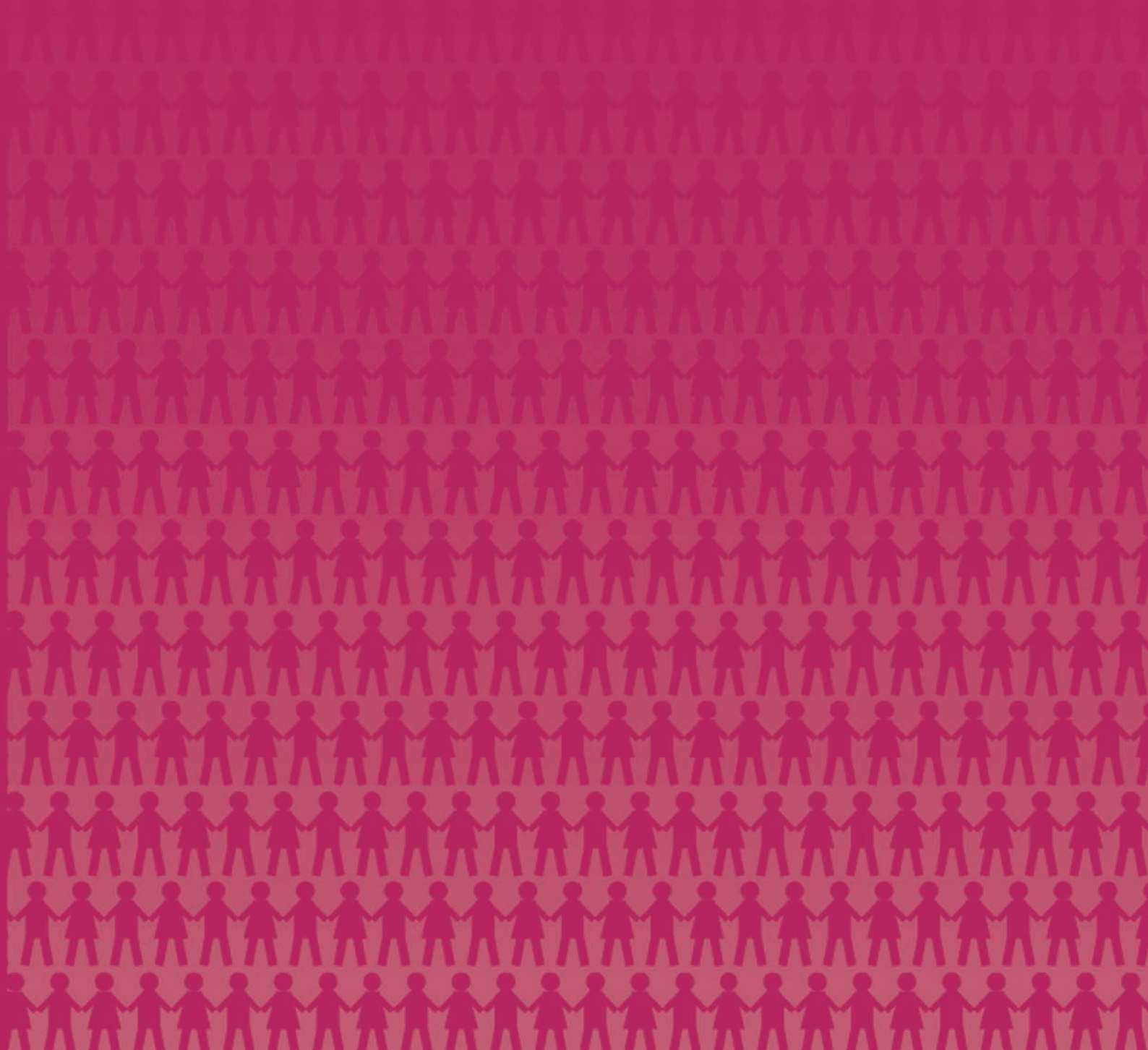


PART 2.

