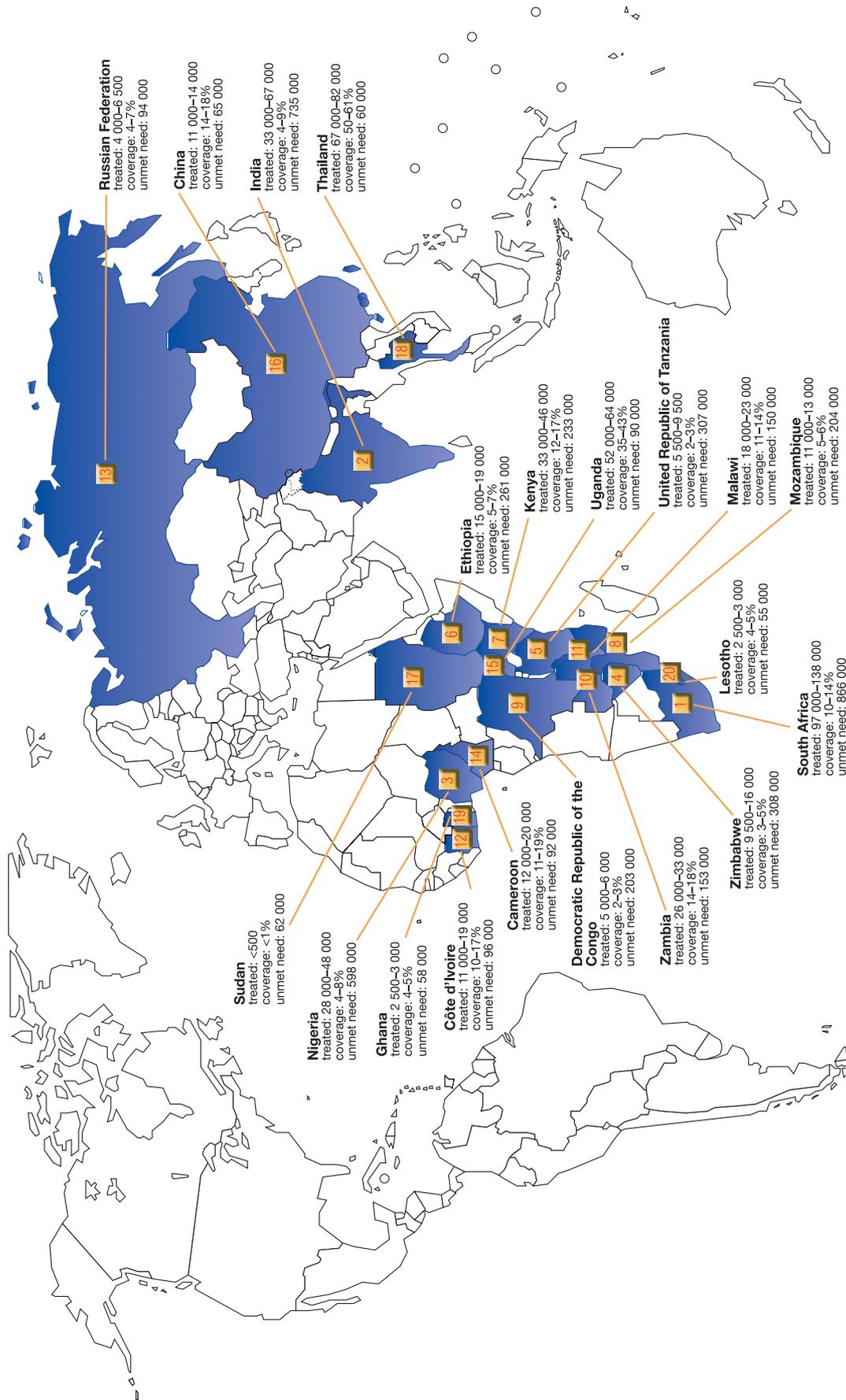
Progress in Asia, the region with the second highest need for treatment, has also been significant, with the number of people receiving treatment increasing nearly three-fold – from 55 000 to 155 000 – in the year to June 2005. In the last six months, the number of people on treatment has increased by more than 50 per cent (up from 100 000) and overall coverage has increased to 14 per cent of those in need.

In eastern Europe and central Asia the number of people on treatment has almost doubled in the last 12 months, from 11 000 to 20 000 people. The majority of countries in this region aim to be providing universal access by the end of 2005, but this does not include the two countries with the largest unmet treatment need, the Russian Federation and Ukraine.

In Latin America and the Caribbean, WHO estimates that the total number of people on treatment grew from 275 000 to 290 000 in low- and middle-income countries during the first half of 2005, which indicates that about two out of three people who need treatment in this region are actually receiving it. The most populous countries in the region – including Argentina, Brazil and Mexico – already have relatively high coverage, but several other countries are lagging behind. In north Africa and the Middle East, coverage remains low at about 5 per cent with little change in the number of people on treatment, currently estimated at about 4000.

In many of the most highly affected countries, governments have risen to the challenge of “3 by 5”. Of a total of 49 focus countries (see Annex 2), 40 have declared national treatment targets, compared to only four in December 2003. Thirty-four of these countries have also completed or are developing national treatment scale-up plans, up from only three in December 2003. Many countries have committed their own resources to scale-up and are rapidly expanding the number of HIV testing, treatment and care sites.

Figure 1. Estimated number of people receiving ARV therapy and percentage coverage in 20 countries with the highest unmet need, June 2005^a



^a Unmet need is expressed as the total number of people aged 0–49 in need of antiretroviral treatment in 2005 minus the estimated number of people on treatment in June 2005.

Overcoming Obstacles to Progress

Moving ahead in the highest-burden countries

The "3 by 5" target was based on the feasibility of providing ART to 3 million people in low- and middle-income countries – only half of those in need in these countries. With almost 1 million people receiving ART by the end of June 2005, another 2 million people still need to initiate and remain on treatment to achieve the target.

Of the world's unmet need for ART, an estimated 76 per cent is in sub-Saharan Africa and 17 per cent in Asia. Furthermore, WHO estimates that just 20 countries represent 85 per cent of the unmet need for ART. These 20 countries are by no means homogenous, varying widely in terms of size, population, infrastructure and capacity. The characteristics of their epidemics and affected populations also differ. However, the obstacles that they currently face are in many instances similar to those that have been overcome in a number of countries through a combination of political will, adequate resources and effective technical support from collaborating partners. The remainder of this section highlights recent efforts to increase political, technical and financial support to countries so that the remaining obstacles to scale-up can be overcome as quickly and effectively as possible.

