

**Report of the
Fifth annual meeting of the
Stop TB Working Group on MDR-TB
(formerly DOTS-Plus for MDR-TB)**

**Atlanta, GA, USA
12 May 2006**





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Summary

The fifth annual meeting of the Stop TB Working Group on DOTS-Plus for MDR-TB was held on 12 May 2006 in Atlanta, GA, USA. It followed a two-day meeting organized by PARTNERS,¹ the purpose of which was (i) to review the accomplishments and progress in global control of multidrug-resistant tuberculosis (MDR-TB) over the past six years and (ii) to discuss the challenges of scaling up management of MDR-TB as called for in the Global Plan to Stop TB, 2006–2015.²

The meeting was structured around four sessions (Annex 1) representing the major constraints to scaling up management of MDR-TB worldwide:

1. Advocacy and resource mobilization
2. Management of second-line anti-TB drugs
3. Human resources for management of MDR-TB
4. Laboratory capacity for management of MDR-TB.

A fifth session summarized the Working Group's response to the challenges of scaling up MDR-TB management in these four areas.

More than 80 participants attended the meeting, representing countries, bilateral and multilateral agencies, international organizations, nongovernmental organizations, pharmaceutical industries and universities (Annex 2).

This report summarizes the presentations, discussions, conclusions and recommendations of the meeting.

Meeting objectives

The objectives of the meeting were:

- To review the major constraints to scaling up management of MDR-TB worldwide.
- To outline an operational plan for the Working Group to address these constraints in order to attain the goals and objectives of the Stop TB Partnership Global Plan to Stop TB, 2006–2015,² and the new WHO Stop TB Strategy.³
- To discuss and agree on governance and operational issues of the Working Group.

¹ The PARTNERS project was funded by the Bill & Melinda Gates Foundation in 2000 to develop a replicable model for controlling MDR-TB in resource-limited settings. The grant supported a five-year collaborative effort between the Harvard Medical School, the United States Centers for Disease Control and Prevention, Partners In Health, the Task Force for Child Survival and Development, and WHO.

² Stop TB Partnership. *The Global Plan to Stop TB, 2006–2015*. Geneva, World Health Organization, 2006 (WHO/HTM/STB/2006.35).

³ *The Stop TB Strategy*. Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.368).

Session 1. Advocacy and resource mobilization

The Global Plan to Stop TB, 2006–2015, projects the cost of treating 800 000 MDR-TB cases at US\$ 5.8 billion, of which US\$ 5 billion is for activities at country level. Full implementation of Global Plan activities for MDR-TB control requires more ambitious plans at country level, as well as major increases in funds for resource mobilization from both domestic and donor sources. The success will largely depend on planning, resource mobilization and implementation efforts in six countries of the former Soviet Union (Russian Federation, Ukraine, Uzbekistan, Kazakhstan, Kyrgyzstan and the Republic of Moldova) plus China and India.

The Green Light Committee (GLC) is currently the only mechanism available to ensure the quality of programmes for MDR-TB treatment and prevent the development and spread of incurable TB strains by enabling access to low-price quality-assured second-line anti-TB drugs. In its initial phase, 2000–2005, the GLC approved 12 805 MDR-TB patients for treatment and established that the management of MDR-TB is feasible and cost-effective in low-income settings. The demand for GLC services from MDR-TB treatment programmes is rising substantially, mainly as a result of increasing amounts of external financial assistance to countries, especially through the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), which has determined that all applications for such programmes must be approved by the GLC.

In 2006, the GLC has already approved treatment for almost 9000 MDR-TB patients and is witnessing a dramatic increase in the number of applications. To meet this increasing demand, and in order to scale-up activities as outlined in the Global Plan, the GLC has developed a Business Plan for 2006–2008, and a Resource Mobilization Plan.

Should global MDR-TB control be scaled up according to the Global Plan, the GLC would need an additional US\$ 25 million for 2006–2008. Despite the recent decision by the GFATM to provide funding for the GLC to support proposals approved from round 6 onwards, and perhaps also for previous rounds, the funding situation remains precarious.

