

PART I

Strategic directions

1. ACHIEVEMENTS IN 2000–2005 AND CHALLENGES FOR 2006-2015

1.1 A thriving Partnership

The Stop TB Partnership has built an effective network to promote and coordinate the contributions of a wide and increasing range of stakeholders. A thriving Partnership, its global membership grew to over 400 organizations in 2005. Regional and national Stop TB partnerships are now being formed to support long-term expansion of DOTS at country level.

See Figure 1: Structure of the Stop TB Partnership

The Partnership is governed by a Partners' Forum and a Coordinating Board, supported by a strong Secretariat housed in WHO. Large, lively and successful Partners' Forum meetings were held in 2001 and 2004 to set the strategic direction and ensure consensus on priorities for action. The Partnership Coordinating Board meets every six months to provide leadership and direction, and to monitor the implementation of policies, plans and activities of the Partnership.

The Partnership has structured its seven working groups to address directly the major challenges of TB today:

- DOTS Expansion Working Group, with individual subgroups on laboratory capacity strengthening, public-private mix, childhood TB, and poverty and TB;
- Working Group on DOTS-Plus for Multidrug-resistant TB;
- TB/HIV Working Group;
- Working Group on New TB Diagnostics;

- Working Group on New TB Drugs;
- Working Group on New TB Vaccines;
- Advocacy, Communications and Social Mobilization Working Group.

One of the great strengths of the Stop TB Partnership is that it brings together the TB research community with those engaged in programme implementation. As this Plan makes clear, their effective collaboration is critical to the rapid development and deployment of sorely needed new tools.

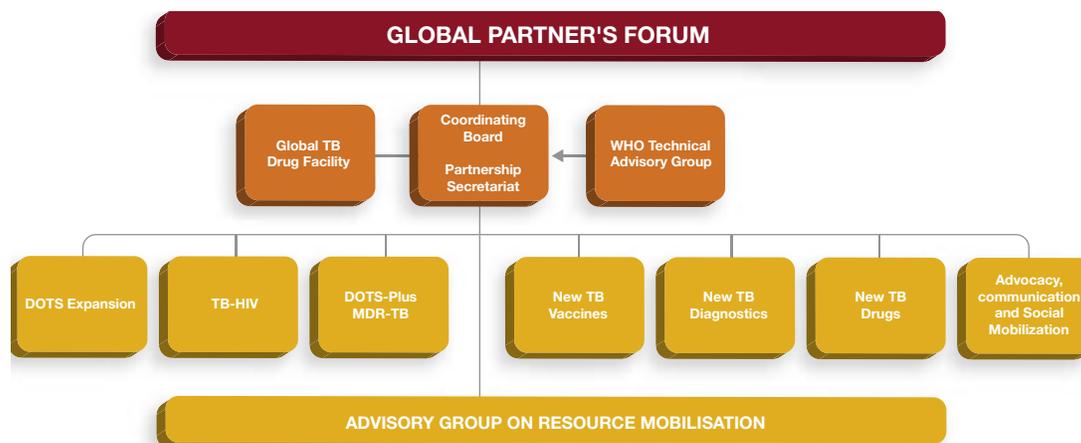
Under the Partnership's basic framework, the working groups are the primary means of coordinating activities mandated by the Board. The plans of the working groups and the Secretariat provide the basis for action, resource allocation and accountability within the Global Plan 2006–2015.

1.2 Achievements in global TB control since 2000

The Partnership will publish a full report of achievements within its first Global Plan to Stop TB 2001–2005 after the end of the plan period. The following are a few highlights to date.

Evaluation: As confirmed by an independent external evaluation in 2003, the Stop TB Partnership has established itself, in a very short period of time, as a successful public-private partnership for health.

FIGURE 1: STRUCTURE OF THE STOP TB PARTNERSHIP



Coordination and planning: The Partnership's Global Plan to Stop TB for 2001–2005 provided the first integrated plan of action for implementation and research, and identified the funding required. Most of the planned investment was for implementation of the DOTS strategy in the 22 priority countries with the largest number of TB cases (listed in Annex 2). The DOTS Expansion Working Group, in collaboration with the DOTS-Plus and TB/HIV Working Groups, coordinated implementation of the DOTS strategy and its adaptations. At country level, the 22 high-burden countries established interagency coordination committees and implemented DOTS expansion plans.