Political commitment

In the years since HIV/AIDS emerged as a global health crisis, it has been repeatedly shown that high-level political commitment is a prerequisite for an effective national response. Mobilizing the resources necessary to confront the epidemic, raise social awareness and reduce the stigma and discrimination that keeps many of those at risk of or living with HIV from accessing services requires firm commitment and leadership from politicians, decision-makers and prominent members of the community.

A number of countries are leading by example in implementing comprehensive responses that include treatment, care and prevention. Botswana, Cambodia, Malawi, Uganda and Zambia have shown how ambitious national target-setting and commitment of local resources have mobilized action, leveraged external resources and partnerships and enabled the rapid introduction of ART into health services without the need for sophisticated infrastructure to be in place. In Burundi and Ethiopia, the President and the Prime Minister respectively launched the national ART roll-out plan, an acknowledgement of the gravity of the epidemics in their countries and of their resolve to tackle it. Elsewhere, the Prime Minister of Lesotho and parliamentarians in Zimbabwe have taken HIV tests in public to encourage their fellow citizens to know their HIV status. Brazilian parliamentarians continue to be active in promoting access to affordable ARVs in that country. Such actions, large and small, will remain essential to mobilize national efforts against HIV/AIDS, sustain prevention efforts over the long term - including in low-prevalence settings - and improve access to, and uptake of, testing and treatment.

Leveraging national resources

Zambia is confronting a generalized epidemic with approximately 16 per cent of the population living with HIV/AIDS. Women constitute 54 per cent of people living with HIV/AIDS and the Government estimates that there are now some 600 000 children orphaned by premature adult deaths. The severity of the epidemic has generated a strong political commitment to HIV/AIDS prevention and care programmes. The Government originally moved to make ART available through public health services to 10 000 people in need in 2002. Funded initially with US\$3 million from the national budget, and beginning at two pilot sites, Zambia's treatment programme has since expanded to 33 districts.

Zambia was one of the first countries to request WHO support through the "3 by 5" initiative and quickly set a national "3 by 5" target of providing treatment to 100 000 people by the end of 2005. Though not yet signed, a Round 4 grant from the Global Fund was approved with a two-year budget of US\$26.7 million. Fifty per cent of the proposed budget is dedicated to the purchase of ARVs.

Consistent with "3 by 5" principles, the President of Zambia announced in October 2004 that it was Zambia's policy to provide ARVs free of charge at the point of delivery in public institutions. This policy has contributed substantially to both access and retention of people on treatment. As of March 2005, government reports indicate that 22 000 people were receiving ART, an average increase of 1000 people per month since December. WHO estimates that between 26 000 and 33 000 are on treatment as of June 2005.

Financial sustainability

The large sums devoted to HIV/AIDS at the international level in recent years have created an unprecedented opportunity. The most recent UNAIDS resource estimates recognize 2005 as a year of extraordinary importance in making progress on the UNGASS targets, the Millennium Development Goals and poverty alleviation, especially in Africa. It is expected that over the next three years - 2005 to 2007 - US\$27 billion will be pledged or available for HIV/AIDS globally from all sources for HIV/AIDS comprehensive responses in low- and middle-income countries; however this is still inadequate to cover all identified needs. The anticipated total need for this period amounts to US\$45 billion, leaving an unmet gap of at least US\$18 billion for the three years. This figure includes funding for capacity building to ensure efficient and effective utilization of funds.

One encouraging development over the last few years has been the increasing commitment countries have shown to use their own resources. For example, in 2001, Bahamas committed to providing free and universal access through the public health sector, using its own resources. Botswana followed suit in 2002. On World AIDS Day 2003, as the "3 by 5" strategy was being launched, China announced its "Four Frees and One Care" Policy, which aims to rapidly scale up access in rural and poor urban districts by providing treatment, counselling and testing, medicines to prevent mother-to-child-transmission (MTCT) of HIV and free schooling for AIDS orphans. South Africa has committed US\$1 billion over the next three years to scaling up ART, by far the largest budget allocation of any low- or middle-income country. The recent G8 proposal to cancel debt owed to the International Monetary Fund, the World Bank and the African Development Bank provides a further opportunity - especially for the 10 "3 by 5" focus countries that are immediately eligible for debt relief - to reallocate resources from debt payments to HIV/AIDS efforts.

For most high-burden countries, however, providing ART on a wide scale will be sustainable in the medium term only with substantial external resources. The goal of sustainable, universal access will therefore require mechanisms to ensure recurrent funding from both internal and external sources, while ensuring that those who are least able to afford treatment are able to access it.

At the country level, sustainability can be enhanced through strategies to ensure more predictable funding, improved planning to ensure that finance and health systems can cope with large scale-up and continuing costs, and through building national capacity to estimate financial needs, track sources and uses of funds, and use funds more effectively and efficiently. WHO is currently increasing its technical support in these areas.

A sector-wide approach to ART scale-up

Mozambique is confronting a severe generalized HIV/AIDS epidemic, with high rates of infection in particular areas and population groups. In 2003, the Government estimated that there were over 1.1 million people living with HIV/AIDS – about 12.2 per cent of the adult population. However, much higher adult infection rates have been found in the central provinces along transportation routes and in Southern Gaza province. If current trends are not reversed, the Government has estimated that the number of people living with HIV/AIDS will grow to 1.8 million by 2007.

The scale-up of ART in Mozambique is taking place against a backdrop of weak health infrastructure – caused by years of civil conflict – and the involvement of a wide range of international, bilateral and NGO partners. In order to improve coordination and ensure that financing the HIV/AIDS response reflects national priorities, the Government has shifted its international aid management system from a project-based to a Sector-Wide Approach (SWAp). This strategy provides that governments and development partners reach agreement on priority areas to be addressed in the health sector, pool resources in a common 'basket' to address those priorities and develop a common mechanism for reviewing progress.

Working out specific SWAp arrangements between the government of Mozambique and funding partners involved in ART scale-up will require new approaches. Recently, the Global Fund reached agreement with Mozambique to use the country as a test case for implementing Global Fund-supported programmes through SWAps. The World Bank's Treatment Acceleration Programme in Mozambique has also been aligned with the SWAp process. Monitoring and evaluating the experience of the SWAp approach to HIV/AIDS financing in Mozambique will be important in order to assess the extent to which this initiative has increased national autonomy and flexibility in funding its HIV/AIDS response.

Equitable access

Even where HIV/AIDS treatment, care and support are available, there has been widespread concern that women will not have equitable access due to prevailing cultural attitudes which can have the effect that the health needs of men are often given priority over those of female family members. Gender power imbalances also mean that women and adolescent girls are often not only the least empowered to access health care, they are also at highest risk of contracting HIV.