Towards Universal Access



1. Building on lessons learned

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

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

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

1.1 Targets mobilize commitment and action

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

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

1.2 Policy reforms maximize programme effectiveness

- *Human resources*

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

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

- *User fees*

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

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

Box 13. Countries explore alternatives to user fees

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

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

- *Testing and counselling*

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

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

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

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

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

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

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

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

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

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

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

1.3 Key operational approaches facilitate scale-up

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

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

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

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

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

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

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

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

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

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

- *Treatment and prevention must go together*

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

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

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

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

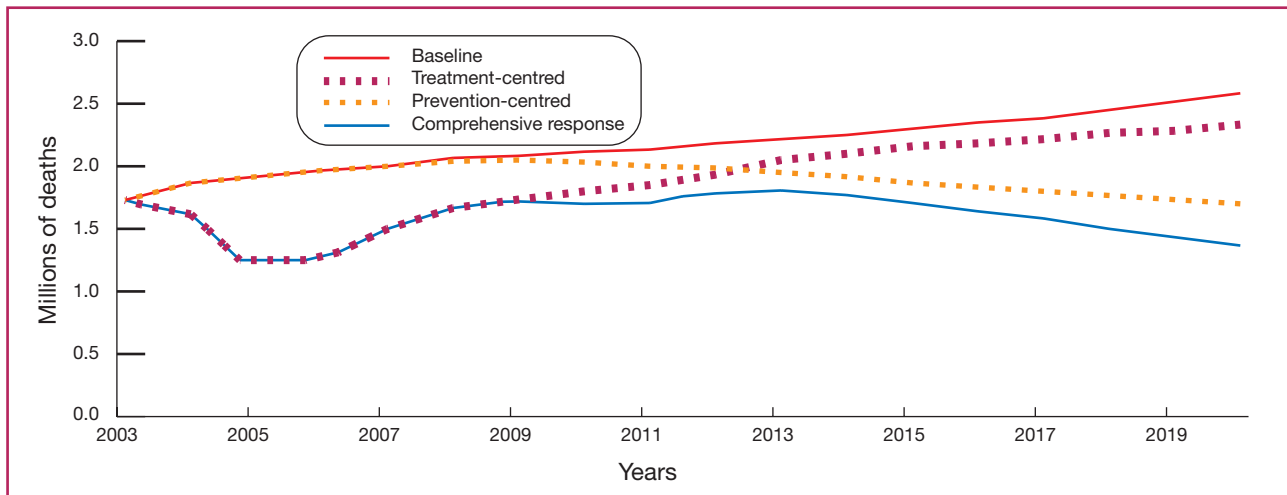
37 Elford J. Changing patterns of sexual behaviour in the era of highly active antiretroviral therapy. *Current Opinion in Infectious Diseases*, 2006, 19:26–32.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

Box 16. Treatment and prevention are mutually reinforcing in Lesotho

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

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

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

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

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

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

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

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

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

1.4 Persistent challenges must be overcome

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

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

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

- *Partnerships, alignment and harmonization*

Although important steps have been taken to promote effective partnerships between technical agencies and to ensure harmonization of efforts in scaling up programmes, more can be done to address implementation bottlenecks being experienced at the country level. Lessons from the Global Task Team on Improving AIDS Coordination among Multilateral Institutions and International Donors and the Global Joint Problem-solving and Implementation Support Team (GIST) processes established by UNAIDS highlight the need for closer harmonization between United Nations System agencies, major donors and other implementing partners at country level (Box 18).

