1. DOTS EXPANSION AND ENHANCEMENT

INTRODUCTION: DEFINITIONS, TARGETS AND PROGRESS TO DATE

An estimated 9.4 million new cases of TB occur each year. TB exists in all parts of the world, but there are 22 HBCs[1] that account for around 80% of the world's TB cases. Globally, the highest rates of TB per capita are in the African Region (Figure 9). Most people who develop TB have drug-susceptible forms of TB (more than 95% of all cases worldwide): that is, TB that can be treated and cured with six months of chemotherapy using 'first-line' drugs.[2]

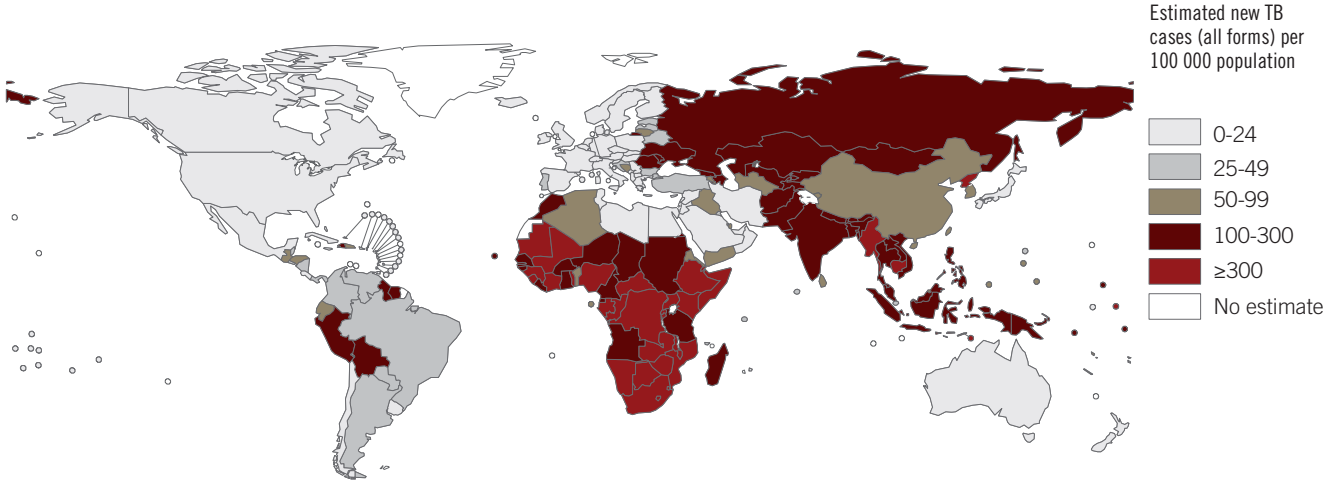
The so-called 'DOTS' strategy was developed in the mid-1990s as the internationally-recommended approach to TB control, and was subsequently expanded worldwide. The strategy was built on model programmes developed in African countries from the late 1980s, and has five components:

1. Political commitment. This is the foundation of the strategy. One indicator of political commitment is the percentage of funding for TB control that is provided from domestic sources.

2. Early case detection through quality-assured diagnosis. Initially, great emphasis was given to diagnosis of the most infectious cases of TB (i.e. sputum smear-positive cases of pulmonary TB), detected using sputum smear microscopy. More recently, there has been increasing emphasis on the role of diagnosis based on culture and molecular tests as well as smears, as highlighted in the Laboratory strengthening component of the Global Plan.

3. Standardized treatment with supervision, and patient support. The recommended treatment for drug-susceptible TB is a short-course (six months) regimen of four drugs: isoniazid and rifampicin, the two most powerful first-line anti-TB drugs, plus pyrazinamide and ethambutol. For patients with drug-susceptible TB, these regimens will cure around 90% of TB cases when treatment is fully adhered to and drugs are quality-assured. Treatment and patient support can usually be provided on an outpatient basis, with no need for hospital admission, within general primary health care services.[3]

FIGURE 9 ESTIMATED TB INCIDENCE RATES, BY COUNTRY, 2009



[1] These countries, in alphabetical order, are: Afghanistan, Bangladesh, Brazil, Cambodia, China, the Democratic Republic of the Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, the Philippines, the Russian Federation, South Africa, Thailand, Uganda, the United Republic of Tanzania, Viet Nam and Zimbabwe. Combined, India and China account for an estimated 35% of the world's cases of TB.