Encouragingly, currently available data from those countries that disaggregate by gender do not suggest wide disparities between men and women accessing treatment. In the WHO EURO region, for example, it is estimated that access is equitable, with the number of registered cases among women at 28 per cent and 32 per cent of all people on ART being women. In sub-Saharan Africa, available data continue to support the broad analysis presented in the December 2004 progress report. Nearly 6 out of 10 adults on treatment are women, which reflects an equitable distribution because more women are infected than men.

However, data collection systems in many countries still require strengthening to enable monitoring and evaluation of ART programmes based on data disaggregated by both sex and age and identification of who is being reached and who is not. One joint project set up in recent months by WHO, Equinet and the Southern African Development Community will analyse barriers to equitable access to HIV care in the region, develop policy responses, and build working examples of equity and health systems monitoring.

Globally, access to HIV care and ART has not extended widely to children, despite the fact that 50 per cent of HIV-infected children will die before their second birthday in the absence of treatment⁶. In Malawi and Mozambique, for example, 5 per cent and 7 per cent of those on treatment are children, whereas equitable access would require coverage of approximately 13 per cent. The delivery of cotrimoxazole preventive treatment to HIV-infected children has been shown to reduce mortality in HIV-infected children by as much as 43 per cent in a study in Zambia⁷. Clearly, this life-saving intervention must be made more widely available⁸.

WHO, UNICEF and UNAIDS have just released initial regional estimates of children needing ART and cotrimoxazole⁹ which provide a basis upon which countries can set specific treatment targets for children. The estimates suggest that 660 000 children globally need access to ART in 2005. The estimates of need for cotrimoxazole prophylaxis are for 4 million children; early diagnosis of HIV infection could reduce this to 2.1 million by avoiding the need for presumptive treatment in uninfected children. The greatest need for treatment and prophylaxis among children is in sub-Saharan Africa, with 370 000 children in need of ART, and 3.5 million children in need of cotrimoxazole.

A number of recent technical developments will support the expansion of treatment for children. These include new technical recommendations to help simplify the clinical management of HIV in children, the development of indicators for paediatric HIV care that should enable national programmes to better monitor and track progress made, and validation of simplified dosing tables to optimize the use of existing formulations for children.

Much more attention must also be given to ensuring that all the elements of programming for prevention of MTCT are put into place, including linking these programmes to ongoing treatment and care for both children and their mothers. As the world strives to meet the UNGASS and Millennium Development Goals, it is important to ensure that those women and children who have been failed by past prevention efforts now receive the care which they and their families need.

There is increasing evidence that charging fees for ART at the point of service delivery presents a major barrier to access for poor people in many countries, and can depress rates of adherence to treatment as well as treatment uptake. Aware of the obstacles to access presented by such fees, several countries, including Senegal and Zambia, have recently taken steps to provide treatment free at the point of service. Others, concerned about the long-term sustainability of treatment programmes, are reluctant to do so. There is growing international consensus on the need to help countries make the necessary policy changes to enable free access to ART at point of service, which requires close attention to the development of sustainable, long-term health financing strategies.

Ensuring access to ART for the most vulnerable and marginalized populations remains a huge challenge. ART scale-up has been slowest in many of those countries where HIV is concentrated among injecting drug users and sex workers, and where there is major conflict, political instability or population movement. Contrary to the available evidence, myths persist that drug users are unable to adhere to ART. Meanwhile, attitudes prevail that sex workers are not worthy of treatment. Elsewhere, continuity of treatment may not be guaranteed for prisoners released into the community, and refugees or displaced populations may not be entitled to access existing local health services.

⁶ Fassinou P., Elenga N., Rouet F., Laguide R., Kouakoussui K.A., Timite M. et al., Highly active antiretroviral therapies among HIV-1-infected children in Abidjan, Côte d'Ivoire, *AIDS* 2004, 18(14):1905-1913.

⁷ Chintu C., Bhat G.J., Walker A.S., Mulenga V., Sinyinza F., Lishimpi K. et al., Cotrimoxazole as prophylaxis against opportunistic infections in HIV-infected Zambian children (CHAP): a double-blind randomised placebo-controlled trial, *Lancet* 2004; 364: 1865-71.

⁸ Cotrimoxazole is an antibiotic that is highly effective in the treatment of pneumocystis pneumonia. In HIV-infected children it also offers protection against other infections. Cotrimoxazole remains important even with increased access to ART, as its use can improve child survival independently of ART. Current recommendations suggest it should be used before children require ART because it may postpone the time at which ART needs to be started.

⁹ The predictions for cotrimoxazole prophylaxis are based on two related assumptions: 1) in the absence of early diagnosis of HIV infection using polymerase chain reaction, all children below age 18 months born to HIV-positive mothers, plus all HIV-infected children 18 months to 14 years require cotrimoxazole; and 2) where early HIV infection diagnosis is available, this can be reduced to provide cotrimoxazole only to all HIV-infected children (up to 14 years). Survival of children on treatment at one year was assumed to be 90% for antiretroviral therapy, 91% for cotrimoxazole, and 94% for the combination of ART and cotrimoxazole.

These different situations pose critical challenges for many countries. Among the low- and middle-income countries with greatest ART needs many have epidemics concentrated among vulnerable populations, for example injecting drug users (including Brazil, China, India, Thailand and the Russian Federation) and sex workers (including Cambodia, India and Thailand), or are experiencing complex emergencies related to conflict (including Côte d'Ivoire, Democratic Republic of the Congo and the Sudan). Special attention needs to be given to the establishment of comprehensive prevention and treatment services that reach these populations and address their specific needs.

Measuring the progress of scale-up

Mapping the actual availability of treatment and prevention services, commodities and information in a specific setting provides a method for shaping country-level responses in a way that can help to ensure equitable access.

WHO has developed a tool that allows countries to monitor health systems capacity by measuring the availability of services in countries down to the district and community levels. The Service Availability Mapping (SAM) tool is based on HealthMapper software, which was developed by WHO to simplify the use of computerized geographical information systems for public health. The SAM provides a clear map of the range and coverage of available health services (including those providing ART and voluntary counselling and testing) by district, as well as the availability of health workers, laboratories and other infrastructure. By charting health service delivery points as well as the distribution of the population, SAM can be used to help rapidly identify under-served populations that are hard to reach.

WHO has recently assisted four high-HIV burden countries to complete SAM exercises. Over the next few months, SAM will be completed in at least 10 more high-burden countries, with the longer-term goal of institutionalizing mapping of district health services, including ART facilities, in many low- and middle-income countries. A new module on the availability of HIV prevention services is also being developed in close collaboration with selected countries.