It was therefore decided that the Working Group should engage more actively to:

1. Strengthen advocacy, social mobilization and communication by:
 - building stronger networks with civil society and affected communities;
 - raising awareness about MDR-TB and extreme or extensive drug resistance (XDR-TB) and the possible devastating effects when combined with human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS);
 - developing an advocacy report on XDR-TB;
 - advocating for MDR-TB at international conferences and meetings including in 2006: Global Fund Partnership Forum, Durban, 2–3 July; G8 Summit in St Petersburg, 15–17 July; International AIDS Society Conference, Toronto, 13–18 August; Ministerial Forum on the TB Emergency in Europe, Copenhagen, 16–17 October; World AIDS Day, 1 December and in 2007: World TB Day, 24 March; and the G8 Summit in Germany, June, 2007.

2. Enhance resource mobilization efforts by:
 - pursuing discussions with the GFATM on its role in funding GLC services;
 - including MDR-TB in the recently launched initiative by Brazil, Chile, France and Norway on the international drug purchase facility for AIDS, TB and malaria;
 - attracting new donors including non-traditional bilateral donors and the corporate sector.

Session 2. Management of second-line anti-TB drug

The management of second-line anti-TB drugs by GLC-approved projects is challenging, mainly as a result of the limited number of manufacturers, the high costs of treatment (despite concessional prices provided by Eli Lilly), the short shelf-lives of some of the products and the long lead-times (ranging from 2 to up to 6 months).

With only one single source for each second line anti-TB drug, only one manufacturer approved in terms of good manufacturing practice by WHO through its prequalification project, and a limited number of manufacturers in the prequalification pipeline, market interest in these drugs remains limited and competition between manufacturers is non-existent. Most GLC-approved projects are concerned about the limited number of suppliers proposed through the GLC mechanism, the delays in receiving drugs from the procurement agent and the payment modalities for the drugs.

The immediate priorities are therefore to mobilize and provide technical assistance to manufacturers to enter into the market for second-line anti-TB drugs. Funds to create a buffer stock of such drugs are also urgently needed. Discussion with the GFATM about direct payment to the procurement agent could solve the payment issue for GLC-approved projects receiving grants from the GFATM.

The procurement of second-line anti-TB drugs for GLC-approved projects is further challenged by their lack of experience in drug management, particularly in drug forecasting. In several projects receiving grants from the GFTAM, the principal recipient is also in contact with the procurement process but often not coordinating with the project. Technical assistance for drug management should therefore be a priority in the work of WHO and partners with countries. Training of consultants with expertise in anti-TB drug management and management of second-line anti-TB drugs should be planned for the near future. The creation of a forum, either virtual or actual, for GLC projects to interact, communicate and share procurement experience should be explored. Procurement of ancillary drugs should be considered in the list of services provided by the GDF to GLC-approved projects. Finally, a subgroup on drug management should be created and its terms of reference developed.

Session 3. Human resource capacity for management of MDR-TB

Discussion of the development of human resource capacity for management of MDR-TB identified four main challenges. These were to ensure:

- staff availability
- competent staff
- a motivated workforce
- the needed support to do tasks.

Ensuring staff availability

To ensure the availability of staff, it is necessary to identify the number and the characteristics of staff needed for programme implementation, to analyse workloads and turnover, identify the obstacles for staff retention and to evaluate the possibility of involving the private health sector in MDR-TB management.

Ensuring competent staff

To ensure and maintain competent staff, a systemic approach to staff training and education is required. All staff should receive formal training before starting the job followed by refresher training on the job. In addition, supervision and follow up are important components of programme implementation to ensure the quality of services and maintain competent staff.

Ensuring a motivated workforce

The health workforce is often poorly motivated because of inadequate salaries and benefits, poor career opportunities and lack of job security. Scarce responsibility, lack of support from supervisors and unsafe conditions in the workplace are also important determinants in the level of staff motivation.

Ensuring support to carry out tasks

The availability of well trained and motivated staff is not enough to guarantee high-quality care services if functioning equipment, medical supplies, drugs and adequate funding for programme implementation are not available. In addition, and therefore, political commitment is a requirement for any TB control activity, including human resource development.

