

THE STOP TB STRATEGY

Building on and enhancing DOTS to meet
the TB-related Millennium Development Goals

MDG

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WHO/HTM/STB/2006.37

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ACKNOWLEDGEMENTS

The Stop TB Strategy described in this document has been developed collectively, over a period of more than a year, in close collaboration with numerous colleagues and partners worldwide and under the overall guidance of Mario Raviglione, Director, Stop TB Department.

The preparation of this document was coordinated by Mukund Uplekar who led the Writing Group comprising Jose Figueroa-Munoz, Katherine Floyd, Haileyesus Getahun, Ernesto Jaramillo, Dermot Maher, Diana Weil and Brian Williams.

The Writing Group gratefully acknowledges the contributions to developing the Strategy and its approval by the members of WHO's Strategic, Technical and Advisory Group on TB. Constructive input and endorsement of the Strategy by the Stop TB Partnership's Coordinating Board is also acknowledged.

For their critical feedback and input, thanks are due to the staff of the Stop TB Department and of the Partnership Secretariat, especially Mohammad Aziz, Karin Bergstrom, Leopold Blanc, Chris Dye, Marcos Espinal, Giuliano Gargioni, Malgorzata Grzemska, Motoky Hayakawa, Jun Kwon, Knut Lonroth, Robert Matiru, Paul Nunn, Salah Ottmani, Thad Pennas, Ted Torfoss and Lana Velebit.

The TB teams in WHO's Country Offices and Regional Offices provided very useful comments. The Writing Group is grateful to all for their contributions and especially to Dongil Ahn, Daniel Chin, Erwin Cooreman, Mirtha del Granado, Khandaker Haque, Wieslaw Jakubowiak, Pratap Jayvant, Nani Nair and Pieter van Maaren.

Several experts from WHO's technical and financial partners reviewed and commented on the document. The Writing Group is grateful to them all, particularly Susan Bacheller, Amy Bloom, Rachel Guglielmo, Myriam Henkens, Arnaud Trébuq, Francis Varaine and John Walley.

Constructive comments from participants at the joint meeting of the Stop TB Partnership's Working Groups in October 2005, where the strategy was presented and discussed, are gratefully acknowledged.

Special thanks are due to Case Gordon and colleagues representing people with TB for input in drafting and for making the Patients' Charter for Tuberculosis Care an integral part of the strategy.

Glenn Thomas coordinated the design and layout of the document.

PREFACE

The major progress in global tuberculosis (TB) control seen in the past decade has been due in large part to the development and widespread implementation of the DOTS strategy, especially in countries with a high burden of TB. Building on current achievements, and in accordance with the 2005 World Health Assembly resolution on sustainable financing for TB control, the major task for the next decade is to achieve the Millennium Development Goal (MDG) and related Stop TB Partnership targets for TB control, which have been set for 2015. As with the DOTS strategy, some of the targets relate to TB diagnosis and cure; others are concerned with epidemiological impact, including reversing incidence and halving the 1990 level of TB prevalence and death rates. Meeting these targets requires a coherent strategy that is capable of sustaining existing achievements and addressing remaining constraints and challenges more effectively. This document defines such a strategy – the Stop TB Strategy.

The Stop TB Strategy sets out the steps that national TB control programmes and their partners need to take, assisted actively by all stakeholders. It is based both on experience gained over the past decade and on continuing consultations with stakeholders at the global, regional, national and local levels. Implementation of the strategy should ensure equitable access to care of international standards for *all* TB patients – infectious and non-infectious, adults and children, with and without HIV, with and without drug-resistant TB – regardless of whether they receive care from a public or a private provider.

Stopping TB must be seen within the framework of country-owned strategies to reduce poverty and advance development. The Stop TB Strategy must be aligned with other strategies and partnerships to meet all major public health challenges. Tackling TB effectively requires addressing all the risk factors that make individuals vulnerable to infection with *Mycobacterium tuberculosis* and to developing the disease. It also means reducing the adverse effects of the disease, including its social and economic consequences. Clearly, the main focus of the Stop TB Strategy is on making the best use of currently available tools for diagnosis, treatment and prevention of TB and of the improved tools that are likely to become available through research and development.

The strength of global efforts to control TB lies in the coordinated and collaborative efforts of the Stop TB Partnership, which now has more than 400 partners worldwide. The Stop TB Strategy presented here underpins the Global Plan to Stop TB (2006–2015), developed by the Stop TB Partnership.

With a clear global strategy and related global plan, the framework is in place for unprecedented efforts in TB control over the next 10 years. Full implementation will require substantial resources – while funding is rising, more is needed. I am confident that WHO and its partners will continue to work closely with countries to help achieve the MDG and Stop TB Partnership targets for TB control, and set us on the path to elimination of this ancient scourge of humanity.



Mario Raviglione
Director, Stop TB Department

I. BACKGROUND

Achievements in the past 15 years

Global efforts to control TB were reinvigorated in 1991, when a World Health Assembly (WHA) resolution recognized TB as a major global public health problem (1). Two targets for TB control were established as part of this resolution – detection of 70% of new smear-positive cases, and cure of 85% of such cases, by the year 2000. In 1994, the internationally recommended control strategy, later named DOTS, was launched (2). Its key components included: government commitment; case detection by predominantly passive case-finding; standardized short-course chemotherapy to, at least, all confirmed sputum smear-positive cases, provided under proper case management conditions; a system of regular drug supply; and a monitoring system for programme supervision and evaluation. The DOTS framework has subsequently been expanded (3), further clarified, and implemented in 182 countries. DOTS implementation has helped countries to improve national TB control programmes (NTPs) and make major progress in TB control. By 2004, more than 20 million patients had been treated in DOTS programmes worldwide and more than 16 million of them had been cured. Mortality due to TB has been declining and incidence diminishing or stabilizing in all world regions except sub-Saharan Africa and, to some extent, eastern Europe. The global treatment success rate among new smear-positive TB cases had reached 83% by 2003 (just short of the WHA target of 85% by 2005), and in 2004 the case detection rate, which has accelerated globally since 2001 (4), was 53% (against the target of 70% by 2005).