[2] Diagnosis and treatment of patients with drug-resistant strains of TB, in particular multidrug-resistant TB (MDR-TB), is covered in the Drug-resistant TB component of the plan.

[3] A small number of countries provide treatment on an inpatient basis for two months or more, sometimes in specialist TB hospitals. A small proportion of TB patients with severe forms of TB need to be managed in hospitals in many countries.

4. Drug supply and management system. A reliable supply of quality-assured first-line drugs is fundamental to high-quality treatment. GDF was established by the Stop TB Partnership in 2001 to help ensure the availability of quality-assured drugs at affordable prices.[4]

5. Monitoring and evaluation. Routine monitoring of the performance of TB control is crucial. The main indicators to monitor DOTS implementation are the number of cases diagnosed and notified, and the percentage of patients who are successfully treated.

A critical milestone in DOTS implementation was a high-level ministerial conference held in Amsterdam, the Netherlands in 2000. At this conference, the 22 HBCs committed to achieving global targets set for TB control for 2005, through implementation of the DOTS strategy.[5] The global targets were: (i) to detect 70% of new smear-positive cases of pulmonary TB (i.e., to diagnose 70% of the estimated number of new cases of smear-positive pulmonary TB[6] that occur each year, a target known as the CDR); and (ii) to successfully treat 85% of detected cases. These targets were first set by the Forty-fourth World Health Assembly in 1991,[7] for the year 2000, and were subsequently reset to 2005. In line with these commitments and targets, the first *Global Plan to Stop TB 2001–2005*,[8] gave particular emphasis to implementation of DOTS and achievement of the 70/85% targets in the 22 HBCs.

Building on the success of the DOTS strategy, but recognizing the need to broaden its scope, WHO launched the *Stop TB Strategy* in 2006[9] (see Box 2 in the Overview of this plan). DOTS is the first component (of six) and the foundation of the *Stop TB Strategy*. The *Global Plan to Stop TB 2006–2015*, launched in the same year, set out the scale at which DOTS (and other components of the strategy) should be implemented. The major targets were to reach a CDR of 84% by 2015 and a treatment success rate of 87% by 2015.

There has been enormous progress in DOTS implementation in the past 15 years. The total number of countries implementing DOTS reached 180 in 2003 (up from around 70 in 1995), and has since remained stable at around this level. All 22 HBCs have implemented the DOTS strategy since 2000. By 2008, more than 99% of the TB cases reported to WHO by NTPs were being treated through the DOTS approach. Of the 5.8 million cases of TB (new cases and relapse cases) that were treated by NTPs in 2009, 2.6 million (45%) were new smear-positive cases of pulmonary TB, 2.0 million (35%) were new smear-negative cases of pulmonary TB (including cases for which smear status was unknown), 0.9 million (15%) were new cases of extrapulmonary TB and 0.3 million (5%) were relapse cases.

The percentage of new cases of smear-positive TB detected (the CDR) was 56–68% in 2008, with a best estimate of 62%. Globally, the treatment success rate reached 86% in the 2007 and 2008 cohorts, and 87% in HBCs.

In the fifteen years from 1995 to 2009, 49 million TB patients were treated according to the DOTS strategy, 41 million successfully. The TB incidence rate (per 100 000 population) peaked in 2004, and has since fallen each year. By 2009, the mortality rate at global level had fallen by 35% compared with a baseline of 1990.

Building on the achievements of the last 15 years, the DOTS component of the Global Plan to Stop TB 2011–2015 sets out how TB control can be further improved, reaching more people with TB and achieving higher rates of treatment success. This

[4] For more information about the Global Drug Facility, see the section of this plan that explains the mechanisms of the Stop TB Partnership.
[5] http://www.stoptb.org/assets/documents/events/meetings/amsterdam_conference/decla.pdf
[6] Pulmonary TB – or TB of the lungs – is the most common form of TB (about 85% of TB patients treated in 2008). Typically, around 50–60% of notified patients with pulmonary TB have smear-positive TB. TB patients with extrapulmonary TB accounted for about 15% of TB patients notified to WHO in 2008.
[7] www.who.int/tb/publications/tbresolution_wha44_8_1991.pdf
[8] www.stoptb.org/assets/documents/global/plan/GLOBAL_PLAN_TO_STOP_TB_2001_2005.pdf
[9] *The Stop TB Strategy: building on and enhancing DOTS to meet the TB-related Millennium Development Goals*. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.368).