DOTS Expansion: DOTS is an internationally recognized strategy for delivering the basics of TB case-finding and cure. It is not simply a clinical approach to patients, but rather a management strategy for public health systems, including political commitment as well as case-detection through quality-assured bacteriology, short-course chemotherapy, ensuring patient adherence to treatment, adequate drug supply, and sound reporting and recording systems. The first Global Plan 2001-2005 estimated that US\$5 billion would be needed for DOTS expansion. In practice, about US\$5 billion was mobilized and spent effectively. By the end of 2003, over three-quarters of the world's population lived in countries that had officially adopted DOTS. The proportion is expected to reach over 90% by the end of 2005.

See Figure 2. Effect of the Global DOTS Expansion Plan (GDEP) on the case detection rate

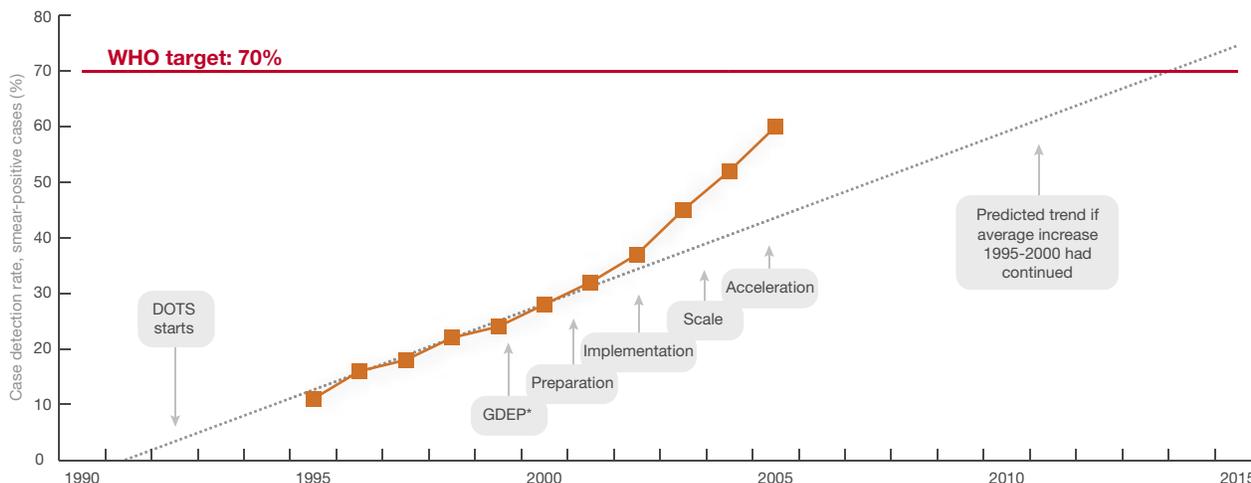
In 2000, the Partnership adopted targets for 2005 set by the World Health Assembly, of detecting 70% of new smear-positive cases, and successfully treating 85% of those detected. In the absence of HIV, achieving these targets should lead to a substantial decrease in the TB prevalence rate, and an annual decrease in the incidence rate of about 5–10%¹. This expected epidemiological impact has been demonstrated recently in, for example, Peru and the areas of China that are implementing the DOTS strategy (comprising half the country).

As illustrated in Figure 2, TB case detection under the DOTS strategy has accelerated over the past few years with implementation of the Global DOTS Expansion Plan. TB cases notified under DOTS programmes in 2003 represented 45% of estimated new smear-positive TB cases. Continuation of the upward trend would result in a case-detection rate of 60% by 2005 – short of the 70% target but a significant improvement since the launch of the first Global Plan to Stop TB, when the case-detection rate was 27%. The treatment success rate in the 2002 DOTS cohort was 82% on average, on track to achieve the 2005 target of 85% on time. However, the treatment success rate remains substantially below the average in the WHO regions of Africa (73%) and Europe (76%).

Increased technical support: With the significant influx of resources for TB control from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), banks and bilateral donors, new coordinated mechanisms to provide technical cooperation have been created. They focus on increasing the efficiency of support, as well as building the cadre of human resources capable of providing technical cooperation, and promoting exchange of expertise among countries with a high burden of TB. The aim is to improve technical capacity in order to make most effective use of the new funding, and so accelerate DOTS expansion towards the 2005 targets.