The value of targets in providing focus and a sense of urgency is now clear. Mapping the availability of services can be the tool that will provide the same focus and urgency in efforts to reach the collective goal of universal access to HIV prevention and treatment services.

Integration of prevention and treatment

Expanded access to treatment initially gave rise to concern that HIV treatment could divert both resources and attention away from prevention. As treatment scale-up has progressed, these reservations have given way to the realization that access to treatment provides new opportunities and possibly new models for the expansion of prevention. UNAIDS has recently led an initiative to intensify global prevention efforts and is developing a position paper which emphasizes these opportunities¹⁰. Recent epidemiologic modelling also shows that expanding care activities with prevention in a comprehensive manner can dramatically reduce the resource needs for treatment over the long term. Treatment makes prevention more effective, while prevention makes treatment more affordable.¹¹

Most countries now recognize that prevention and treatment are mutually reinforcing, and that both need to be scaled up simultaneously. However, many have struggled to prioritize from the range of potential models and interventions. For this reason, WHO is currently developing "essential packages" of treatment and prevention interventions specifically for the health sector. The approach also involves strengthening and expanding capacity, outreach and training to support the most efficient possible use of existing human resources.

In addition to treatment and care, essential intervention packages include those components of HIV prevention that can make the greatest difference in terms of slowing transmission. These include risk reduction, prevention

¹⁰ Intensifying HIV Prevention: UNAIDS Policy Position Paper, June 2005.

¹¹ Integrating HIV prevention and treatment: from slogans to impact, J.A. Salomon, D.R. Hogan, J. Stover, K.A. Stanecki, N. Walker, P.D. Ghys and B. Schwartländer, PLoS Medicine, Vol 1 Issue 2, January 2005.

for people living with HIV/AIDS, prevention of MTCT, control of sexually transmitted infections and special services for those at greatest risk. While multisectoral efforts remain essential, these interventions are key for an integrated health sector response, and can generally be scaled up for wide coverage in health care settings. Training health care providers to provide prevention at the same time as treatment and care is an important part of this approach. However, since even the best interventions are of little use if people do not access them, increased efforts are required at community level to raise awareness and increase utilization of health services.

Other new opportunities for prevention are emerging. During the WHO/UNAIDS consultation on HIV testing and counselling in the African region held in late 2004, countries emphasized that the availability of treatment is proving to be a strong incentive to be tested for HIV. A study in one district in Uganda has found that the introduction of ART led to a 27-fold increase in the number of people accessing testing and counselling services¹²; more research in this area is urgently needed to guide programming.

Many countries have expanded access to testing and counselling by making effective use of entry points in existing health services, notably tuberculosis (TB), MTCT and maternal and child health services. In Brazil, a 369 per cent increase in testing and counselling uptake was seen between 2001 and 2003 when testing was decentralized and Basic Health Centres began carrying out counselling and testing as a routine part of health care. Likewise, Kenya has reported a dramatic increase in the number of people tested and counselled between 2000 and 2004 due to a major expansion of testing sites in both clinics and community-based settings.

For testing to be rapidly scaled up, a range of innovative approaches may be needed in different settings and for different populations. Where they have been adopted, family and couples counselling and testing models are proving effective. Initial results suggest high acceptance rates for community outreach approaches in which people are offered testing and counselling in their homes. Botswana, Burkina Faso, the Dominican Republic, Haiti, Malawi, Rwanda, Thailand and Uganda all report that they are increasing the routine offer of testing and counselling in a wide range of clinical settings,¹³ while Botswana, Lesotho, Zimbabwe and other countries are promoting the benefits of testing through “Know Your Status” campaigns. New technology is also key to increasing demand, as shown in Malawi, where the uptake of testing more than doubled after the introduction of rapid HIV tests. In all cases, especially in countries where testing is being performed on a large scale, close attention is needed to ensure that the quality of counselling is adequate and that the human rights of people taking HIV tests are being protected.

Increased testing presents new opportunities to link people to prevention and treatment services, to supply commodities such as condoms and clean injection equipment, and to provide appropriate prevention support for people living with HIV/AIDS as part of the continuum of care.

Injecting drug users have specific prevention and treatment needs, including testing and counselling, needle and syringe programmes, drug substitution therapy and ART. While the need to implement and integrate these services for this population is becoming increasingly clear in the era of ART, political commitment is still lacking in many of the countries where these services are needed most.

¹² Increased demand for VCT services driven introduction of HAART in Masaka district, S. Mpiima, S. Wangalawa, K. Mugisha, D. Namusoke, I. Dambya, B. Onkongo, XV International AIDS Conference, Abstract ThPeE7940.

¹³ Report on Consultative Meeting on HIV Testing and Counselling in the Africa Region, Johannesburg, South Africa, WHO/UNAIDS, 2005.

Integration of ART and drug treatment programmes

In the past five years, Indonesia has witnessed a rapidly growing HIV epidemic among injecting drug users. HIV prevalence among injecting drug users has reached as high as 53 per cent in Bali and 48 per cent in Jakarta. At the end of 2003 there were an estimated total of 110 000 people living with HIV/AIDS.

The Government has committed to scaling up both HIV prevention and treatment programmes and has set a national ART target of having 10 000 people on treatment by the end of 2005. In 2004, an estimated 11 500 people were in need of ART. In July 2004, the President committed to providing subsidized ART to all patients in need of treatment with further support being provided through provincial governments. This was followed by the issuance in October 2004 of a compulsory licence for the production of two ARVs. In view of the vast geographic spread of the country, 25 ART referral sites have been initiated in 13 provinces of Indonesia with a particular focus on the six highest-burden provinces. These hospitals act also as mentor/reference hospitals to other satellite hospitals in the same provinces caring for AIDS patients.

The HIV epidemic in the country has played a major role in the government decision to establish pilot methadone programmes in Jakarta and Bali, including prison methadone programmes in both provinces. Recognizing the need to provide equitable access to ART for all those in need, ART services have been located in near proximity to selected drug dependence treatment services, including methadone maintenance programmes. Early experience from services providing joint management of both HIV and drug dependence, including the provision of ART for methadone clients, has been positive, with good ART adherence rates and significant improvements in the health of clients.

As part of its scale-up plan, the Ministry of Health is already preparing to build care, support and treatment capacity in another 50 hospitals. At the same time, action is being planned as a multi-pronged approach: expansion of substitution treatment (methadone) to 10 additional sites, within provinces and in identified hospitals during 2005; building capacity of health workers to provide cross-cutting care and treatment needs such as ART and methadone; and extension of ART care, support and follow-up from major hospitals to district hospitals and the primary health care level over the next two years. Resources have been mobilized through the Global Fund (US\$65 million) as well as the "Indonesian Partnership Fund" to which the United Kingdom Department for International Development (DFID) has allocated £25 million (US\$ 46 million) for intensifying the HIV/AIDS prevention, care, support and treatment programme.