includes giving attention to elements of TB control that are more broadly related to health system strengthening (HSS). The six building blocks of HSS, as defined by WHO, are as follows: health financing; human resources; health information systems; working with all care providers; medical products, vaccines and technologies; and leadership and governance.[10] The plan for DOTS includes objectives and targets related to human resource development, infection control in health care facilities, monitoring and evaluation (including strengthening of notification and vital registration systems), engagement of all care providers through public-private mix (PPM) approaches, and the share of funding that is provided from domestic sources.

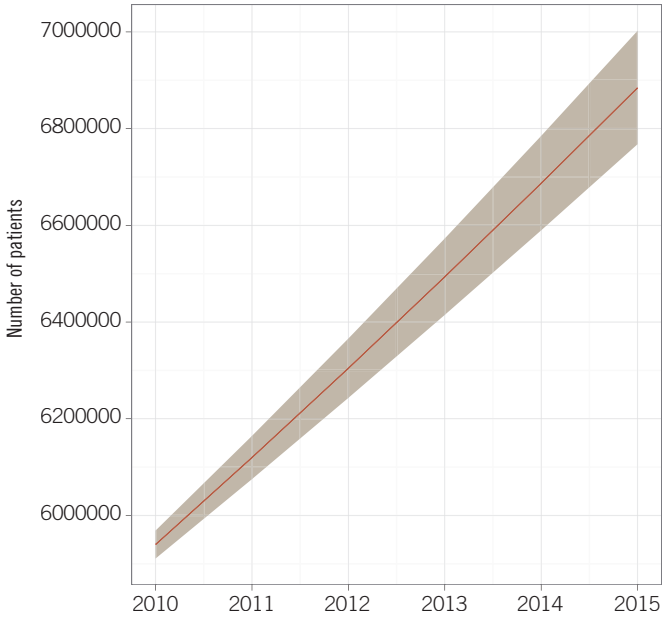
OVERVIEW OF PLAN GOALS, OBJECTIVES, TARGETS AND ACTIVITIES, 2011–2015

The main goal of the DOTS component of the Global Plan is to reduce the global burden of TB in line with the targets set for 2015 as part of the Millennium Development Goals (MDGs) and by the Stop TB Partnership, through early TB diagnosis, high-quality treatment of all cases, and prevention of TB transmission. As explained in the Overview section of this plan, the MDG target is that incidence should be falling by 2015; the Stop TB Partnership targets are to halve mortality and prevalence rates by 2015, compared with a baseline of 1990. The main target highlighted in the strategic plan for DOTS is the reduction of TB mortality by 50% by 2015, compared with 1990.

To achieve this goal, there are six critical objectives and associated targets, which are explained below.

Objective 1: Ensure early diagnosis of all TB cases. By 2015, approximately 7 million people should be receiving accurate diagnosis of TB and effective treatment (Figure 10), an increase of more than 1 million compared with 2009.[11] To facilitate this, diagnosis should be easily accessible, with no or minimal financial and geographic barriers to care. All countries should have at least one laboratory able to conduct sputum smear microscopy per 100 000 population (see also the Laboratory strengthening component of the Global Plan), and access to care needs to be improved through strengthening and expansion of basic health-care services (especially for hard-to-reach populations, as in TBREACH[12] projects). Particular efforts including outreach activities and selective active case finding are needed to detect TB in vulnerable groups, which can include pregnant women and young children, the urban poor, contacts of TB cases, migrants, prisoners, alcohol users, drug users, displaced people, smokers and people with diabetes. In addition, NTPs need to establish links and collaborate with the full range of care providers through PPM approaches. There is good evidence that PPM approaches can increase the percentage of people who are diagnosed and receive high-quality treatment by between one quarter and one third, with health care providers such as pharmacists, traditional healers and private practitioners often the first point of contact for

FIGURE 10 DOTS: NUMBER OF PATIENTS TO BE TREATED, 2011-2015[a]



[a] Shaded areas represents uncertainty band.