The first Global Plan to Stop TB set out the actions that were needed in TB control over the period 2001–2005 (5) and helped to steer global TB control efforts during that time. Global TB control has also been boosted by increased political commitment from high-burden countries and partners in the Amsterdam Declaration (2000), the Washington Commitment to Stop TB (2001), and the Stop TB Partners' Forum in Delhi (2004). In 2005, the WHA passed a resolution advocating “sustainable financing for TB control and prevention”, with Member States making a commitment to strengthen efforts to achieve the TB-related targets included in the MDGs (6) – see section III for details. This resolution built on the report of the

Commission on Macroeconomics and Health (2001), the High-Level Forum on the Health Millennium Development Goals (MDGs) in 2004, and the Second Ad Hoc Committee on the TB Epidemic (2005) (7).

Since the development of the DOTS strategy, WHO and partners have worked on complementary policies and strategies to address the remaining major constraints to achievement of global TB control targets. These include expanding access to diagnosis and treatment through community TB care, and public–private mix (PPM) approaches aimed at engaging all care providers – state and non-state – in DOTS implementation. Innovative mechanisms such as the Global Drug Facility and the Green Light Committee have been developed to improve access to quality-assured and affordable drugs in resource-poor settings. The collaborative activities that need to be implemented by TB and HIV/AIDS control programmes have been defined, and strategies for managing multidrug-resistant TB (MDR-TB) have been developed and tested. Impact assessment is being pursued as a means of evaluating progress towards the MDGs. New partnerships and academic research initiatives for development of new tools are beginning to produce results, and several new diagnostics, drugs and candidate vaccines are in the pipeline.

Challenges for 2006–2015

Current rates of progress are insufficient to allow the targets of halving TB mortality and prevalence by 2015 to be achieved (8). Particularly urgent action is needed where the epidemic is worsening, notably in Africa but also in eastern Europe. While there has been substantial progress in extending and improving NTPs in sub-Saharan Africa, this region has to face the challenge of the rapid rise in TB cases produced by the HIV epidemic, often in places where human resources in the health care sector are already overburdened. In eastern Europe, the socioeconomic crisis that followed the dismantling of the Soviet Union in the early 1990s and impoverished public health systems have contributed to a major increase in the incidence and prevalence of TB, including MDR-TB.

Increased and sustained efforts are also needed in Asia, which continues to bear two-thirds

of the global burden of TB, with India and China ranking first and second in terms of total number of TB cases. An emerging HIV epidemic in Asia also threatens recent progress in TB control, and in some parts of China MDR-TB is a major problem.

In all regions, identifying and reaching all those in need of care, especially the poorest of the poor, poses a major challenge. Efforts to control TB must progress hand-in-hand with efforts to strengthen health systems as a whole. The ultimate goal of eliminating TB depends on new diagnostics, drugs and vaccines. New approaches to overcoming the obstacles to TB control have been developed, but greater resources are needed to allow these approaches to be widely implemented.

Opportunities for 2006–2015

New resources are becoming available, from increased domestic funding in some high-burden countries and rising international funding, including that from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), development banks and bilateral development agencies. Partnerships to respond to health system and disease control challenges are being developed across and within countries and among a wide array of stakeholders. As noted above, a variety of new policies and strategies have been developed which, if implemented more widely, would make a major contribution to improving TB control.

The need for a new strategy

The past decade has seen major progress in global TB control – in large part as a result of the development and widespread implementation of the DOTS strategy. Building on current achievements, the major task for the next decade is to achieve the MDG and related Stop TB Partnership targets for TB control. Meeting these targets requires a coherent strategy to provide the context for the second Global Plan to Stop TB (2006–2015) (9) – a strategy that enables existing achievements to be sustained, effectively addresses the remaining constraints and challenges, and underpins efforts to strengthen health systems, alleviate poverty and advance human rights.

This document defines such a strategy – the Stop TB Strategy – and is divided into four major sections:

- **The Stop TB Strategy at a glance.** Provides an overview of the strategy.
- **Vision, goal, objectives, targets and indicators.** Explains the goal and related objectives, targets and indicators of the Stop TB Strategy, as well as the overall vision to which the Strategy will contribute.
- **The six principal components of the Stop TB Strategy.** Explains the major components of the strategy in more detail: pursuing high-quality DOTS expansion and enhancement; addressing TB/HIV, MDR-TB and other challenges; contributing to health system strengthening; engaging all care providers; empowering patients and communities; and enabling and promoting research.
- **Measuring global progress and impact.** Explains how progress towards TB control targets will need to be measured and evaluated.