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

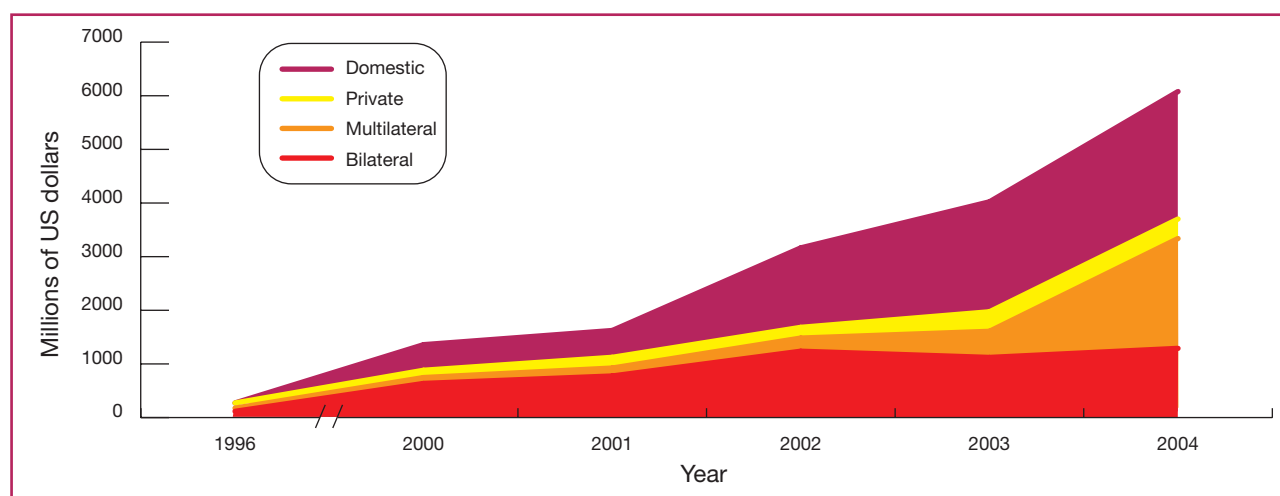
Box 18. New mechanisms to improve utilization of resources

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

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

- *Sustainable financing*

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

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

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

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

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

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

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

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

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

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

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

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

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

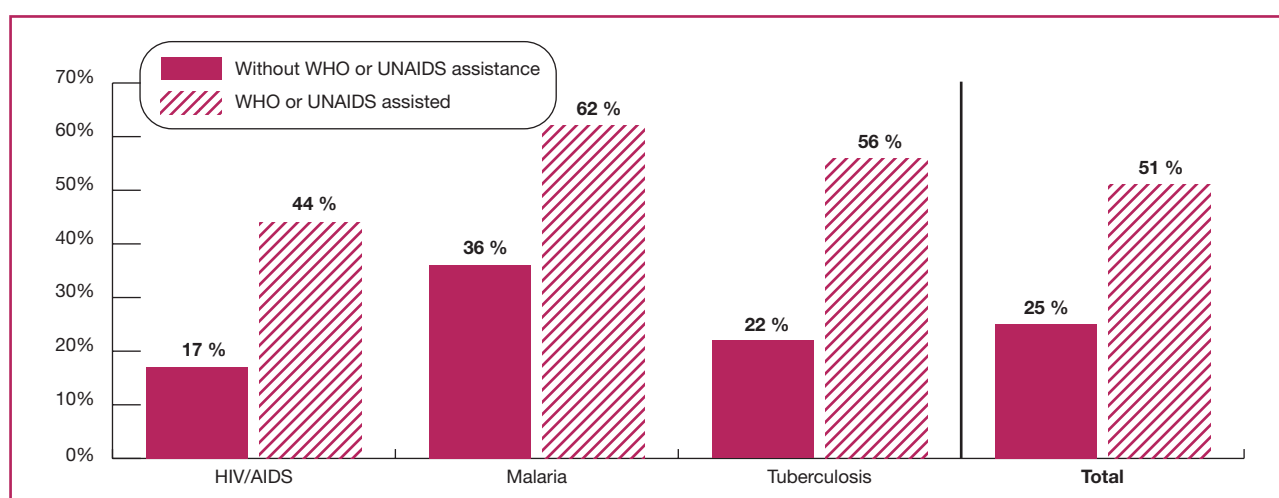
As donor countries continue to increase their financial commitments for health and development, contradictions remain between the higher levels of public spending required to meet the Millennium Development Goals and the amount of spending possible under the macroeconomic framework model favoured by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

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

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

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

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



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

• *Drugs and other commodities*

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

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

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

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

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

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

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

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

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

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

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

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

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

- *Constraints in health systems, including human resources*

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

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

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

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

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

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

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

- ***Ensuring equitable access***

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

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

- ***Monitoring, evaluation and research***

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

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

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

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

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

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

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

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

Box 20. Surveillance of HIV drug resistance moves ahead

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


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

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

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

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

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

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

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

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