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Workplan of the MDR-TB Working Group of the Stop TB Partnership 2008-2009



### Workplan of the MDR-TB Working Group 2008-2009

### Summary

This document lays out the activities and the costs, that the partners of the Working Group on MDR-TB (WG) of the Stop TB Partnership plan to conduct between 2008 and 2009. It includes both the technical assistance to countries *and* operations of the WG and its subgroups, needed to address the rising problem of TB drug resistance. It draws on the Global MDR-TB and XDR-TB Response Plan 2007-2008, launched in June 2007 by WHO and the Stop TB Partnership. This plan is the blueprint for the WG to operationalize the drug resistant TB component of the Global Plan to Stop TB 2006-2015. The global budget necessary to respond to MDR-TB and XDR-TB in 2008-2009 is estimated to be US\$2,7 billions. The total estimated needs for technical cooperation by, and operations of, the WG partners amount to US\$ 129 million. Considering that USD\$5.5 million have been pledged for 2008, the funding gap is US\$ 123.5 million (US\$54.5 million in 2008 and US\$ 69 million in 2009) but does not consider the funding received by partners other than WHO. *Cost of operations of the WG are estimated in US\$2,1 millions, with a funding gap of USD\$1,7 millions for 2008-2009*.

## Objectives of the response to MDR-TB/XDR-TB (2008 and 2009)<sup>1</sup>

- 1. Strengthen basic activities to control TB and HIV/AIDS
- 2. Scale-up the programmatic management of MDR-TB and XDR-TB
- 3. Strengthen laboratory services for adequate and timely diagnosis of TB
- 4. Expand surveillance of MDR-TB and XDR-TB
- 5. Foster sound infection control measures to avoid MDR-TB and XDR-TB transmission to protect patients, health workers, and the broader community.
- 6. Strengthen advocacy, communication and social mobilization for sustained political commitment and a patient centred approach to treatment
- 7. Pursue resource mobilization at global, regional and country levels
- 8. Promote research and development into new diagnostics, drugs, vaccines, and operational research on MDR-TB management to shorten treatment

### **Partnerships**

All seven working groups of the Stop TB Partnership are already working on the threat of MDR-TB and XDR-TB, and presented their work during that last meeting of the WG on MDR-TB in Tbilisi, Georgia, Sept 2007.

The WG is in need of USD\$2,1 millions in 2008-2009, to fund the chairmanship of the WG, its subgroups, and the respective secretariats; the operations of the subgroups (see Table 1), which promote, coordinate and facilitate the implementation of key activities of the response plan (see Annex 1); and the annual meeting of the WG, which has more participants every year as more countries get approved by the Green Light Committee, and more partners join the WG.

<sup>&</sup>lt;sup>1</sup> Annex 1 describes the activities corresponding to each objective. Activities that are already being implemented or with a concrete action plan agreed with responsible partners are highlighted.

Table 1. Products of the sub-groups of the Working Group on MDR-TB (2008-2009)

Subgroups	Products
Advocacy and resource mobilization	Updated business plan of the GLC; resource mobilization plan; advocacy products on MDR-TB, including quarterly newsletter
Research	Updated research agenda published; promotion of operational research; assistance to WHO in updating guidelines; two in-person meetings to assess progress and strategize next steps
Drug management	Plan of action to tackle the drug procurement crisis; six regional meetings to promote WHO Prequalification of second-line anti-TB drugs; four in-person meetings of the sub-group to assess progress and strategize next steps as per TORs
Core Group	Annual monitoring report on progress in implementing response plan; strategic guidance to WG and subgroups.

#### **Funding available for 2008**

- UNITAID will support the GDF/GLC Secretariat in 2008 with USD\$300,000.
- USAID will support the WG Secretariat with USD\$400,000, plus US\$300,000 for TA.
- Eli Lilly will support technical assistance through GLC with US\$1 million in 2008
- The United States Global AIDS Coordinator through USAID, has pledged US\$ 1.5 millions for 2008, to support technical assistance to programmes approved by Global Fund with MDR-TB component.
- The Global Fund will support GLC services in 2008 with at least USD\$1 million.
- CIDA has pledged USD\$1 million for 2008 for strengthening laboratory capacity for drug resistance surveys in Africa, plus technical assistance.

Table 2. Costs of the operations of the WG and sub-groups, and technical assistance on MDR-TB for 2008-2009 (in USD\$ thousands).

	Required		Available	Gap
Working Group				
WG Chairmanship	100		0	100
MDR-TB WG Secretariat	800		400	400
Activities of core group and subgroups	800		0	800
Annual meeting of the WG (two meetings)	400		0	400
Subtotal		2,100	400	1,700
Technical assistance and GLC <sup>2</sup>				
GLC (according to its business plan)	31,500		3,800	27,700
Technical assistance other than GLC	95,400		1,300	94,100
Subtotal		126,900	5,100	121,800 <sup>2</sup>
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<sup>2</sup> This does not include pledges received by partners of the WG other than WHO; and includes technical assistance for laboratory strengthening

Total 129,000 5,500 123,500<sup>2</sup>

#### **Annex 1**

# Objectives and Activities of the Global MDR-TB and XDR-TB Response Plan 2007-2008

1. Strengthen basic activities to control TB and HIV/AIDS, as detailed in the Stop TB Strategy and the Global Plan, to avoid additional emergence of MDR-TB and XDR-TB