Session 4. Laboratory capacity for management of MDR-TB

The Working Group discussed the strengthening of laboratory capacity for the management of MDR-TB and highlighted several priority areas that require either strengthening or further exploration. There was general consensus that the supranational TB reference laboratory (SNRL) network provided the main system of support for laboratory quality assurance for culture and drug susceptibility testing. Expansion of the links between national reference laboratories and SNRLs was needed in order to extend this international support system. In addition, it was generally recognized that the SNRL network itself should be expanded and strengthened.

Comprehensive strengthening of the national laboratory network requires the development of national plans specifically for laboratory capacity strengthening for TB control (needs assessment, operational plan with a programmatic perspective and budget) in high MDR-TB burden countries. To further support this move towards planning and review of laboratory networks, it was suggested that TB consultants receive training in laboratory network development and laboratory planning, in order to provide appropriate technical assistance in this area. Priority areas for further exploration included considering a systems-based approach to harmonize new laboratory technologies as well as determining the role of new technologies in various settings. For operational research, it was recommended that a meeting be held to review standardization of methods for drug susceptibility testing for second-line anti-TB drugs and to develop recommendations on who/when/where to test, as well as on the role and levels of laboratories required for rapid diagnostic testing: screening. It was also agreed that a plan should be developed for resource mobilization separate from the GLC Business Plan.

The focal point for the Laboratory Task Force for MDR-TB Management will liaise with the laboratory strengthening subgroup of the DOTS Expansion Working Group to follow-up on the priority actions described above.

Conclusions and recommendations

The Working Group made the following conclusions and recommendations:

1. Following discussions with Working Group members, the operational plan should be finalized at the joint meeting of the core groups (DOTS Expansion, MDR-TB, TB/HIV) and high TB burden countries in Paris, France, on 30 October 2006.
2. The name of the Working Group should be changed to the Stop TB Working Group on MDR-TB (omitting the term DOTS-Plus, which was used for the pilot projects on MDR-TB control).
3. The Working Group should create a subgroup on research to develop an agenda on the main research needs for global MDR-TB control.
4. Advocacy and resource mobilization
 - A task force should be established to improve advocacy and communication activities at major political and technical events and to raise additional funds (efforts should be made to attract funds from the European Union), particularly for the GLC.
 - A scientific and an advocacy report on XDR-TB, including the threat when combined with HIV, should be launched in 2007.
5. Second-line anti-TB drug management and supply
 - A subgroup on second-line anti-TB drug management and supply should be set up with support from the secretariat.
 - Efforts to continue mobilizing second-line anti-TB drug manufacturers for prequalification should be pursued.

- Training on drug management at regional and country levels should be expanded and future training possibilities for drug management consultants should be explored.
 - Funds should be identified to expand the limited buffer stock of second-line anti-TB drugs and procure ancillary drugs.
6. Human resource capacity for MDR-TB management
- At global level, generic training modules based on existing WHO guidelines for the programmatic management of drug-resistant TB should be produced and disseminated.
 - Modules produced by partners of the Eli Lilly MDR-TB initiative should be considered by countries and technical agencies.
 - At regional and country levels, a systematic approach to human resource development for MDR-TB control needs to be ensured. Training of consultants on MDR-TB management should be conducted and the human resource development component should be included in any plan of the national TB control programme.
7. Laboratory capacity for MDR-TB management
- A laboratory task force should be organized and selection of members and terms of reference should be developed and approved.
 - Curricula and training workshops for consultants should be developed.
 - A template of a plan for laboratory capacity strengthening at country level for TB control should be developed.
 - The operational plan for the laboratory task force should be drafted by October 2006.
 - More systematic resource mobilization should be pursued for laboratory strengthening.
 - Additional international consultants should be trained in order to scale up technical support.

At the end of the meeting, an outline of an operational plan for scaling-up MDR-TB management worldwide was discussed. This outline will be used to develop an operational plan for the Working Group in order to reach the short-term goals of the Global Plan to Stop TB, 2006–2015.