[10] *Everybody's business: Strengthening health systems to improve health outcomes.* Geneva, World Health Organization, 2007.
[11] The target has been set in terms of the number of people diagnosed and treated, as opposed to the CDR. This is because of uncertainty in estimates of the CDR (given uncertainty in the underlying incidence of TB) and because progress in the numbers diagnosed and treated can be directly measured as well as projected more reliably from existing numbers of notified cases.
[12] For more information about TBREACH, see the section of this plan that explains the mechanisms of the Stop TB Partnership.

people with symptoms of TB. Educating health workers about the Practical Approach to Lung Health (PAL)[13] including smoking cessation and coordinated management of respiratory illnesses can also increase case detection, as can raising awareness about TB among the general population.

Objective 2: Ensure high-quality treatment of all diagnosed cases of TB. The global treatment success rate should reach 90% by 2015, a level that has already been achieved in several HBCs and other countries. This will require drug management and rational use of anti-TB drugs that meet the pre-qualification standards established by WHO, according to international guidelines for all patients (including paediatric formulations). Procurement through GDF is an excellent way to ensure that first-line drugs meet these standards. Use of fixed-dose combinations (FDCs) of drugs should be encouraged and interruptions to drug supplies must be avoided at all costs. High rates of treatment success also depend on provision of care and support in health care facilities and the community, including use of enablers and incentives where appropriate, effective programme management and supervision and engagement of all care providers through PPM and the International Standards for TB Care (ISTC).[14] Ensuring good health outcomes among TB patients also requires that relevant co-morbidities and risk factors (such as HIV, smoking, respiratory illnesses, diabetes, undernutrition, and substance abuse) are identified and managed optimally, in collaboration with other health programmes. Community engagement can improve the quality of care through direct patient support, and have a very positive and immediate impact on adherence to TB treatment.

Objective 3: Strengthen monitoring and evaluation including impact measurement. Monitoring and evaluation is the fifth component of the DOTS strategy, and is essential to document progress and to show whether TB control is having the expected impact on the burden of disease. By 2015, all countries should be reporting treatment outcomes for all cases (not just those with smear-positive pulmonary TB, which was the original emphasis in recording and reporting when the DOTS strategy was launched in the mid-1990s). This should be done using electronic systems for recording and reporting of data wherever possible. Following the recommendations agreed by the WHO Global Task Force on TB Impact Measurement,[15] systematic assessments of the quality and coverage of notification and vital registration (VR) data need to be undertaken on a regular basis, using the framework and associated tools developed by the Task Force; vital registration systems need to be developed or strengthened and surveys of the prevalence of TB disease are needed in selected countries (the Task Force has identified 21 so-called 'global focus' countries where surveys are strongly recommended). Prevalence of TB risk factors and comorbidities should also be monitored, as well as indicators of implementation of actions to address them.

Objective 4: Strengthen human resource development for TB control in the context of overall health workforce development. Expanding access to TB care relies heavily on the availability of well-trained health workers within the primary health care system. NTPs need to coordinate with the human resource (or equivalent) departments in ministries of health to promote the availability of sufficient levels of staffing, of both multipurpose health care workers and staff who work full-time (or for most of their time) on TB control. In most countries, diagnosis and treatment of TB is integrated into general health care services, with some full-time staff working in the NTP (these staff typically focus on activities such as policy guidance, supervision and monitoring and evaluation, rather than direct patient care).

Objective 5: Scale-up measures to ensure appropriate infection control. To prevent TB transmission in health care settings, countries should implement the recommended package of measures for infection control. These include use of protective masks by health care workers, administrative controls (for example, in waiting areas for people attending outpatient services) and environmental measures such as ventilation systems. Some of these measures are simple yet effective: for example, use of natural ventilation and separation of potentially infectious patients from other people in outpatient

[13] For more information, see http://www.who.int/tb/health_systems/pal/.
[14] *International standards for tuberculosis care: diagnosis, treatment, public health.* The Hague, Tuberculosis Coalition for Technical Assistance, 2006.
[15] For further details, see the Task Force website at http://www.who.int/tb/advisory_bodies/impact_measurement_taskforce/en/index.html

settings. The best indicator to assess the quality of infection control is the ratio of the notification rate of TB among health care workers to the notification rate among the general population. This ratio should be around one. Infection control is also of specific importance in settings where the prevalence of HIV is high and in settings where there is a risk of transmitting drug-resistant TB.