Drug supply: The Global Drug Facility (GDF), established by the Partnership, has provided treatment for more than 4.5 million patients, at the same time as catalysing a worldwide improvement in the quality of TB drugs, and a reduction in their cost. In addition, the Green Light Committee (GLC) promotes access to, and rational use of, second-line drugs with activity against multidrug-resistant TB. It has secured price reductions of 95% for some second-line drugs. To help prevent misuse of these drugs, the GFATM selected the GLC as its mechanism for procurement of second-line drugs and monitoring of approved projects. The GDF and the GLC are merging in a phased programme.

FIGURE 2: EFFECT OF THE GLOBAL DOTS EXPANSION PLAN ON THE CASE DETECTION RATE



Note: The 2005 value is a prediction based on current activities and trends.
* Global DOTS Expansion Plan

Multidrug-resistant TB: Multidrug-resistant TB (MDR-TB) is formally defined as resistance to isoniazid and rifampicin, the two most effective anti-TB drugs. Projects have demonstrated that management of MDR-TB is feasible and effective in resource-limited settings. As a result of additional funding for control of MDR-TB, there has been a rapid increase in the number of countries implementing DOTS-Plus. By July 2005, 36 DOTS-Plus pilot projects treating more than 10 000 patients with MDR-TB had been established in 27 countries.²

TB/HIV: The TB/HIV Working Group has published a core set of strategy and policy guidance documents to assist countries in implementing and monitoring collaborative TB/HIV activities.³ There has until now been limited collaboration between TB and HIV/AIDS control programmes, but many are beginning to adopt elements of the WHO interim policy for collaborative TB/HIV activities. By 2003, 29 of the 41 countries with the highest prevalence of TB/HIV had a national policy on TB/HIV collaboration and 16 had a national TB/HIV coordinating body.

New diagnostic tests: The creation of the Working Group on New TB Diagnostics in 2001 established a platform for focused development of new diagnostic products. Through the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND), promising technologies have been screened, and an exciting series of new product developments initiated, supported, and/or subjected to field trials. Currently there are 15 new diagnostics under development. At the same time, tools such as sample and strain banks have been developed to assist researchers.

New drugs: With support from the Working Group on New TB Drugs and the Global Alliance for TB Drug Development, there is

now a coordinated portfolio of promising new compounds, some of which have the potential to become the cornerstone drugs for TB control and even contribute to the elimination of TB in the future. There are 27 drugs in the pipeline, with research and development activity in virtually all stages of TB drug discovery and development – from early discovery projects through to clinical testing. This remarkable achievement is the result of critical collaborations between public and private partners that have leveraged the scientific and clinical knowledge of industry, the public health sector, and academic laboratories throughout the world.

New vaccines: In 2000, the Working Group on New TB Vaccines took note of the historic opportunities for development of new TB vaccines that resulted from the availability of techniques for the genetic manipulation of mycobacteria, and completion of the genome sequence of *M. tuberculosis*. By 2005, five new vaccine candidates were in phase I trials, and three more were due to start shortly. Important factors in success include major strategic investments by donors and foundations to support the Aeras Global TB Vaccine Foundation.

Advocacy and funding: The profile of TB has been raised at global level and in many countries with dedicated advocacy and communications activity to embed TB in the political agenda. Heightened political and funding support for the activities outlined in the first Global Plan to Stop TB (2000–2005) has assisted progress against TB worldwide. Expressions of support for TB control targets and for commensurate funding have been included in G8 communiqués (2000 and 2005), a World Health Assembly resolution (2005), the declaration of a TB emergency by the WHO Regional Committee for Africa, the Commission for Macroeconomics and Health (2001), and in high-level statements by Nelson Mandela, the African Union, and the

Commission for Africa. There has been substantial improvement in funding available for TB control since 2002. The Global Fund to Fight AIDS, Tuberculosis and Malaria now plays a major role in financing TB control, contributing more than one third of the budget in a number of high-burden countries.

1.3 TB today⁴

There are eight TB epidemiological regions (Figure 3)⁵. The countries in the region comprising the Established Market Economies (EME) and Central Europe have similarly high per capita income levels and low tuberculosis incidence rates. The Plan therefore focuses mainly on the other seven regions: African countries with high HIV prevalence (AFR High HIV); African countries with low HIV prevalence (AFR Low HIV); the American Region (AMR) – Latin America Countries (LAC); Eastern Europe Region (EEUR); Eastern Mediterranean Region (EMR); South-East Asia Region (SEAR); and the Western Pacific Region (WPR). It nevertheless remains important for the Established Market Economies and Central Europe to maintain and strengthen their TB control programmes.

