

10.2.1 DOTS Expansion Working Group: summary strategic plan, 2006–2015

The DEWG strategic plan sets out the Working Group's contribution to meeting the Partnership's 2015 global targets for TB control, linked to the MDGs. It will also help in the achievement of Millennium Development Goal 1: To eradicate extreme poverty and hunger. The DEWG strategic plan acknowledges the profound importance of poverty alleviation and socioeconomic development for long-term control of the TB epidemic, while focusing on mechanisms to implement effectively quality TB diagnosis and treatment for all, particularly the poor, in line with the DOTS strategy.

Strategic vision for global TB control and DOTS

More than a decade of DOTS in countries with diverse characteristics has offered two distinct lessons: DOTS is indeed essential for TB control, but the original five elements of DOTS alone are not enough to control TB globally. The DOTS strategy is now at the heart of the Stop TB strategy, conveying a clear message about its pro-poor and patient-centred approach. The Stop TB strategy reflects the Partnership's mission to ensure that every TB patient has access to effective diagnosis, treatment and cure. As we progress from meeting the 2005 global targets to achieving those for 2015, all members of the Stop TB Partnership need to articulate a comprehensive and inclusive vision for global TB control, including the following essential elements of the Stop TB strategy:

1. **Pursuing quality DOTS expansion and enhancement, through:**
 - (i) Political commitment, with long-term planning, adequate human resources, expanded and sustainable financing, to reach the targets set by the World Health Assembly and the Stop TB Partnership.
 - (ii) Case detection through quality-assured bacteriological testing (microscopy, culture, DST) and strengthening of the laboratory network to facilitate detection of sputum smear-positive, sputum smear-negative, drug-resistant and MDR-TB cases.
 - (iii) Standardized treatment, under proper case management conditions, including directly observed treatment to reduce the risk of acquiring drug resistance, and support of patients to increase adherence to treatment and chance of cure.
 - (iv) An effective and regular drug supply system, with improved drug management capacity.
 - (v) An efficient monitoring system for programme supervision and evaluation, including measurement of impact.
2. **Addressing TB/HIV, MDR-TB and other special challenges**, by scaling up TB/HIV joint activities, DOTS Plus, and other relevant approaches.
3. **Contributing to health system strengthening**, by collaborating with other health programmes and general services in, for example, mobilizing the human and financial resources needed for implementation and impact evaluation, and by sharing and applying achievements of TB control.

4. **Involving all care providers**, public, nongovernmental and private, by scaling up approaches based on a public-private mix, to ensure adherence to the International Standards for TB Care, with a focus on health providers used by the poor.
5. **Engaging people with TB and affected communities**, by scaling up community TB care and providing opportunities for meaningful involvement of patients and communities in increasing awareness, demanding high-quality services, supervising treatment, and reducing stigma.
6. **Enabling and promoting research** to improve programme performance and to develop new drugs, diagnostics and vaccines.

Broadening the scope of DOTS expansion

DOTS expansion is more than simply expanding the geographical coverage of DOTS. It implies ensuring equitable access to quality TB diagnosis and treatment for all patients, i.e. for patients with all types of TB, patients of all age groups and from all socioeconomic strata, and men and women equally.

This will necessitate expanding quality TB diagnosis and treatment to all parts of the health sector and beyond, i.e. ensuring that all health care providers use the International Standards for TB Care, and expanding the involvement of patients and communities in TB control.

The DEWG will also assist countries to expand use of existing and new technologies. This includes existing, but underutilized, technologies, such as culture and drug susceptibility testing and isoniazid preventive treatment, as well as new diagnostic and treatment tools that will become available in the future.

Objectives for DOTS expansion 2006–2015

The DEWG and its partners will continue to assist countries to work towards two main outcome objectives.

Outcome objective 1: To achieve and sustain performance beyond the "70/85" targets.

In order to achieve and sustain performance beyond the targets of 70% case detection 85% successful treatment, continued efforts are needed to improve the quality of DOTS, through improvement of programme management, supervision, and laboratory services for sputum smear microscopy, and strengthening of human resources. However, in most countries this will not be enough. Meaningful and effective involvement of all relevant partners, including patients and communities, is essential to reach patients who are treated outside DOTS programmes, as well as those who are currently not diagnosed or not treated. The PPM DOTS, community DOTS, TB/HIV and PAL approaches can help increase case detection and should be applied more widely. To achieve and sustain performance beyond the 70/85 targets, all partners need to be involved in DOTS implementation.

Outcome objective 2: To ensure equitable access to quality TB care for all people with TB, especially the poor and marginalized.

DOTS expansion starts with the achievement of the "70/85"

targets and ends with all people with TB having access to quality TB services. Neither the type of TB, nor financial capacity, nor social status should determine access to quality TB services. "All people with TB" includes people of all ages and everyone with extrapulmonary disease or pulmonary sputum smear-negative disease. It also includes people with TB/HIV coinfection and people with multidrug-resistant TB. Given the poor socioeconomic status of most people with TB, a pro-poor and equity-based approach requires that health services pay special attention to the needs of the most disadvantaged groups. Improving access to quality services also means reducing the harmful effects of poor medical practice. The key strategies are to make sure that all health care providers adopt the International Standards of TB Care, and to educate patients to use available services in a rational way and to advocate for high-quality care.