Objective 6: Coordinate global-level efforts of the DOTS Expansion Working Group. Major activities include maintaining the operations of the Working Group, advocacy, facilitating the provision of appropriate technical assistance (through TBTEAM and other mechanisms) and resource mobilization.

Further details are shown in the corresponding strategic framework (see pp32-33).

In addition, new diagnostic methods and shorter treatment regimens are now on the horizon (see the New diagnostics and New drugs components of this plan, in Part II). Rapid adoption and scale-up of their use will help to achieve earlier diagnosis and contribute to improved TB care and treatment outcomes.

FUNDING REQUIREMENTS

The total cost of DOTS implementation according to the targets described above (and in the strategic framework) is estimated to be US$ 22.6 billion for the five years 2011–2015. This amount is equivalent to almost two-thirds of the total funding required for the implementation of TB control (i.e. two-thirds of the total funding required for the DOTS, TB/HIV, Drug-resistant TB and Laboratory strengthening components of the Global Plan). The amount of funding required annually will increase from around US$ 4 billion in 2011 to US$ 5 billion in 2015 (Figure 11).

The total of US$ 22.6 billion includes all resources needed for treatment of DOTS patients. The cost of diagnosis is accounted for in the section on laboratory strengthening; the amount specific to DOTS implementation is US$ 1.7 billion. Together, the diagnosis and treatment costs take into account:

- inputs and activities managed directly by NTPs and that are often funded through NTP budgets in high-burden or high-incidence countries. These include first-line drugs, staff who work full-time on TB control at national and sub-national levels, programme management and supervision activities, laboratory supplies and equipment for smear microscopy and PPM;

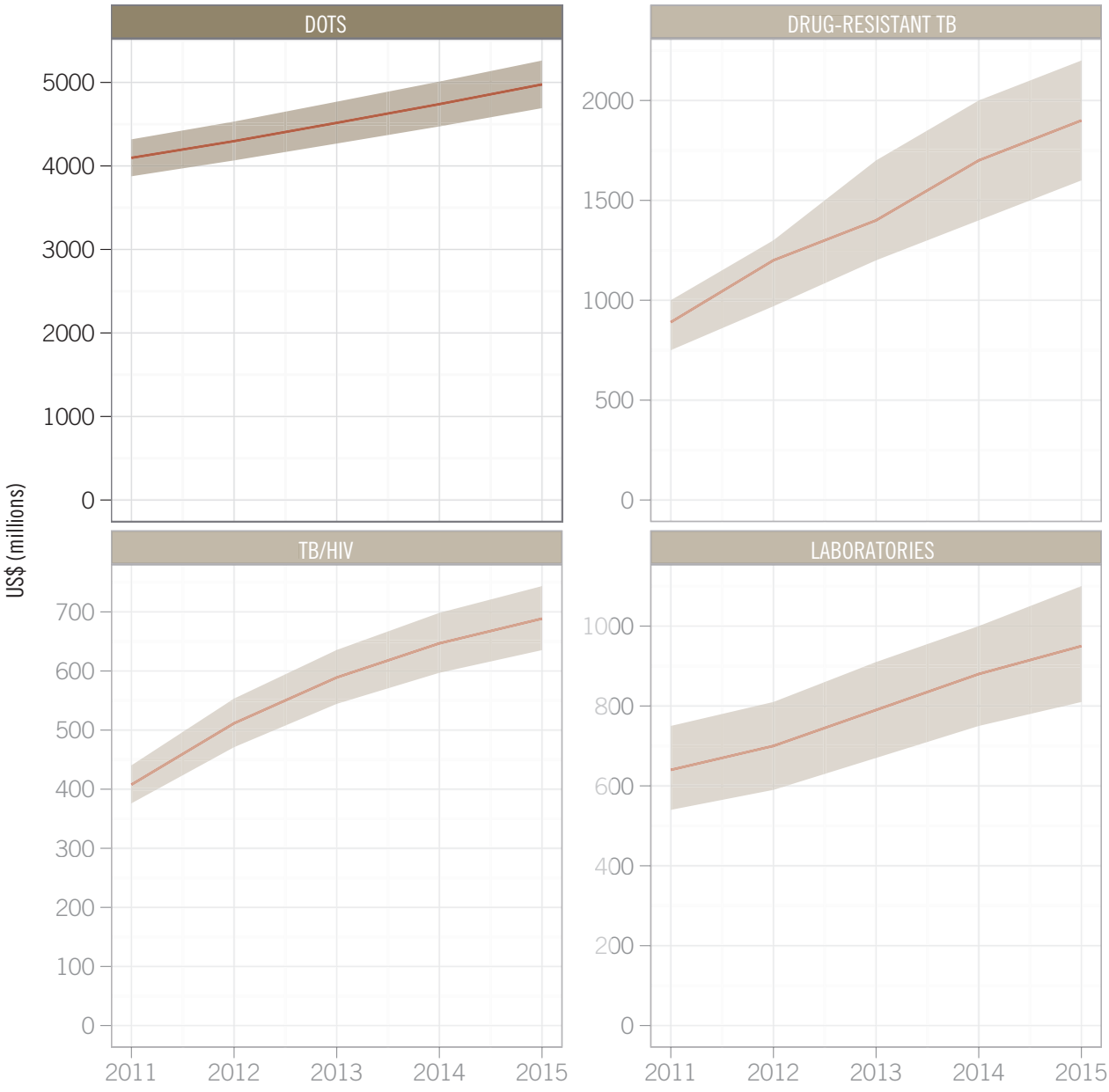
- the costs of using resources that are part of the general health system – notably, multi-purpose staff in hospitals and outpatient clinics who spend time on TB diagnosis and patient management, and a share of the infrastructure and other overhead costs required for such care.