II. THE STOP TB STRATEGY AT A GLANCE

VISION	A WORLD FREE OF TB
GOAL	<ul style="list-style-type: none">To reduce dramatically the global burden of TB by 2015 in line with the Millennium Development Goals and the Stop TB Partnership targets
OBJECTIVES	<ul style="list-style-type: none">To achieve universal access to high-quality diagnosis and patient-centred treatmentTo reduce the suffering and socioeconomic burden associated with TBTo protect poor and vulnerable populations from TB, TB/HIV and MDR-TBTo support development of new tools and enable their timely and effective use
TARGETS	<ul style="list-style-type: none">MDG 6, Target 8 – ...halted by 2015 and begun to reverse the incidence...Targets linked to the MDGs and endorsed by the Stop TB Partnership:<ul style="list-style-type: none">by 2005, detect at least 70% of new sputum smear-positive TB cases and cure at least 85% of these casesby 2015, reduce TB prevalence and death rates by 50% relative to 1990by 2050, eliminate TB as a public health problem (<1 case per million population)

COMPONENTS OF THE STRATEGY AND IMPLEMENTATION APPROACHES

- Pursue high-quality DOTS expansion and enhancement**
 - Political commitment with increased and sustained financing
 - Case detection through quality-assured bacteriology
 - Standardized treatment, with supervision and patient support
 - An effective drug supply and management system
 - Monitoring and evaluation system, and impact measurement
- Address TB/HIV, MDR-TB and other challenges**
 - Implement collaborative TB/HIV activities
 - Prevent and control MDR-TB
 - Address prisoners, refugees and other high-risk groups and situations
- Contribute to health system strengthening**
 - Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
 - Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
 - Adapt innovations from other fields
- Engage all care providers**
 - Public–Public and Public–Private mix (PPM) approaches
 - International Standards for Tuberculosis Care (ISTC)
- Empower people with TB, and communities**
 - Advocacy, communication and social mobilization
 - Community participation in TB care
 - Patients' Charter for Tuberculosis Care
- Enable and promote research**
 - Programme-based operational research
 - Research to develop new diagnostics, drugs and vaccines

III. VISION, GOAL, OBJECTIVES, TARGETS AND INDICATORS

This section explains the goal and related objectives, targets and indicators of the Stop TB Strategy, as well as the overall vision to which the Strategy will contribute. Targets are also summarized in Box 1 (for the MDGs) and Box 2 (for the Stop TB Partnership).

Vision

The Stop TB Strategy has been developed within the context of an overall vision for TB control – that is, a world free of TB.

Goal

The goal of the Stop TB Strategy is to reduce dramatically the global burden of TB by 2015 in line with the MDGs and the Stop TB Partnership targets and to achieve major progress in the research and development needed for TB elimination.

Objectives

The Stop TB Strategy has the following four major objectives which, in combination, are designed to achieve the goal:

- To achieve universal access to high-quality diagnosis and treatment for people with TB.
- To reduce the suffering and socioeconomic burden associated with TB.
- To protect poor and vulnerable populations from TB, TB/HIV and MDR-TB.
- To support the development of new tools and enable their timely and effective use.

Targets

Targets for TB control have been established by the WHA, by the United Nations as part of the MDGs, and by the Stop TB Partnership. The Stop TB Strategy is designed to achieve the targets set for the period 2006–2015.

World Health Assembly targets for tuberculosis control

In 1991, a WHA resolution set “a global target of cure of 85% of sputum-positive patients under treatment and detection of 70% of cases by the year 2000”. These targets were based on epidemiological modelling, which suggests that achievement of an 85% cure rate and 70% case detection will reduce the prevalence of infectious (sputum smear-positive) TB cases, the number of infected contacts, and the incidence of infectious cases (10, 11). Further, achievement of these targets for case detection and cure (measured as treatment success, i.e. the sum of cases cured and patients completing treatment) is expected to reduce the annual TB incidence rate by 7–12% per year, in the absence of HIV coinfection (12). By 1998, however, it had become apparent that the targets would not be met by the specified date; in 2000, the fifty-third WHA therefore postponed the target year to 2005 (13).

Millennium Development Goals

The MDGs, established by the United Nations, provide both a framework and the opportunity for international cooperation to reduce poverty, including improving the health of the poor. As a disease of poverty, responsible for the loss of more years of healthy life than any other communicable disease except HIV/AIDS, TB is one of the priorities included in the MDGs. Goal 6, Target 8 (14) – the MDG target relevant to TB – is to have halted and begun to reverse incidence by 2015 (see Box 1). The interpretation of Target 8 is that the incidence of *all forms* of TB should be falling by 2015, and two indicators have been defined for this target – TB prevalence and deaths (Indicator 23), and the proportion of cases detected and successfully treated under the DOTS strategy (Indicator 24).

Stop TB Partnership Targets

The Stop TB Partnership has endorsed two epidemiological targets linked to MDG 6, Target 8 – the reduction of TB prevalence and deaths by 50% by 2015, in comparison with a 1990 baseline. Achievement of these *impact* targets globally requires sustained progress in implementation (8). That is, national control programmes around the world must not only reach at least 70% case detection and 85% treatment success, but must also implement the wider range of activities described in the Stop TB Strategy and the related second Global Plan to Stop TB (2006–2015) (9). In addition, the Stop TB Partnership has made a commitment to eliminate TB as a public health problem by 2050 (see Box 2) (15, 16).

Box 1. Millennium Development Goal, Target and Indicators relevant to TB

Millennium Development Goal 6

Combat HIV/AIDS, malaria and other diseases

Target 8

To have halted by 2015 and begun to reverse the incidence of malaria and other major diseases

Indicator 23

Prevalence and death rates associated with tuberculosis

Indicator 24

Proportion of tuberculosis cases detected and cured under DOTS

Box 2. Stop TB Partnership Targets

By 2005

At least 70% of people with infectious TB will be diagnosed (under the DOTS strategy), and at least 85% of these patients will be cured.

By 2015

The global burden of TB (disease prevalence and deaths) will be reduced by 50% relative to 1990 levels. Specifically, this means reducing prevalence to 155 per 100 000 or lower and deaths to 14 per 100 000 per year or lower by 2015 (including TB cases coinfecting with HIV). The number of people dying from TB in 2015 should be less than about 1 million, including those coinfecting with HIV.