In 2003, there were 8.8 million new cases of TB, of which 3.9 million were smear-positive; 674 000 of the patients were coinfecting with HIV. There were a total of 15.4 million cases, of which 6.9 million were smear-positive. An estimated 1.7 million people died from TB, including 229 000 people coinfecting with HIV.

See Figure 4: Estimated TB incidence rates, 2003

While the TB incidence rate is decreasing or stable in all regions except Africa, the latest available figures (2003) show that the

global incidence rate grew by 1% from 2002. This is a slower rate of growth than in previous years, but is still alarming. The continuing increase is largely due to the increasing rate in Africa, fuelled by the HIV epidemic and by the adverse social and economic situation. In Eastern Europe⁶, the incidence rate increased during the 1990s, which was a period of rapidly increasing inequity and deteriorating public health systems. It peaked around 2001 and has since fallen slightly. The rise in global incidence is slowing because the HIV epidemic in Africa is slowing.

In terms of the global distribution of the burden of TB, in 2003 the South-East Asian region notified 35% of all cases, the African region 24%, and the Western Pacific region 22%. The 22 high-burden countries account for approximately 80% of all estimated new TB cases each year. China and India alone account for 35%. India, the country with the greatest burden of TB, is also the country where the most dramatic advances are being made in DOTS expansion. Thanks to a massive recent scale-up, China expects to achieve nationwide DOTS coverage in 2005.

Although the global TB incidence rate is still slowly rising, prevalence and death rates are falling. WHO calculates that the expansion of the WHO-recommended DOTS strategy between 1990 and 2003 led to a fall in the global TB prevalence rate from 309 to 245 per 100 000 (including HIV-positive patients), including a 5% fall between 2002 and 2003.