About 25% of the total for DOTS is for NTP staff, another 25% is associated with the cost of using general health system resources (multipurpose staff and infrastructure) during hospital admissions and outpatient visits.

The target is that at least 70% of the required funding should be mobilized from domestic sources – this was the global-level average of funding provided from domestic sources in the period 2006–2009.[16] Domestic funding can be mobilized from multiple sources including government budgets, loans and social insurance schemes.

[16] *Global tuberculosis control 2010*. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2010.7).

FIGURE 11 FUNDING REQUIRED FOR DOTS IMPLEMENTATION, IN THE CONTEXT OF THE OTHER "IMPLEMENTATION" COMPONENTS OF THE PLAN [a]



[a] Shaded areas represent uncertainty bands.

DOTS: STRATEGIC FRAMEWORK, 2011–2015

VISION: UNIVERSAL ACCESS TO HIGH-QUALITY TB CARE AND PREVENTION, MAKING A MAJOR CONTRIBUTION TO TB ELIMINATION

GOAL AND OBJECTIVES	MAJOR ACTIVITIES	INDICATOR(S)	BASELINE (2009)	TARGET FOR 2015
Goal: To reduce the global burden of TB in line with the 2015 MDG and Stop TB Partnership targets through early TB diagnosis, high-quality treatment of all cases and prevention of TB transmission		Percentage reduction in global TB mortality relative to 1990 baseline	35%*	50%
		% total annual funding needs financed from domestic sources	70%	≥70%
Objective 1: Ensure early diagnosis of all TB cases (pulmonary, both smear-positive and -negative; extrapulmonary; adults and children)	Provision of diagnostic services (smear and/or culture and molecular tests plus chest X-rays, as appropriate) for all those with signs and symptoms suggestive of TB, with laboratory tests conducted in quality-assured laboratories; decentralization of these services to increase access; elimination of user fees that affect both access to care and the timing of access to care; promotion of the use of guidelines on the management of childhood TB; programme management and supervision; contact investigations; active case finding in selected high risk groups; engagement of all care providers through PPM and use of the international standards for TB care (ISTC); scale-up of PAL (including smoking cessation and prevention) and ACSM.	Global annual notifications of TB	5.8 million	6.9 million
		Number of HBCs (n=22) in which diagnosis of TB is provided free-of-charge or is fully reimbursable via health insurance	4	22
		Number of countries with ≥ 1 AFB microscopy laboratory per 100 000 population**	≥75	149
		Number of countries among the 22 HBCs and 27 high MDR-TB burden countries with ≥1 culture laboratory per 5 million population**	18–21	36
		Proportion of notified cases reported from non-NTP care providers, in selected countries	n/a***	15–20%
Objective 2: Ensure high-quality treatment of all diagnosed cases of TB (pulmonary, both smear-positive and -negative; extrapulmonary; adults and children)	Drug management and rational use of anti-TB drugs according to international guidelines for all patients (including paediatric formulations); treatment in health care facilities and the community, including provision of enablers and incentives, and management of co-morbidities and risk factors where appropriate; programme management and supervision; engagement of all care providers through PPM and the ISTC; ACSM.	Treatment success rate (global) among notified cases of smear-positive pulmonary TB	86%	90%