By 2050

The global incidence of TB disease will be less than 1 case per million population per year.

IV. THE SIX PRINCIPAL COMPONENTS OF THE STOP TB STRATEGY

Tuberculosis control demands a comprehensive and sustained response, complementing measures to address the social and environmental factors that increase the risk of developing TB. Poor people bear most of the burden of illness, suffering and death caused by TB. The Stop TB Strategy should therefore be viewed as a key component of broader international, national and local strategies to alleviate poverty. It both builds on the DOTS strategy and expands its scope to address remaining constraints and challenges to TB control – an expansion that is critical to achievement of the MDG and related Stop TB Partnership targets for TB control. The Stop TB Strategy has six principal components:

1. Pursue high-quality DOTS expansion and enhancement
2. Address TB/HIV and MDR-TB and other special challenges
3. Contribute to health system strengthening
4. Engage all care providers
5. Empower people with TB, and communities
6. Enable and promote research

The first component – DOTS expansion and enhancement – is the cornerstone of the Strategy and provides the foundation for the remaining five. It is crucial to understand that the sequence and the scale of implementation and the speed of activities building on DOTS will vary with the setting and with the soundness of basic DOTS implementation. The following subsections explain each of the six components in more detail.

1. Pursue high-quality DOTS expansion and enhancement

To enable known constraints to be addressed and new challenges met, further strengthening of the basic components of the DOTS strategy is required on the following lines:

- a. Political commitment with increased and sustained financing
- b. Case detection through quality-assured bacteriology
- c. Standardized treatment, with supervision and patient support
- d. Effective drug supply and management system
- e. Monitoring and evaluation system, and impact measurement

1a. Political commitment with increased and sustained financing

Clear and sustained political commitment by national governments is crucial if basic DOTS and the Stop TB Strategy are to be effectively implemented. Political commitment is needed to foster national and international partnerships, which should be linked to long-term strategic action plans prepared by NTPs. Strategic action plans should address technical and financial requirements and promote accountability for results at all levels of the health system; they should include TB-related and other relevant indicators, and – where appropriate – political commitment should be backed up by national legislation (17). Local partnerships with many potential contributors will help improve TB care in terms of access, equity and quality.

Adequate funding is essential. Current resources are inadequate, and further effort is required to mobilize additional resources from domestic as well as international sources, with a progressive increase in domestic funding. The global financing and partnership resources now available for poverty reduction, health systems improvement and disease control offer new opportunities for TB control programmes. Even with adequate financing, critical deficiencies in human resources in the health

sector will impede progress in many low- and middle-income countries, especially in Africa. Political commitment is required to support the overall structural and financial changes needed to improve the availability, distribution and motivation of competent health workers. Special efforts, including good strategic planning, will be needed to ensure the availability of adequate and competent human resources for health care in general and TB care in particular (18, 19).

1b. **Case detection through quality-assured bacteriology**

Bacteriology for diagnosis. Bacteriology remains the recommended method of TB case detection, first using sputum smear microscopy and then culture and drug susceptibility testing (DST), as indicated below.

Strengthened laboratory network. A wide network of properly equipped laboratories with trained personnel is necessary to ensure access to quality-assured sputum smear microscopy. This is likely to require additional investments in the laboratory network in many countries. In addition, every country should have a well-resourced and fully functioning national reference laboratory.

The laboratory network should be based on the following principles:

- adoption of national standards in accordance with international guidelines;
- decentralization of diagnostic services, with high proficiency levels maintained;
- communication among members at various levels of the network; and
- functioning internal and external quality management, including supervision.

Culture and DST services should be introduced, in a phased manner, at appropriate referral levels of the health system. Their functions should include diagnosis of sputum smear-negative TB, diagnosis of TB among HIV-positive adults and children, diagnosis and monitoring of response to treatment of MDR-TB, and testing related to periodic surveys of the prevalence of drug resistance. Maintaining the quality of the laboratory network depends on regular training, supervision and support, and motivation of laboratory staff. Best use should be made of existing public and private laboratories.

1c. **Standardized treatment, with supervision and patient support**

Treatment services. The mainstay of TB control is organizing and administering standardized treatment across the country for all adult and paediatric TB cases – sputum smear-positive, smear-negative, and extrapulmonary. In all cases, WHO guidelines on patient categorization and management should be followed (20). These guidelines emphasize use of the most effective standardized, short-course regimens, and of fixed-dose drug combinations (FDCs) to facilitate adherence to treatment and to reduce the risk of the development of drug resistance. Separate WHO guidelines are also available for management of patients with drug-resistant TB (21).

Supervision and patient support. Services for TB care should identify and address factors that may make patients interrupt or stop treatment. Supervised treatment, which may have to include direct observation of therapy (DOT), helps patients to take their drugs regularly and complete treatment, thus achieving cure and preventing the development of drug resistance. Supervision must be carried out in a context-specific and patient-sensitive manner, and is meant to ensure adherence on the part both of providers (in giving proper care and support) and of patients (in taking regular treatment). Depending on the local conditions, supervision may be undertaken at a health facility, in the workplace, in the community or at home. It should be provided by a treatment partner or treatment supporter who is acceptable to the patient and is trained and supervised by health services. Patient and peer support groups can help to promote adherence to treatment. Selected patient groups, for example prisoners, drug users, and some people with mental health disorders, may need intensive support including DOT.