See Figure 5: Estimated prevalence of HIV infection in TB cases, 2003

FIGURE 3: THE EIGHT TB EPIDEMIOLOGICAL REGIONS

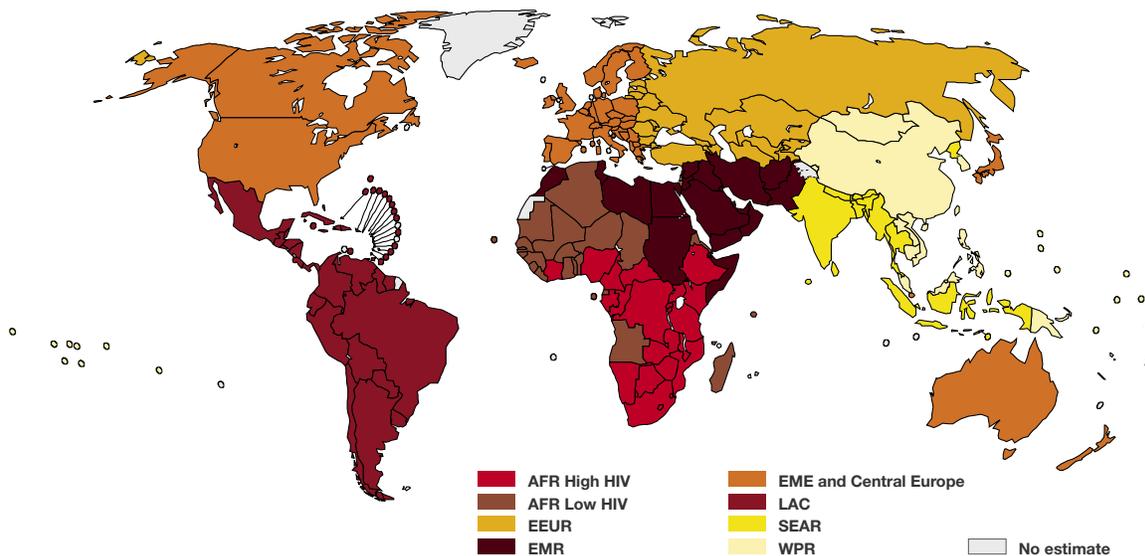


FIGURE 4: ESTIMATED TB INCIDENCE RATES, 2003

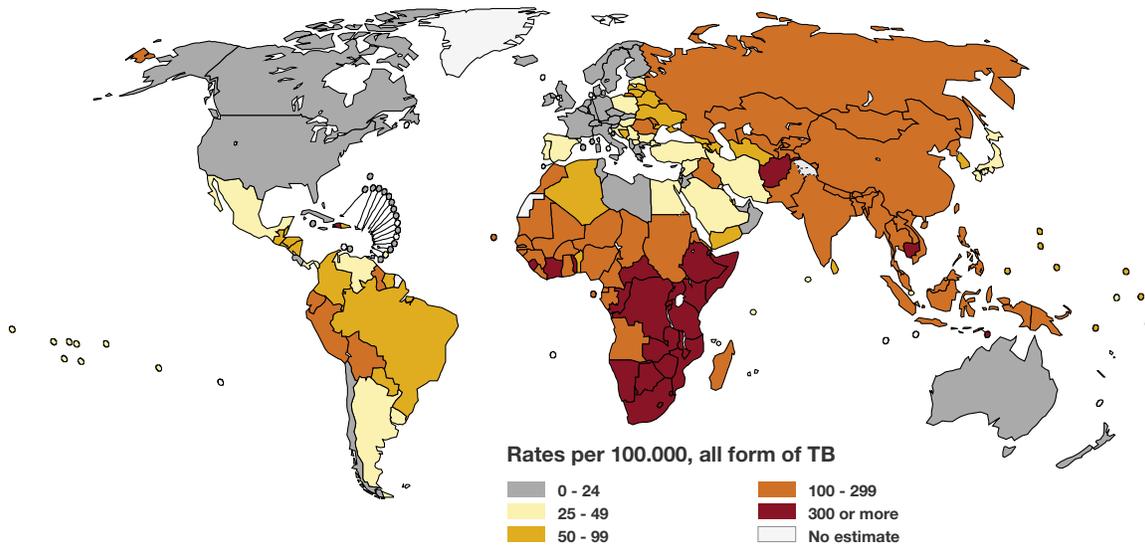
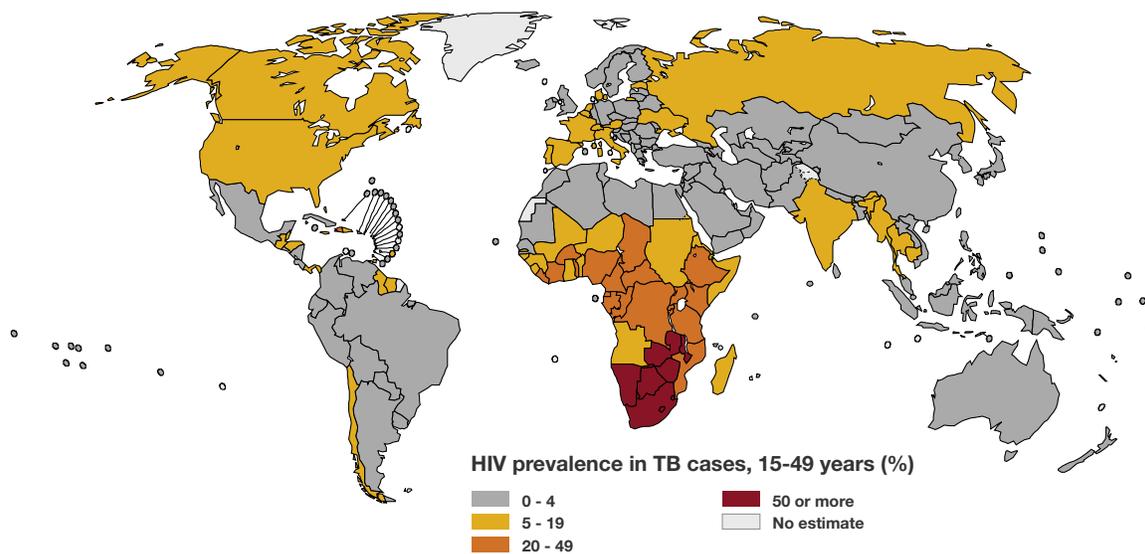


FIGURE 5: ESTIMATED PREVALENCE OF HIV INFECTION IN TB CASES, 2003



The global death rate from TB peaked during the 1990s. Between 2002 and 2003, it fell by 2.5% overall, and by 3.5% among HIV-negative patients. If not for the strongly adverse trends in Africa, prevalence and death rates would be falling more quickly worldwide.