* The baseline shown here is based on the latest time-series of estimates published by WHO. Time-series from 1990 onwards are updated each year and thus the baseline figure shown here may be updated in future years.
** This indicator is also included in the strategic framework for Laboratory strengthening. Among the 149 countries (all countries except high-income countries) included in the Global Plan that reported data to WHO in 2009, 75 had at least 1 AFB laboratory per 100 00 population while 26 did not report data, and 48 had less than 1 AFB laboratory per 100 000 population. Among the 27 high MDR-TB burden countries, 18 countries had at least 1 culture laboratory per 5 million population and 3 did not report data.
*** Abbreviations and notes: ACSM - Advocacy, communication and social mobilization; AFB - acid-fast bacilli; HBC - high burden country; ISTC - International Standards for TB Care; PAL - Practical Approach to Lung Health; PPM - public-private mix; n/a - not available. A baseline for PPM is not available because too few countries have reported data.

OBJECTIVES (CONTINUED)	MAJOR ACTIVITIES	INDICATOR(S)	BASELINE (2009)	TARGET FOR 2015
Objective 3: Strengthen monitoring and evaluation including impact measurement	Assessments of the quality and coverage of notification and vital registration data according to the framework developed by the WHO Global Task Force on TB Impact Measurement and associated tools; development and strengthening of vital registration (VR)* systems; prevalence surveys in selected countries; monitoring of risk factors and co-morbidities and interventions to address them.	Number of countries that have conducted a recent assessment of the quality and coverage of notification and VR data	63	119
		Number of countries that meet VR quality and coverage criteria	46	60
		Number of countries that have successfully completed a national survey of the prevalence of TB disease between 2008 and 2015, among the 21 countries where such a survey is strongly recommended	1	21
		Number of countries reporting treatment outcomes for all cases (not just smear-positive cases)	116	149
		Number of countries with electronic and case-based recording and reporting systems	55	119
Objective 4: Strengthen human resource development for TB control in the context of overall health workforce development	Training and continued education of all health care workers (including community health workers)** involved in TB control; coordination between the NTP and Human Resources for Health (or equivalent) departments regarding staffing, filling of vacancies, and retention packages; supportive supervision; TB screening among health care workers (including community health workers).	Number of HBCs (n=22) with <15% vacancy rates** at peripheral-level health care facilities	5	22
		Number of countries in which 100% of health care workers with job descriptions that include tasks related to TB control in peripheral-level health care facilities have been trained by the NTP in the past five years	≥10**	149
Objective 5: Scale-up measures to ensure appropriate infection control	Implementation of infection control (IC), including administrative, personal protection and environmental measures, in TB hospital wards, outpatient settings where TB is diagnosed and treated, and congregate settings, according to international and national guidelines; monitoring.	Ratio of TB notification rate among health care workers to notification rate among general population	n/a	~1
Objective 6: Coordinate global-level efforts of the DOTS Expansion Working Group	Development and monitoring of DOTS Expansion Working Group (DEWG) plan; meetings; conference calls; advocacy efforts.	Number of countries participating in DEWG	22	30

* Abbreviations: IC - infection control; VR – vital registration; n/a - not available.

** The World Health Report 2006 defined health workers as: a) those who are directly involved in delivering health care services (e.g. physicians and nurses) and b) those who are indirectly involved in providing these services (e.g. health management and support workers such as accountants and administrative officers). Vacancy rates and the status of training will be monitored for four groups of staff: 1) medical officers; 2) nurses (including registered nurses, registered midwives, enrolled nurses and enrolled midwives); 3) health assistants/medical assistants/clinical officers; 4) laboratory technicians/microscopists. The baseline number is an underestimate, due to lack of reporting of data by 99 countries.