Improving access to treatment. Locally appropriate measures should be undertaken to identify and address physical, financial, social and cultural barriers – as well as health system – barriers to accessing TB treatment services. Particular attention should be given to the poorest and most vulnerable population groups. Examples of actions that may be appropriate include expanding treatment outlets in the poorest rural and urban settings, involving providers who practise close to where patients live, ensuring that services are free or heavily subsidized, offering psychological

and legal support, addressing gender issues, improving staff attitudes, and undertaking advocacy and communication activities.

1d.

An effective drug supply and management system

An uninterrupted and sustained supply of quality-assured anti-TB drugs is fundamental to TB control. For this purpose, an effective drug supply and management system is essential. A reliable system of procurement and distribution of all essential anti-TB drugs to all relevant health facilities should be in place. The TB recording and reporting system is designed to provide the information needed to plan, procure, distribute and maintain adequate stocks of drugs.

Anti-TB drugs should be available free of charge to all TB patients, both because many patients are poor and may find them difficult to afford, and because treatment has benefits that extend to society as a whole (cure prevents transmission to others). Legislation related to drug regulation should be in place, and use of anti-TB drugs by all providers should be strictly monitored. The use of FDCs of proven bioavailability and of innovative packaging such as patient kits can help to improve drug supply logistics as well as drug administration, promote adherence to treatment and prevent development of drug resistance.

The Global Drug Facility and the Green Light Committee offer countries with limited capacity the benefit of access to quality-assured TB drugs at reduced prices and also facilitate access to training on drug management (22).

1e.

Monitoring and evaluation system, and impact measurement

Recording and reporting system. Establishing a reliable monitoring and evaluation system with regular communication between the central and peripheral levels of the health system is vital. This requires standardized recording of individual patient data, including information on treatment outcomes, which are then used to compile quarterly treatment outcomes in cohorts of patients. These data, when compiled and analysed, can be used at the facility level to monitor treatment outcomes, at the district level to identify local problems as they arise, at provincial or national level to ensure consistently high-quality TB control across geographi-

cal areas, and nationally and internationally to evaluate the performance of each country. Regular programme supervision should be carried out to verify the quality of information and to address performance problems.

Enhanced recording and reporting. Both developed and developing countries now have additional diagnostic information at their disposal, including sputum culture, DST and HIV test results, all of which can be used to guide patient management. TB programme managers also need to monitor records and reports from public and private care providers not directly linked to the NTP. Special attention must be paid to ensuring the confidentiality of patient information. Currently, WHO and its partner organizations are considering what additional data should be routinely collected and how these data should be compiled, collated, analysed and used to inform TB control. Use of electronic recording systems will be considered where appropriate.

Making the best use of data at all levels will mean many countries having to train staff in the analysis and interpretation of data, as well as in the use of the computer software that can greatly facilitate this work. As electronic recording systems become more widely available, consideration should be given to storing individual patient data, which will make more detailed analyses of aggregated data possible.

2. Address TB/HIV, MDR-TB and other challenges

2a.

Implement collaborative TB/HIV activities

The HIV epidemic fuels the TB epidemic. HIV promotes the progression of recent and latent *Mycobacterium tuberculosis* infection to active TB disease; it also increases the rate of recurrent TB. The HIV epidemic has caused a substantial increase in the percentage of cases of smear-negative pulmonary and extrapulmonary TB disease. HIV-positive patients with smear-negative pulmonary TB have worse treatment outcomes and higher mortality than HIV-positive patients with smear-positive pulmonary TB. In the long term, only effective control of the HIV epidemic will reverse the associated increase in TB incidence. In the meantime, interventions to reduce HIV-related TB morbidity and mortality need to be implemented (23).

Collaborative TB/HIV activities. WHO has published an interim policy on collaborative TB/HIV activities (24). Twelve collaborative activities between TB and HIV/AIDS control programmes are recommended in three broad categories: establishing the mechanisms for collaboration, reducing the burden of TB in people living with HIV/AIDS (PLWHA), and reducing the burden of HIV in patients with TB. These activities should be included in national TB control plans.

The four activities involved in mechanisms for collaboration are:

- creation of a joint national TB and HIV coordinating body that includes TB and HIV patient support groups;
- development and implementation of a joint national plan;
- HIV surveillance among TB patients, irrespective of HIV prevalence rates; and
- a system of monitoring and evaluation.

For monitoring and evaluation, a core set of indicators should be agreed upon, based on WHO guidelines for monitoring and evaluation of collaborative TB/HIV activities (25).

The three activities to reduce the burden of TB in PLWHA are:

- intensified TB case-finding in all HIV/AIDS programme outlets and among high-risk populations, with a referral system between HIV and TB services;
- provision of isoniazid preventive therapy as part of the package of care for PLWHA when active TB is excluded; and
- ensuring that infection control is in place in health care and congregate settings.

The five activities to reduce the burden of HIV in TB patients are:

- HIV testing and counselling for all TB patients when HIV prevalence among TB patients exceeds 5%;
- provision of HIV prevention services (including harm reduction measures when injecting drug use is a problem);
- provision of co-trimoxazole preventive therapy to TB patients with HIV infection;
- provision of antiretroviral therapy to TB patients with HIV infection; and
- provision of care and support services to TB patients with HIV infection.

2b.

Prevent and control multidrug-resistant TB

A global threat. Evidence shows that MDR-TB is a threat to global TB control. This is aggravated by inadequate treatment of those already affected with MDR-TB; the rise in drug resistance resulting from the widespread misuse of second-line anti-TB drugs; and the absence of new effective drugs to treat TB. Global surveillance of anti-TB drug resistance indicates that drug-resistant TB is present everywhere and that it is especially severe in parts of China and in countries of the former Soviet Union. If MDR-TB is not properly addressed in these areas, TB cannot be controlled. This means that every patient with MDR-TB should be diagnosed and receive adequate treatment with second-line anti-TB drugs. Increasing evidence shows that management of MDR-TB under programmatic conditions is feasible, effective and cost-effective when implemented in the context of a well-functioning DOTS programme and based on WHO's DOTS-Plus policy guidelines (21).