Main activities for DOTS expansion in countries

To achieve these two objectives, the partners of the DEWG will assist countries in implementing the following seven interlinked activities. Detailed regional and country implementation plans for DOTS expansion are being developed, based on the DEWG strategic plan. Country planning, setting of local targets, and implementation require local situational analysis to determine local challenges, barriers and opportunities.

1. Complete DOTS coverage.

Global target: All public health basic management units in all countries will provide TB care according to the DOTS strategy by 2010.

Basic coverage of DOTS within public health structures will soon be complete in the 22 high-burden countries, but some countries do not yet provide free treatment under DOTS to patients with sputum smear-negative pulmonary TB or extrapulmonary TB, or to children with TB. In addition, all countries should work towards free provision of sputum smear microscopy and other TB diagnostic tests. Finally, isoniazid preventive treatment for children needs to be implemented in countries that have not yet done so; this process will be facilitated by the work of the Childhood TB Subgroup of the DEWG.

2. Improve quality of DOTS.

Global target: All countries will provide quality diagnosis and treatment and achieve at least 85% treatment success rate by 2015.

The core element of improved quality is improved human resource capacity for undertaking the tasks needed in DOTS, including sputum smear microscopy, drug management, case management, supervision, recording and reporting, and laboratory diagnosis. Plans to improve DOTS quality should be tailored to national and local conditions, while taking into account general health systems challenges and competing needs within the health services. Increased political commitment and increased financing of DOTS are essential in most countries.

3. Public-private mix DOTS.

Global target: All countries will have developed guidelines, by 2010, for the involvement of relevant public and private health care providers in DOTS, and will have implemented them by

2015. By 2015 about 3.8 billion people will live in areas with PPM DOTS initiatives.

PPM DOTS is a comprehensive approach involving all relevant health care providers in DOTS, ensuring that they apply the International Standard of TB care and provide TB care free of charge or at very low cost to patients. PPM DOTS has been shown to increase case detection and cure rates, while reducing the financial burden on poor patients. The PPM DOTS approach is particularly relevant in settings where large numbers of public and private health care providers are not yet involved in DOTS. While there is a potential role for all providers in delivering DOTS services, the PPM DOTS approach emphasizes that the national TB programme should retain and strengthen its stewardship functions, including regulation, financing, monitoring, evaluation and surveillance. The PPM DOTS Subgroup of DEWG will continue to assist countries in developing national policies and operational guidelines to scale up and evaluate PPM DOTS initiatives, and will stimulate further research on PPM DOTS.

4. Community DOTS.

Global target: All countries in Africa will have scaled up community DOTS initiatives by 2010. By 2015, about 1.9 billion people globally will live in areas with community DOTS initiatives.

There is an acute need to further decentralize the provision of TB services beyond health facilities, in order to increase geographical access and to foster people's participation in supporting patients. Community DOTS has been shown to result in improved treatment success rates through decreased default and transfer out rates. A subsequent impact on case detection rates, related both to improved awareness and better access to care, has also been reported. Furthermore, community DOTS reduces treatment costs for patients, NTPs and society.

5. Practical Approach to Lung health.

Global target: PAL will be introduced in 20% of developing countries by 2010 and in 50% by 2015. Approximately 2 billion people will live in areas with PAL initiatives by 2015.

PAL is a primary health care (PHC) strategy for the integrated management of respiratory conditions in patients aged five years and over. It aims to improve: (i) the quality of care for every respiratory patient, and (ii) the efficiency of PHC services in treating respiratory conditions, with a focus on TB, acute respiratory infections and chronic respiratory diseases.

6. Culture services, drug susceptibility testing and new diagnostic tests.

Global target 1: All countries will have developed capacity by 2015 to perform culture and DST according to national policies. Global target 2: From 2010 new diagnostic tools will be introduced gradually and are expected to cover at least 50% of the eligible population by 2015.

The Subgroup on Laboratory Capacity Strengthening will continue to assist countries in improving performance of TB laboratories to provide reliable diagnostic services to NTPs.

Since high-quality sputum smear microscopy is the cornerstone of DOTS and remains the highest priority for case detection and TB control, the primary focus will be on improving performance of sputum smear microscopy, including ensuring external quality assurance (EQA). Strengthening of services for culture of *M. tuberculosis* and for DST is necessary, especially in high HIV and MDR-TB prevalence settings. The introduction and progressive scale-up of culture and DST will depend on the local epidemiological situation.

The DEWG and its Subgroup on Laboratory Capacity Strengthening will assist countries in introducing new diagnostic tools in routine NTP operations, as they become available from 2010 and gradually replace sputum smear microscopy, conventional culture and DST. The Subgroup will also support the development of operational research capacity and of prioritised research agenda.

7. Prioritize the needs of the poor and vulnerable.

Global target 1: By 2010 all countries will have developed capacity to monitor the extent to which DOTS reaches and serves the poor and vulnerable.

Global target 2: By 2010 all countries will have developed key strategies for improving access to DOTS for the poor and vulnerable.