Several regions of the world are experiencing severe epidemics of multidrug-resistant TB that threaten TB control and translate into low cure rates. New estimates suggest that there are about half a million MDR-TB cases each year, including new and previously treated cases. The highest prevalences of MDR-TB have been observed in countries in Eastern Europe and some provinces of China. However, most regions have reported one or more countries with an MDR-TB prevalence of 5–6% among new cases. Drug resistance is also more severe in Eastern Europe than in other regions. For example, 50% of MDR-TB cases detected in these countries are resistant to all four first-line drugs, compared with only 12% in the rest of the world. While surveillance is not yet standardized, many countries in Eastern Europe also report high levels of resistance to second-line drugs.

1.4 Challenges ahead

Despite the achievements of recent years, there are still tremendous barriers to ensuring equitable access to high quality DOTS services and achieving TB control targets:

The rapid scale-up of DOTS coverage has put high demand on programme management, supervision and quality control.

In many countries, it is difficult to meet these demands because of generally weak health systems, a lack of human resources, limited funds and, ultimately, insufficient political commitment. This situation is exacerbated because governments are also rapidly scaling up interventions against other health priorities, such as HIV/AIDS and malaria. Planning and implementing DOTS programmes in settings with high rates of HIV or MDR-TB require skills and resources for interagency collaboration, programme management, supervision, monitoring and evaluation.

New tools remain urgently needed to increase the speed and precision of TB diagnosis, as well as to improve the effectiveness of treatment and reduce its duration. Progress has been impressive, but large-scale investment will continue to be necessary to make actual and potential new tools available for use.

HIV continues to present one of the greatest challenges to efforts to achieve the global TB control targets. In 2003, national TB programmes reported that few TB patients were being tested for HIV; still fewer were assessed for antiretroviral therapy (ART), and a very small fraction began ART. Even in Brazil, where ART is provided free of charge in the public sector, in 2003 only half of the notified TB patients were reported to have been tested for HIV.

Multidrug-resistant TB threatens the potential salutary impact of DOTS programmes. Although progress in widespread DOTS implementation will help prevent the further emergence of drug-resistance, expansion of effective DOTS-Plus programmes is vital to stem the contribution of drug-resistant cases to the overall TB epidemic. Too few countries have national policies for the diagnosis and treatment of MDR-TB. In some of those that do, treatment commonly fails to meet acceptable standards.

Access to good quality services is still inequitable in many settings. People in remote rural areas have serious difficulty in obtaining services unless they are highly decentralized. Poor people in general often have problems accessing services because of high direct and indirect costs. Many are caught in a disease-poverty trap, because of their high expenditure on health care. Reaching the poor with affordable, quality services is a problem not only for remote rural populations, but also for the growing population of urban poor – the slum dwellers, the homeless, and the migrants. Developing appropriate pro-poor strategies will require a broad approach involving communities, civil society, nongovernmental organizations, and all relevant health care providers.

There is still limited awareness of TB. Stigma, and poor knowledge about what types of TB services are available and effective, contribute to underuse of services and to the social costs of TB. Where quality services are available and truly accessible, it is essential to devise communication strategies to raise awareness of TB and the available treatment services, and to counter stigma. Limited awareness of TB in countries with low TB incidence is a barrier to raising donor funds for TB control in countries with high or medium TB incidence.

In most countries, large parts of the health system are still not involved in implementing DOTS. Many public and private health care providers do not use evidence-based approaches to TB diagnosis and treatment. This leads to overdiagnosis, missed or delayed diagnosis, poor treatment results, drug resistance, and wasted resources (including patients' own resources when they have to make out-of-pocket payments). In the future, the new International standards for tuberculosis care should be implemented by all health care providers involved in TB diagnosis and treatment.⁷

Sustained funding remains uncertain. Although the funding available for global TB control has increased in recent years, it will be a continuing challenge for the Partnership to help mobilize sufficient resources to reach the targets outlined in this Global Plan. Existing gaps in funding and uncertainty about future financing impede planning and implementation for both treatment and research. For example, recent data indicated that funding fell about 20% short of total needs for DOTS expansion in 2004 and 2005. A 2005 World Health Assembly resolution called for sustainable financing for TB control.⁸