As Indonesia is geographically spread out over thousands of islands, a key challenge for the future will be to increase coverage of services for drug users and to strengthen partnerships between treatment services and community-based organizations, including harm reduction services, to ensure that effective referral networks are established and drug users receive the necessary community support to improve both their ART adherence and management of their drug dependence.

Expanding human resource capacity

Effective responses to HIV/AIDS in low- and middle-income countries have been greatly undermined by specific weaknesses in the area of human resources. Lack of capacity in the educational system has led to an overall shortage of qualified health personnel. In addition, loss of trained nurses and physicians to the private sector, to metropolitan areas, to developed countries and to the epidemic itself has starved the public sector of the people on whom delivery of ART depends. The distribution of health workers is heavily weighted to a few key urban areas, limiting coverage and making the integration of treatment with prevention more difficult.

The shift to a standardized and integrated approach to service delivery means in part making better use of the human resources that exist. Simplification of treatment regimens and clinical monitoring allows a shift from a physician-centred model to one that relies on an expanded clinical team including nurses, clinical

officers and people living with HIV/AIDS employed and trained to perform community outreach and treatment support. Scale-up of the clinical team model allows more efficient sharing of the tasks of delivering therapy, clinical management and referral between the health service and community settings. If programmes are to be scaled up rapidly to serve the millions in need of treatment, such an evolution in human resource management is critical and urgent.

Together with numerous partners, WHO is currently helping to implement a training and service delivery model which facilitates such a shift for HIV/AIDS treatment and prevention in the health sector. Pioneered in Uganda and South Africa, the approach is now in various stages of adaptation and implementation in Burkina Faso, Cambodia, China, Eritrea, Ethiopia, India, Lesotho, Mozambique, Papua New Guinea, Senegal, the Sudan, Swaziland, Tanzania, Zambia and Zimbabwe. The goal is to implement the approach in 30 countries by the end of 2005.

Integrated service delivery and training model to support ART scale-up

The training of health care providers to deliver ART is a critical task requiring intensive effort at this time. The modular training initiative developed by WHO and many partners - including Family Health International, the Institute for Tropical Medicine in Antwerp, The AIDS Service Organization in Uganda, the International Training and Education Center on HIV and others - consists of simplified guidelines, training materials and patient education aids which address clinical care, counselling, patient monitoring and district ART coordination. These tools follow the recommendations of the WHO ART guidelines, using a syndromic approach to patient management but incorporating a limited number of laboratory tests. Short, efficient training courses teach health care workers the essential skills and knowledge to deliver ART and support the task shifts necessary, not just for ART scale-up, but for chronic care in general. The training tools are readily adaptable to different contexts. For example, modules on treatment and care for injecting drug users are now being incorporated.

In addition to training tools, the initiative includes a service delivery model for use in health services in low-resource countries using a primary health care approach suitable for first-level facilities and in district hospitals. The delivery model aims to contribute directly to health systems strengthening by bringing together multiple case management, prevention interventions and patient monitoring in a manageable way for both the health worker and the facility and district manager. It integrates the management of TB and HIV and helps alleviate human resource limitations by shifting tasks such as treatment support, medicine supply needs and simple monitoring, to trained community workers. It also encourages and supports the involvement of people living with HIV/AIDS both as expert patient trainers and as members of the clinical team, task shifts which have a growing evidence base.

Alongside new service delivery and training tools, there is a need for multi-institutional technical support to help countries address health workforce challenges. With WHO support, a number of countries have begun sophisticated initiatives to better manage human resources and estimate workforce needs in the health sector. Botswana, Burundi, Ethiopia, Guinea, Malawi, Mozambique, Myanmar, Nigeria, Swaziland and Tanzania have all developed detailed human resources plans for the health sector. Elsewhere, Burkina Faso and Uganda are in the process of doing so as part of their Round 5 applications to the Global Fund. HIV/AIDS “knowledge hubs” established in eastern Europe and being set up in Africa are helping to coordinate regional and sub-regional capacity building, training, and technical assistance.

It is clear that additional, exceptional actions are needed on many fronts to address current human resource deficiencies in low- and middle-income countries. These efforts need to include urgent steps to address the impact of macroeconomic development frameworks on public sector hiring policies.

A global initiative to support grassroots responses

Preparing communities for ART is essential to ensure that people come forward for testing, receive the information and support they need to adhere to medication in the long term and contribute their experience and capacity to treatment scale-up. Yet to date, community-driven responses have been greatly under-resourced. In response, more than 19 organizations are now providing financial support to the Collaborative Fund for HIV Treatment Preparedness – a unique global partnership between the Tides Foundation and the International Treatment Preparedness Coalition. The Fund provides support for HIV treatment, advocacy and education in Africa, Asia, Latin America, the Caribbean, eastern Europe and Central Asia through the distribution of small grants, strengthening of regional treatment advocacy networks, technical assistance to organizations undertaking treatment advocacy and education and programme evaluation. Community Review Panels, comprised of HIV treatment advocates, educators and people living with HIV/AIDS, set all funding priorities and make all decisions about how funds are disbursed.

The Collaborative Fund first piloted its grant-making activities in the former Soviet Union in 2003. Processes to develop and implement treatment preparedness activities are now under way in eight funding regions, and it is anticipated that by the end of 2005 each of the Fund's eight funding regions will distribute between US\$150 000 and US\$200 000 in grants to groups of people living with HIV/AIDS and other NGOs to undertake treatment preparedness activities. The Fund is also establishing a ninth funding region in China and developing a process to fund treatment preparedness activities which specifically target the needs of women and families in sub-Saharan Africa.

In January 2005, WHO increased its initial US\$1 million commitment to the Collaborative Fund by an additional US\$500 000 with resources made available through its Preparing for Treatment Programme, and has committed a further US\$250 000 to monitoring and evaluation.

Strengthening procurement and supply management systems

Major issues related to drug pricing, procurement and supply management continue to be of concern to many countries. These include the need for more affordable drug prices, especially for paediatric and second-line ARVs, enhanced support for developing procurement and in-country supply chain management capacity, and greater access to new drugs through exercising TRIPS flexibilities. Steps are currently under way to solve the many technical issues that exist around the choice of second-line therapy for both adults and children. More resources are also being invested in the WHO prequalification process which is being extended to include laboratory equipment and diagnostics. At the same time, as experience with treatment access increases, the focus for many countries is shifting from decision-making on procurement to include the longer-term challenges of supply management. This is particularly the case in sub-Saharan African countries, where scale-up necessarily involves the decentralization of treatment sites. Countries are finding it important not only to strengthen national planning, demand forecasting, budgeting, and quality assurance for bulk purchases of ARVs, but also to build capacity at lower levels of the health system for activities such as storage and inventory control, reporting and quantification, and ensuring the security of commodities.