Managing drug-resistant TB. Detection and treatment of all forms of MDR-TB should be an integral part of NTP activities. While the challenges involved in achieving such integration should not be underestimated, NTPs need to take steps to ensure that patients with MDR-TB have access to the right treatment. Experience shows that developing capacity for MDR-TB management can strengthen the overall capacity of an NTP to implement TB control measures.

The key actions for preventing and controlling drug-resistant TB include use of recommended treatment regimens, a reliable supply of quality-assured first- and second-line anti-TB drugs, and adherence to treatment by patients and to its proper provision by health-care providers. Implementing these actions requires that a needs assessment be conducted to determine the capacity of TB control programmes to manage drug-resistant TB. On the basis of this assessment, those districts or administrative areas where integration is most likely to succeed should be prioritized. The WHO guidelines on the management of drug-resistant TB, based on the best available evidence, provide full details on the implementation of activities to control drug-resistant TB (21).

2c.
Address prisoners, refugees and other high-risk groups and special situations

Risk groups and special situations. TB control programmes need to pay special attention to certain population groups and special situations that are associated with a higher TB risk. In health care and congregate settings, where people with TB and HIV are frequently crowded together, the risk of contracting TB is increased (24). The risk groups that need special attention include prison populations, refugees and other displaced people, migratory workers, illegal immigrants, cross-border populations, the orphaned and homeless, ethnic minorities, other marginalized groups, alcohol abusers and injecting drug users. People with diabetes and smokers are other common examples of risk groups. Special situations requiring extra attention include unexpected population movements such as occur, for example, when there is political unrest, war or natural disaster.

Among risk groups and in special situations, social networks may be disrupted, and this breakdown of social support adds to the effects of poverty, alters health-seeking behaviour and limits access to services. TB services need to adapt to address the specific needs that arise in these circumstances (26).

Addressing risk groups and special situation. The first step in addressing the needs of risk groups is recognition and acknowledgement of their existence and their special requirements. Both low- and high-prevalence countries must first define the special situations and vulnerable groups that need attention. Identification of risk groups and their locations, assessing the problems they face in accessing care and of the services currently available to them, and defining strategies to ensure access to high-quality TB care will be the logical next steps. These steps should be undertaken in collaboration with all the stakeholders and should also involve representatives of the beneficiaries themselves. Each health care and congregate setting should have a TB infection control plan that includes administrative, environmental and personal protection measures to minimize the risk of TB transmission (24). Implementation of the TB infection control plan should be undertaken in a phased manner with the support of, and in coordination with, relevant partners and care providers (26).

3. Contribute to health system strengthening

3a.
Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery and information systems

Progress on all of the health-related MDGs depends substantially on the strengthening of health systems. This is particularly true in Africa. If access to good-quality health services can be increased and sustained, this should have major benefits for TB control, including the elements covered in subsections 1 and 2 above.

Health system strengthening is defined as “improving capacity in some critical components of health systems, in order to achieve more equitable and sustained improvement across health services and outcomes” (27). Tuberculosis control programmes and their partners should participate actively in both country-led and global efforts to improve action across all major areas of health systems, including policy, human resources, financing, management, service delivery (including infrastructure and supply systems) and information systems. This means working across all levels of systems and with all actors in the public sector, non-state sector and communities and may incorporate: ongoing contributions to well-defined sector strategies and plans; helping build system-wide responses; and working on initiatives to devise, test and share new solutions. Many NTPs began this type of work in response to health reform initiatives of the past 10 years. WHO guidelines produced in 2002 are still highly relevant and will be supplemented with new tools (28). Partners should also help to reduce any duplication or distortions caused in local systems by rapid scaling up or by expanded financing for TB control efforts, and help to build coordination across disease-specific initiatives.

3b.
Share innovations that strengthen systems, including the Practical Approach to Lung Health

A variety of new approaches to accelerating and sustaining the impact of TB control are being implemented by NTPs, and these now form part of the Stop TB Strategy. They include community TB care, PPM approaches to engage all care providers, a syndromic ap-

proach to addressing respiratory care (see next paragraph), and innovations in health information and drug management systems. They all seek to make more efficient use of the health system resources that are often in short supply (e.g. human resources, infrastructure, information). These innovations should be adapted and scaled up in ways that allow their broader application to advance a range of health outcomes, and best practices should be shared across health systems and countries.

The Practical Approach to Lung Health (PAL) is among the innovations initiated within the TB control community that can strengthen the health system as a whole. Pulmonary TB is often manifest as a cough, and people with TB symptoms first present to primary care services as respiratory patients. By linking TB control activities to proper management of all common respiratory conditions, NTPs and the staff who implement DOTS services at local level can help to improve the quality of care and the efficiency with which it is provided. In practice, this requires a systematic, standardized and symptom-based approach. PAL has been developed by WHO on the basis of operational research in diverse country settings (29) and is designed to help to integrate TB services within primary care, strengthen general health services, prevent irrational use of drugs and improve management of resources. Implementing PAL can improve TB case detection and also enhance the quality of care for common respiratory illnesses (30). NTPs should implement PAL in relevant settings, using the available evidence-based guidelines.