Global target 3: By 2015 all countries will have developed the capacity to demonstrate and monitor the contribution made by DOTS to poverty alleviation.

The TB and Poverty Subgroup of the DEWG has outlined options for NTP managers to choose from in addressing poverty issues in DOTS implementation. The Subgroup will stimulate operational research to improve access to DOTS and, as experience and evidence accumulates, these options will be revised and reformulated into formal guidelines for use at national and international levels.

Support to countries

In order to assist countries in implementing the activities outlined above, the partners of the DEWG and its subgroups (Childhood TB Subgroup, Subgroup on Laboratory Capacity Strengthening, PPM DOTS Subgroup and TB and Poverty Subgroup) will focus on the following three main areas:

- Country support: both strategic and technical support to countries; and capacity-building at global and regional levels.
- Monitoring of DOTS expansion and MDG indicators, covering (1) monitoring of progress towards targets; (2) monitoring of implementation of national plans, and (3) financial monitoring, including tracking of financial flows and estimation of sources and expenditure areas within NTP budgets.
- Operational research and policy development.

The DEWG will continue to prioritize high-burden countries. Currently, DEWG is targeting 22 high-burden countries that together make up 80% of the global TB burden. In the coming 10 years, the classification of high-burden countries may change according to changing TB epidemiology as well as changing needs for technical support.

Case detection and treatment outcome

A central assumption to the estimated impact on case detection and treatment outcome is that the different activities are synergistic and dependent on each other. If all the proposed activities are implemented according to the scenario, it is expected that the case detection target will be reached in all regions by 2010, and that case detection will be 80% or above in all regions by 2015. Treatment success rate is expected to reach 85% or more in all regions at the latest by 2010 and to be sustained from then onwards.

Impact on TB burden

Under the present scenario, incidence, prevalence and death rate trends will go down rapidly over the next 10 years in all regions, as a result of the various TB control activities of the DEWG in conjunction with those of the DOTS-Plus and TB/HIV Working Groups. The MDG target – to have halted, and begun to reverse by 2015 the spread (incidence) of TB – will be met in all regions.

Key risk factors

Key risk factors for not achieving the objectives of the Working Group include:

- Deteriorating health systems: Many TB programmes today struggle to implement quality services in the context of health workforce crises, continuous low levels of public funding for health care, weak government stewardship, and on occasion collapsed health service networks. The DEWG has identified a range of mechanisms through which DOTS expansion strengthens health systems, as well as how health systems development creates better conditions for TB control.
- Devolution of TB control responsibilities from the public sector: The risk that the role of the government sector is played down as a result of a new focus on the involvement of private sector and civil society should be seriously addressed. The DEWG and the Stop TB Partnership need to advocate strongly for increased resources to strengthen the public sector as a core condition for involving other sectors.
- Dilution of the focus of TB control: As DOTS evolves, there is a risk that the focus on its essential components will be lost. The key to success is to continue to stress the need for high quality in basic DOTS functions, while raising the additional resources needed to implement new approaches.
- Loss of broad support from the public health community, if the TB control community pays too little attention to the impact of poverty on the TB epidemic. The messages need to be clear that long-term TB control depends on economic development, and that DOTS expansion contributes to breaking the disease-poverty circle, both directly (by reducing health care costs to patients), and indirectly (by improving productivity through reducing death and disability).
- Failure to mobilize the domestic and external resources needed for full implementation of the DEWG strategic plan.

See Table 19: Budget requirements for the DOTS Expansion Working Group: 2006–2015 (US\$ MILLIONS)

TABLE 19: BUDGET REQUIREMENTS FOR THE DOTS EXPANSION WORKING GROUP: 2006-2015 (US\$ MILLIONS)

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	ALL YEARS	% TOTAL
COUNTRY NEEDS												
ALL REGIONS	2,404	2,568	2,751	2,906	2,967	2,952	3,013	3,057	3,113	3,173	28,904	92%
AFR- HIGH	759	841	913	983	1,056	1,080	1,123	1,169	1,219	1,276	10,419	33%
AFR LOW	203	224	247	268	291	303	315	325	336	347	2,859	9%
EEUR	418	442	490	520	465	460	479	497	515	525	4,809	15%
EMR	170	187	208	221	236	237	240	241	240	240	2,221	7%
LAC	143	138	145	153	151	133	132	131	129	128	1,383	4%
SEAR	359	373	383	393	402	386	380	373	367	362	3,778	12%
WPR	351	363	365	368	366	353	344	322	306	296	3,434	11%
INTERNATIONAL AGENCY NEEDS												
TECHNICAL COOPERATION*	219	226	232	239	246	254	261	269	277	286	2,510	8%
WG OPERATIONAL NEEDS												
	1	1	1	1	1	1	1	1	1	1	11	0.04%
TOTAL	2,624	2,794	2,985	3,147	3,214	3,207	3,276	3,327	3,392	3,460	31,426	

* Some aspects of technical cooperation will be undertaken jointly for DOTS Expansion, TB/HIV and DOTS-Plus. Since it is difficult to identify what share of these costs applies to each WG, the total is shown here.