With increased access to ARVs comes increased demand for other commodities related to HIV treatment, including medicines to treat opportunistic infections, antibiotics, topical and palliative care medications, tests and reagents for diagnosis and laboratory monitoring, gloves, injection equipment and condoms. The need to avoid a "vertical pipeline" and to integrate ARVs into the mainstream supply chain for essential medicines and health commodities is therefore becoming increasingly evident.

The AIDS Medicines and Diagnostics Service (AMDS) - established as a global partnership of procurement and technical agencies to support "3 by 5" implementation - is emphasizing the development and implementation of supply management information systems, and multiple international and country-level partners are providing supply management training to staff in district and first-level facilities. This training is in support of efforts to build capacity for patient monitoring, with the long-term goal of developing integrated health management information systems that also provide data on logistics and medicines supply. AMDS partners have also held workshops to assist countries receiving resources from the Global Fund to develop procurement and supply management plans, including strategies for ARV price reduction.

Concerns have recently been raised about the capacity of manufacturers to meet the increasing global demand for treatment, highlighting the need for improved demand estimates and longer term scale-up of production facilities.

Responding to gaps in supply management

Malawi has made good progress in scaling up access to ART. Since January 2003, coverage has increased from 1200 patients at three facilities to over 17 500 at 34 facilities as of March 2005. A WHO technical mission and report documenting Malawi's experience in accessing Global Fund grant money was instrumental in releasing an additional US\$14 million by May-June 2005 to cover the remaining 25 sites selected for ART service delivery. But with an estimated 170 000 HIV-positive people in need of ART and over 84 000 deaths annually, there continues to be a very large unmet need for treatment in the country.

As it contemplated scale-up, the government of Malawi knew that simplified and standardized ARV regimens needed to be distributed immediately by a "push" mechanism, in the absence of well developed "pull" systems to handle a more complex formulary at the facility level. The Government responded quickly to the emergency situation by partnering with UNICEF for the distribution of ARV kits. These kits of pre-packaged ARVs, classified as starter and continuation packs, were designed to provide triple fixed-dose combination therapy of d4T, 3TC and nevirapine, including the 15-day lead-in dosing for nevirapine in the starter pack. Continuation packs provide one month's supply of ARVs. Health facilities were classified according to epidemiological data and infrastructure considerations as high-, medium- or low-burden. This determined exactly the number of patients that could be put on treatment per month (High = 150 per month, Medium = 50 per month, Low = 25 per month).

While the push system has up to now worked reasonably well and stockouts for ARVs have largely been avoided, challenges have arisen in the case of medicines for HIV/AIDS-related illnesses (particularly opportunistic infections). These medicines are utilized at more peripheral sites which are entirely dependent on the Central Medical Stores (CMS) distribution system and monitoring systems that either do not exist or are far too weak to enable distribution of medicines on the basis of needs identified by past consumption data.

Opportunities are now being explored to strengthen overall procurement capacity in Malawi for both ARVs and HIV diagnostics at Central Medical Stores and the Technical Services Support unit within the Ministry of Health.

Recently-initiated quarterly monitoring visits are helping to identify site-specific disparities in medicine stocks. Developing a buffer supply of ARVs to cover potential short-term stockouts is currently a high priority, as is establishing inter-clinic mechanisms and protocols for rapid response to emergency stock needs.

Overcoming and improving limited health infrastructure

AIDS has put a spotlight on the weakness of health systems in many countries. Every element of an adequate health sector response to the HIV/AIDS epidemic - referral systems, human resources, laboratory capacity, medicine procurement and supply chains, coverage of services, links with the community sector - is undermined by weak and under-funded institutions at the national, district and local levels. A key challenge for the scale-up of HIV/AIDS treatment is not only to determine how major health system constraints can be overcome in the short term but also to ensure that rapid expansion of HIV/AIDS programmes does not divert effort and resources from other health priorities.

At the same time, AIDS interventions provide a critical opportunity to strengthen health systems and enhance the delivery of services for other chronic diseases. ARV procurement systems, for example, can be designed in such a way that they strengthen other essential medicine supply systems, while training health workers to provide ART can contribute to improved human resource capacity overall. New resources for HIV/AIDS have highlighted the need to strengthen overall financial management in the health sector, as well as systems to monitor and evaluate treatment (including information such as numbers on treatment, gender and other demographic factors, survival rates and medicine costs over time).

Improving service delivery depends not only on the availability of key resources but also on the ways in which those resources and services are managed. New training tools to assist district managers to implement ART

programmes and a new WHO website for health managers¹⁴ are both helping to build management capacity in the health sector.

The harmonization of disease control programmes is crucial for health systems to function effectively in resource-poor settings. Efforts to promote collaboration between HIV/AIDS, TB and malaria programmes and their integration at service delivery level are making solid progress in several countries where the three diseases are prevalent. Effective responses have involved addressing common obstacles faced by control programmes for the three diseases, such as low case detection, challenges with adherence and community mobilization. Most recently, a roadmap has been drafted to accelerate efforts to focus global attention on the devastating impact of TB and HIV/AIDS in Africa. Among other things the roadmap recommends strengthening community involvement in TB and HIV care, enhanced NGO and private sector engagement in collaborative TB/HIV activities, and better coordination by technical agencies of their country support activities.

To date, providers and delivery sites that comprise the non-state sector have been important in making ART available. This includes NGOs, health care provided by international and national corporations, faith-based organizations, individual medical providers and pharmacies and others outside the public health sector. Although shifts are anticipated in where patients seek their care, particularly as public facilities deliver free or subsidized ART, the engagement of these non-state actors will continue to be critical in a number of national settings. Data on patients treated in the non-state sector are often not reported to public authorities. In this regard, it is increasingly important to develop new ways of linking public and non-state sectors to further referral systems, data sharing, and maintaining levels of quality of care for the entire population. Malawi's innovative approach - in which ART is heavily subsidized in the non-state sector for providers who participate in national monitoring and quality assurance - offers one potential model.

Operational research to improve scale-up strategies

Incomplete evidence should not constrain efforts to close the treatment and prevention gap, hence the notion of "learning by doing" inherent in "3 by 5". WHO and the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) are working with five "3 by 5" focus countries - Burkina Faso, Malawi, Tanzania, Uganda and Zambia - to help address the longstanding challenges of linking operational research to policy and providing rapid evidence to support scale-up and improve programmes.