3c. Adapt innovations from other fields

To respond to all six components of the Stop TB Strategy, NTPs and their partners can adapt approaches that have been applied in other priority public health fields and build on some of the common systems that are already in place. Such approaches may include: further integration of TB control activities within the community; primary care outreach pursued in maternal and child health programmes; social mobilization along the lines used by HIV/AIDS control programmes and partners; regulatory actions that have been used in tobacco control; and financing initiatives and means to reach the poorest that have been developed by immunization services. They may also include further collaboration with broader information platforms (surveys, etc.) to advance TB surveillance and programme monitoring.

Effective integration of delivery systems depends on testing, adapting, scaling up and evaluating common approaches.

4. Engage all care providers

4a. Public–Public and Public–Private Mix (PPM) approaches

In most settings, patients with symptoms suggestive of TB seek care from a wide array of health-care providers apart from the public sector TB services. These may include private clinics operated by formal and informal practitioners, and institutions owned by the public, private, voluntary and corporate sectors, e.g. general and specialized public hospitals, nongovernmental organizations (NGOs), prison, military, and railway health services, and health insurance organizations. These non-NTP providers may serve a large proportion of TB patients and suspects but may not always apply recommended TB management practices or report their cases to NTPs. The size, type and role of these non-NTP providers vary greatly across and within countries: in some settings there are large private and NGO sectors while in others there are public sector providers (such as general and specialized hospitals) that operate outside NTPs. Evidence suggests that failure to involve all care providers used by TB suspects and patients hampers case detection, delays diagnosis, causes improper diagnosis as well as inappropriate and incomplete treatment, increases drug resistance and places a large and unnecessary financial burden on patients (31).

The first step in engaging all health-care providers is to map all relevant public and private providers in a given setting. Next, suitable roles for them in implementation of the Stop TB Strategy should be identified. It is essential for the NTP to develop and maintain strong stewardship capacity in order to guide and oversee collaboration between private and public providers. The basic premises of PPM are that the financial resources to establish and sustain the collaboration are provided or facilitated by the NTP, that drugs are provided free of charge or heavily subsidized, and that fees for tests and consultations are waived or kept to a minimum. The feasibility, effectiveness and cost-effectiveness of involving different types of care providers using a PPM approach have been demonstrated, and WHO has produced guidelines on how to engage all care providers in TB control (32).

4b. **International Standards for Tuberculosis Care**

The International Standards for Tuberculosis Care (ISTC) have been based on a wide global consensus of appropriate practices in TB diagnosis and treatment. They are complementary to the PPM approaches described above and should be actively promoted and used to help engage all care providers in implementation of the Stop TB Strategy. The standards of care are evidence based. They can be used to secure a broad base of support for TB control efforts – from NTPs, professional medical and nursing societies, academic institutions, NGOs, and HIV-focused organizations. They can also help to create peer pressure, encouraging providers to conform to the principles, and can serve as a basis for pre-service and in-service training (33).

5. Empower people with TB, and communities

5a. **Advocacy, communication and social mobilization**

In the context of wide-ranging partnerships for TB control, advocacy, communication and social mobilization (ACSM) embrace: *advocacy* to influence policy changes and sustain political and financial commitment; *two-way communication* between the care providers and people with TB as well as communities to improve knowledge of TB control policies, programmes and services; and *social mobilization* to engage society, especially the poor, and all allies and partners in the campaign to Stop TB. Each of these activities can help build greater commitment to fighting TB.

Advocacy is intended to secure the support of key constituencies in relevant local, national and international policy discussions and is expected to prompt greater accountability from governmental and international actors. Communication is concerned with informing, and enhancing knowledge among, the general public and people with TB and empowering them to express their needs and take action. Equally, encouraging providers to be more receptive to the expressed wants and views of people with TB and community members will make TB services more responsive to community needs. Social mobilization is the process of bringing together all feasible and practical

intersectoral allies to raise people's knowledge of and demand for good-quality TB care and health care in general, assist in the delivery of resources and services and strengthen community participation for sustainability. Thus, ACSM is essential for achieving a world free of TB and is relevant to all aspects of the Stop TB Strategy. ACSM efforts in TB control should be linked with overarching efforts to promote public health and social development.

5b. **Community participation in TB care**

Community participation in TB care implies establishing a working partnership between the health sector and the community – the local population, especially the poor, and TB patients, both current and cured. The experiences of TB patients help fellow-patients to cope better with their illness and guide NTPs in delivering services responsive to patients' needs. Ensuring that patients and communities alike are informed about TB, enhancing general awareness about the disease and sharing responsibility for TB care can lead to effective patient empowerment and community participation, increasing the demand for health services and bringing care closer to the community. To this end, NTPs should provide support to frontline health workers to help them create an empowering environment, for example by facilitating the creation of patient groups, encouraging peer education and support, and linking with other self-help groups in the community. Selecting community volunteers and identifying how they could contribute to TB care should be the joint responsibility of the local NTP staff, TB patients and representatives of the community. The training requirements of community volunteers may vary from setting to setting, ranging from "on-the-job" instruction to more formal short courses provided by NTP staff. Community volunteers also need regular support, motivation, instruction and supervision. Where larger systems already exist – such as community-based HIV/AIDS initiatives in Africa – these platforms should be built upon. Evidence shows that community-based TB care is cost-effective compared with hospital-based care and other ambulatory care models (34). Inspiring communities and obtaining their continued support in identifying and providing care for people with TB is essential to sustain community TB initiatives.