Following identification of operational research priorities, a broad consultation took place with stakeholders in each country to develop a nationally-owned operational research programme. Most projects consist of two phases: a situational analysis to identify constraints to scale-up, and a second phase in which strategies to overcome constraints will be tested and evaluated.

- Burkina Faso developed a participatory research project on treatment and care practices, aiming to improve coordination between NGOs and public health care facilities providing treatment, care and support for people living with HIV/AIDS.
- Malawi's objective is to improve uptake of voluntary counselling, testing and treatment by health care professionals in a country where lack of human resources is a bottleneck to scale-up.
- Tanzania's operational research effort will focus on adherence to ART, with the objective of developing a national tool to routinely monitor adherence and evaluate the determinants of this.
- Uganda will study adherence and prevention support measures in relation to the various treatment delivery methods available in the country, with the aim of identifying and disseminating good practices.
- Zambia will seek to identify constraints to ART uptake in TB and antenatal care clinics, in order to facilitate access in these settings.

The experience accumulated in the five countries will offer lessons on integrating operational research into health systems which will be of interest to other countries, major donors and technical agencies.

¹⁴ www.who.int/management

Coordinating technical partnerships

Increased resources and technical support needs have given rise to a large number of organizations now involved in scale-up efforts at country level. In Tanzania, for example, major technical and financial partners contributing to ART scale-up include WHO, UNAIDS, the World Bank Multi-country AIDS Program, the Global Fund, the various partners in the US President's Emergency Plan for AIDS Relief, the Clinton Foundation, Family Health International, the European Commission and the governments of Canada, Denmark, Germany, Norway, Sweden and the United Kingdom. Overall, more stakeholders are also becoming involved in programme development and service delivery at global and country levels, including civil society groups, faith-based organizations and the private sector.

While effective partnerships are driving the rapid expansion of ART programmes at country level, they also give rise to the ongoing challenge of effective coordination. Harmonizing the efforts of external donors, consultants, and international agencies is a central goal of the "Three Ones" approach¹⁵. Since the articulation of this approach, political support for it has grown considerably, most recently with the endorsement of the "Three Ones" by 45 African Union heads of state in January 2005.

Despite the commitment to implementing the "Three Ones", responsibility for scale-up efforts in many countries remains fragmented between policy-setting bodies - such as national AIDS commissions - and implementers, such as national and regional health authorities. Where AIDS coordinating bodies exist, they often lack the authority to make decisions on resource allocation for major AIDS programmes. Consolidation of monitoring and evaluation at country level also remains problematic, with donors continuing to impose multiple reporting requirements.

In order to improve coordination and promote effective partnerships in countries, a Global Task Team is being coordinated by UNAIDS, one of whose tasks is to develop measurable and time-bound targets and indicators for further application of the "Three Ones" in a number of countries over the next 18 months.

Coordinated technical support is a key determinant of country-level success in obtaining funding from the Global Fund. A recent UNAIDS/WHO analysis of proposals to the Global Fund revealed that the success rate for those components which received WHO or UNAIDS technical support after a proposal had been previously rejected was 60 per cent higher than those that did not receive support. Even more telling, three out of four proposals in which the two entities coordinated technical assistance were successful - 50 per cent higher than when either acted alone.

One of the most encouraging trends in the last few years has been the emergence of technical collaborations between low- and middle-income countries. A good example of such "south-south" collaborations is the Technological Network on HIV/AIDS, a joint initiative of Brazil, China, Nigeria, the Russian Federation and Ukraine to cooperate on research, development and production of HIV medicines, diagnostics and other commodities. UNAIDS is leading a drive to establish "Regional Technical Support Facilities" that will contribute to strengthening and better coordinating the provision of technical support by building on regional synergies.

¹⁵ "Three Ones" refers to one agreed HIV/AIDS action framework that provides the basis for coordinating the work of all partners; one National AIDS coordinating authority with a broad-based multisectoral mandate; and one agreed country-level monitoring and evaluation system.

Conclusions and Recommendations

Solid progress has been made in expanding access to treatment over the last 18 months, and the first half of 2005 has seen an acceleration in the growth in numbers of people on treatment in the Africa and Asia regions, where almost nine out of 10 people who do not yet receive treatment live. Despite these efforts, it is unlikely that the target of 3 million people on treatment in low- and middle-income countries can be reached by the end of 2005.

This report has highlighted a number of the major obstacles to scaling up antiretroviral treatment and accelerating HIV/AIDS prevention efforts. Based on their assessment of progress and obstacles to date, WHO and UNAIDS make the following recommendations:

Political Commitment

- Countries must continue to increase their high-level political commitment for a comprehensive response to HIV/AIDS, including ART scale-up. In particular, "3 by 5" focus countries that do not have national treatment targets and ART scale-up plans should put these in place as quickly as possible.

Financial Sustainability

- UNAIDS estimates that at least an additional US\$18 billion above what is currently pledged is needed for global HIV/AIDS efforts over the next three years, including treatment, care and prevention. Donors should continue to increase their financial commitments, and work with countries to develop long-term funding arrangements that assure sustained and predictable support.
- Countries should continue to increase their own financial commitments to HIV efforts. The 10 "3 by 5" focus countries that are immediately eligible for debt relief under the new G8 debt relief proposal should quickly reallocate resources from debt payment to HIV/AIDS efforts.
- Countries and donors should finance ART programmes at a level that does not require poor patients to pay any service fees at the point of service delivery.

Human Resources and Supply Management

- Countries and partners should implement simplified and standardized ART regimens and clinical monitoring procedures that maximize the number of people who can receive quality HIV treatment.
- In many countries, a lack of doctors and nurses to deliver ART is a major bottleneck to scaling up treatment access. Countries and partners should shift from a physician-centred model of delivering ART and increase the number of non-physician health workers who are trained in simplified and standardized approaches for safely and effectively administering ART.
- Countries and partners should invest in improved medicines supply management, including systems to reliably forecast the need for supplies at each treatment site, and systems to store adequate quantities of supplies at central locations from which they can be efficiently transported.

Integrating Treatment and Prevention

- Whenever possible, HIV treatment should be scaled up alongside prevention, so that health workers and service sites are equipped to deliver an essential package of HIV treatment and prevention interventions. These include offering HIV treatment, testing, and counselling at the same sites, and training health workers to deliver both ART and prevention messages and interventions.