5c. Patients' Charter for Tuberculosis Care

Developed by patients from around the world, the Patients' Charter outlines the rights and responsibilities of people with TB and complements the ISTC for health-care providers. It is based on the principles of various international and national charters and conventions on health and human rights. Its purpose is to empower people with TB and communities and to make the patient-provider relationship mutually beneficial. The Charter sets out the ways in which patients, communities, health-care providers and governments can work as partners and enhance the effectiveness of health services in general and TB care in particular. It provides a useful tool for achieving greater involvement of people in TB care (www.wcc-tb.org/charter2006.php).

6. Enable and promote research

6a. Programme-based operational research

The Stop TB Strategy consolidates DOTS implementation and involves the implementation of several new approaches for tackling the challenges facing NTPs. In order to put these approaches into practice, programme-based operational research should be a core component of NTP work. Designing and conducting locally relevant operational research can help in identifying problems and workable solutions, testing them in the field and planning for the scaling up of activities. For this purpose, collaboration between programme managers and researchers is essential. Acquiring basic skills in identifying and addressing issues related to programme operations and performance can help programme managers to initiate operational research in collaboration with researchers and academia. This, in turn, can help managers to sustain and strengthen TB control efforts by expanding existing activities and introducing effective new strategies. The establishment of sustainable partnerships and networks for productive collaboration on operational research is essential.

6b. Research to develop new diagnostics, drugs and vaccines

There is no truly effective vaccine against TB, and the limitations of the available tools for diagnosis and treatment – smear microscopy testing and “short-course” chemotherapy – make standard TB care demanding for both patients and care providers. The need to rely on the available tools has substantially hindered the pace of progress in global TB control. Facilitating the concerted efforts of the Stop TB Partnership's Working Groups on New Diagnostics, Drugs and Vaccines for TB is thus a key component of the Stop TB Strategy. In the spirit of partnership, TB control programmes should actively encourage and participate in this process. Countries should advocate the development of new tools, help to speed up the field testing of new products, and prepare for swift adoption and roll-out of new diagnostics, drugs and vaccines as they become available.

V. MEASURING GLOBAL PROGRESS AND IMPACT

1. Measurement of programme outcomes and impact on burden of disease

The Stop TB Strategy is designed to achieve the MDG and related Stop TB Partnership targets (explained in section III). As well as a final assessment of whether targets have been reached in 2015, progress towards the targets needs to be regularly measured. Table 1 below shows the indicators that relate to each of the targets, and how they can be measured.

The MDG and related Stop TB Partnership targets include three impact indicators: incidence, prevalence and death rates. TB incidence rates can be estimated through longitudinal population-based surveys (or from notification data where these are complete). Prevalence rates can be measured through cross-sectional population-based surveys, or

estimated from the data on incidence and duration of disease. Mortality rates can be estimated from vital registration records, from verbal autopsy studies, or from incidence and case-fatality rates. Countries should consider carrying out surveys of disease prevalence or incidence over the next 10 years in order to measure the change in burden, though it should be borne in mind that such surveys are costly and logistically complex.

The other two targets included in Table 1 – case detection and treatment success rates – relate to the implementation and quality of TB control programmes.

Table1. Selected indicators for monitoring TB control programmes

Indicator	Target	Measurement
Prevalence of disease: Number of people per 100 000 population who have TB disease at a given time	1990 prevalence rate halved by 2015	From cross-sectional surveys (preferably), or estimated from incidence and duration of disease (approximate)
Incidence of disease: Number of new cases of TB disease (all forms) per 100 000 population per year	Incidence rate in decline by 2015	From longitudinal surveys or from case notifications (where complete)
Mortality rate: Number of deaths from TB (all forms) per 100 000 population per year	1990 mortality rate halved by 2015	From vital registration records (where complete), from verbal autopsy studies, or from incidence and case-fatality rates (approximate)
Case detection rate: Number of new smear-positive cases notified in one year divided by the annual incidence	At least 70% by 2005	From notification data and estimates of incidence
Treatment success rate: Percentage of new smear-positive TB cases registered for treatment that are cured or complete treatment	At least 85% by 2005	Routinely collected data on cohorts of patients undergoing treatment

In assessing trends in the total burden of TB and the quality of TB control efforts, it is valuable to take into account, where possible, factors such as the age and sex of patients, the level of MDR-TB and the prevalence of HIV, all of which may affect case detection and treatment outcomes.

As more countries develop better systems for collecting health information routinely, it should be possible to assess the state of the epidemic and the quality of control using annual TB surveillance data, together with data from vital registration records. To complement and check the quality of routine surveillance data, it will be important to carry out population-based surveys of disease prevalence or infection.

2.

Financing for TB control

Achieving the MDG and Stop TB Partnership targets will require increased and sustained financing for TB control, as reflected in component 1a of the Stop TB Strategy. Financing needs to be monitored and evaluated at sub-national, national and international level, to document trends in NTP budgets, available funding for these budgets, funding gaps, expenditures, and total TB control costs (which include costs reflected in NTP budgets plus costs associated with using general health services staff and infrastructure). Categorization of budget line items and funding sources should be consistent to allow analysis of changes over time; however, categories may be modified periodically – for example, to reflect the introduction of a major new source of funding or when a major shift in strategy alters the line items for which it is relevant to collect data.

WHO collects financial data through an annual questionnaire that is sent to all countries. These data are analysed and presented in the annual WHO report on global TB control.

Some of the key indicators that are relevant to financial monitoring and evaluation of TB control are: the annual NTP budget requirement, the NTP budget per patient treated, the percentage of the NTP budget that is funded, the percentage of the NTP budget that is funded by the government (including loans), the percentage of available funding that is spent, the total annual cost of TB control, the cost per patient treated and the cost per patient successfully treated. Unlike the outcome and impact indicators described above, national and international targets for financing have not been established. Nevertheless, monitoring changes over time is useful and should be undertaken regularly.

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