Equitable Access

- To ensure that ART access is equitable by sex, age, location and other factors, countries and partners should improve their systems for monitoring ART coverage.
- To increase the number of children receiving ART, new medicine formulations for children are urgently needed, and current costs must be reduced. In many countries, greater on-the-ground expertise in managing ART in children needs to be built up.
- Countries and partners should work to develop and implement innovative programmes for delivering ART to hard-to-reach populations, including injecting drug users and sex workers, and people living in areas where there is major conflict or social instability.

Coordinating Support and Evaluation

- Donors and partners should better coordinate their financial and technical support to countries, by establishing a rational process for determining support needs on a country-by-country basis and then establishing mechanisms to facilitate rapidly-delivered support. Donors and partners should also better coordinate their monitoring and evaluation of the programmes that they support. One forum for promoting better coordination is the UNAIDS Global Task Team, which has made bold and innovative recommendations to address these needs.

WHO, UNAIDS, and other UN agencies are in the process of assigning additional financial resources and staff to provide countries and other partners with increased technical assistance in each of the above priority areas. WHO is focusing in particular on helping implement simplified and standardized treatment and prevention approaches, training health workers, ensuring equitable treatment access, expanding testing and counselling, improving procurement and supply management at the global and country levels, and improving monitoring of access to ART and other essential health services.

“3 by 5” began as an urgent call for immediate action. Although progress has been slower than expected, many countries now stand at a historic turning point. The target should therefore be seen, not as an end in itself, but as an important milestone in the long-term global effort to achieve the collective goal of universal access to a package of essential HIV/AIDS prevention and treatment interventions. Ultimately, the response to HIV/AIDS must also continue to drive a global agenda that sustains and increases momentum towards attaining the broader health and development objectives set out in the Millennium Development Goals.

ANNEX 1

Estimating the number of people on antiretroviral treatment¹⁶

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

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

A third source of uncertainty arises from the time lag between global reporting, which is for June 2005, and country reporting, which usually relates to an earlier point in time. Given the current rapid expansion in numbers in many countries, it is necessary to make an estimate of monthly increases and project these to June 2005. Thus, the mid-year estimates 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, Table 1 indicates uncertainty ranges for the June 2005 estimate of the number of people on treatment. For the country-reported data, public sector only or public and private sector combined, 5 to 25 per cent uncertainty ranges have been used depending on the strength of the monitoring system. For non-state sector numbers, which were separately reported in a limited number of countries, uncertainty ranges from 10 to 40 per cent were used.

The US President's Emergency Plan for AIDS Relief and the Global Fund to Fight AIDS, Tuberculosis and Malaria are major funders of ART programmes in developing countries. The US President's Emergency Plan focuses on 15 high intensity countries and provides independent estimates of the number of people on treatment on a six-monthly basis. These numbers and those that are provided by the Global Fund are used to cross-validate the reported country numbers. The US President's Emergency Plan and the Global Fund also work together to avoid 'double counting' of people on treatment. In December 2004, 63 000 people were considered to benefit from both initiatives. Some publications have erroneously assumed that the 63 000 patients were counted twice in the WHO/UNAIDS estimate of 700 000 people on ART at the end of 2004. WHO/UNAIDS estimates are based on country reports, not by adding up and double counting data from other sources.

Estimates of the number of people currently receiving ART were validated with reports from the pharmaceutical industry on the amount of ARV drugs shipped to developing countries. Data from the research-based industry, collaborating under the Accelerating Access Initiative, and reports from generic producers indicate that about 1 million patient equivalents of triple drug therapy were distributed in the first quarter of 2005. In addition, trend data from the research-based pharmaceutical industry confirmed the continuing rapid expansion of the ARV market in developing countries, to which they shipped medicines sufficient for 427 000 patient equivalents of triple ART by the end of the first quarter of 2005.

¹⁶ Details on the methodology can be found in Boerma T.J., Stanecki K., Newell M.K., Monitoring progress towards "3 by 5": methods and update, submitted for publication.

Estimating treatment need

UNAIDS and WHO have developed a standard methodology to estimate the size and course of the AIDS epidemic which also generates estimates of the number of new HIV infections, AIDS cases and deaths¹⁷. These numbers are used to estimate the number of adults in need of treatment taking into account the maturity of the epidemic. In a young and growing epidemic a smaller proportion of HIV-infected people will newly need treatment than in a mature or declining epidemic.

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

WHO recommends that in resource-limited settings, HIV-infected adults and adolescents should start ART when the infection has been confirmed and there are signs of clinical advanced disease.¹⁸ Studies have shown that, in resource-poor settings, the median survival time for people with AIDS not receiving ART is just under one year. Ideally, people should start receiving treatment prior to the development of AIDS, once they have advanced HIV infection. The number of people with advanced HIV infection who newly need treatment is estimated as the number of AIDS cases in the current year times two.

The total number of people in need of ART is calculated by adding the number of people newly in need of ART to the number of people who were on treatment in the previous year and survived into the current year. Since some of the people who are projected to develop AIDS in these two years may already have started treatment in the previous year, the number newly in need of ART is adjusted to subtract those who started treatment in the previous year. It is currently assumed that 80 to 90 per cent of people on treatment will survive to the following year, depending on the time of treatment initiation, patient adherence, drug resistance patterns, quality of clinical management and other factors.

ART coverage

The level of coverage is a measure of the number of people on ART by June 2005 divided by the total number of people estimated to be in need of treatment. This method slightly underestimates coverage since the number of people estimated to be in need of ART includes both children and adults and only a small proportion of countries provide treatment data for children. However, children account for only a small proportion of the total number of people on treatment, probably less than 5 per cent.

¹⁷ Walker N., Stanecki K.A., Brown T., et al., Methods and procedures for estimating HIV/AIDS and its impact: the UNAIDS/WHO estimates for the end of 2001, AIDS 2003, 17:2215-25.

¹⁸ HIV disease stage IV, regardless of CD4 cell count; stage III with CD4 cell count below 350 cells per mm³ or laboratory evidence of severe immunosuppression (CD4 cell count below 200 per mm³) or, if not available, lymphocyte count below 1200 mm³ with symptomatic disease. Scaling up antiretroviral therapy in resource-limited settings: Treatment guidelines for a public health approach, WHO, Geneva, 2004.

ANNEX 2

The "3 by 5" focus countries

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

As of June 2005, the 49 countries accounted for 87 per cent of all adults and children living with HIV/AIDS globally, 78 per cent of mortality from AIDS globally and 89 per cent of people needing treatment in low- and middle-income countries. Six countries comprised over 50 per cent of treatment needs in low- and middle-income countries: Ethiopia, India, Nigeria, South Africa, Tanzania and Zimbabwe.

High-burden countries

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

Regionally strategic countries

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

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