In pursuit of Objective One, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Mobilize expert teams to review basic activities for control of TB and HIV/AIDS in countries likely to have a high prevalence of XDR-TB, to accelerate improvements in control measures and gain political commitment to implement the Stop TB Strategy.
- b. Deploy international staff in priority MDR-TB countries, especially in those with high or increasing levels of HIV, to assist NTPs in improving control of TB, TB/HIV, MDR-TB and XDR-TB.
- c. Employ two additional staff at WHO headquarters: one for overall coordination of XDR-TB activities and one for coordination of measures to strengthen laboratories.
- d. Under the leadership of the Secretariat of the Working Group on MDR-TB, revise the Global Plan to link new actions and needs in light of XDR-TB emergence, devoting particular attention to scale up of the laboratory strengthening component and the number of MDR-TB cases to be treated. The costs of treating XDR-TB and of infection control measures to be reflected in the budget of the revised Global Plan.
- e. Assist countries in applying for new rounds of funding from the Global Fund to Fight AIDS, TB and Malaria (the Global Fund) and reprogramming existing grants to reflect actions needed to prevent and control MDR-TB and XDR-TB.
- f. Under WHO leadership, define appropriate responses to MDR-TB and XDR-TB in HIV policy and practice from global to local level, and begin the process of implementation at country level.
- g. Make assessments on the availability and patterns of use of second-line anti-TB drugs in the public and private sectors in selected countries, in order to ensure the use of these drugs according to WHO Guidelines and encourage best practices.
- h. Advocate for and encourage the involvement of all health-care providers in sound TB, MDR-TB and XDR-TB control, including the private sector and prison services.
- Foster the use of quality-assured first and second-line anti-TB drugs according to WHO Guidelines by Member States to avoid additional development of MDR-TB and XDR-TB. Encourage strong regulation of second-line drugs particularly by national governments.

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## 2. Scale-up the programmatic management of MDR-TB and XDR-TB to reach the targets set forth in the Global Plan

In pursuit of Objective Two, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Expand and establish coordination between partners and review global implementation of sound MDR-TB and XDR-TB control activities vis-à-vis the Global Plan through the meetings of the Stop TB Working Group on MDR-TB and its subgroups and the annual WHO Global TB Control Report.
- b. Under the leadership of WHO headquarters (both HIV and Stop TB Departments), update the WHO *Guidelines for the programmatic management of drug-resistant tuberculosis* by commissioning a group of experts to revise in particular the chapter on co-management of HIV infection and MDR-TB, including concomitant treatment with anti-retroviral drugs. The revised version should incorporate guidance on human rights, enforced quarantine and involuntary treatment for XDR-TB as well as address the early use of anti-TB drugs under development on compassionate grounds. The guidelines should promote the standards set forth in the *Patients' Charter for Tuberculosis Care*<sup>3</sup> as well as the ambulatory management of MDR-TB during the full course of treatment to make it more convenient to patients and family, to accelerate the scale up of treatment provision as per the Global Plan, save costs, reduce risk of nosocomial infection, and strengthen community involvement in TB control. In addition, the guidelines and their revisions should be translated into priority languages, printed and widely disseminated.
- c. Strengthen technical assistance on MDR-TB management to countries, and expand the capacity of the Green Light Committee (GLC) mechanism to promote access to quality-assured second-line anti-TB drugs. Enhance the capacity of technical assistance on MDR-TB management available through WHO and technical agencies by expanding the pool of adequately trained MDR-TB consultants.
- d. WHO and technical partners to ensure the dissemination and implementation at country level of the new recording and reporting system for routine management of drug resistant cases.
- e. Continue discussion of the importance of limiting the spread of XDR-TB under the new International Health Regulations<sup>4</sup>, and provide information to Member States on the management of XDR-TB patients and contacts. In addition, define the required steps needed in case of an XDR-TB event at national and international levels.
- f. Develop generic training modules to accompany the WHO *Guidelines for the programmatic management of drug-resistant tuberculosis*.

<sup>&</sup>lt;sup>3</sup> available at http://www.who.int/tb/publications/2006/istc\_charter.pdf

<sup>&</sup>lt;sup>4</sup> The International Health Regulations (IHR) provide for a new communication mechanism for any event with the potential to cause a public health emergency of international concern. The IHR provide a framework for establishing what exactly national authorities are expected to do in order to identify an emergency concerning XDR-TB, notify the international community and provide an effective response.

- g. WHO and partners to expand the training workshops on MDR-TB and XDR-TB management for NTP staff organized at regional level
- h. Accelerate the prequalification of quality-assured second-line anti-TB drug manufacturers and continue to advocate for reduction in second-line anti-TB drug prices.
- i. The Global Drug Facility (GDF) to address the current constraints resulting in long delays in procuring second-line anti-TB drugs to GLC approved programmes. GDF to create and manage a buffer stock of these drugs with funding sought from UNITAID.
- j. Encourage NTPs with established GLC approved MDR-TB control programmes to publish data on the programmatic management of XDR-TB and treatment outcomes.
- k. Plan for introduction of new drugs once they become available, through coordination with the Stop TB Partnership research and development working groups.

## 3. Strengthen laboratory services for adequate and timely diagnosis of MDR-TB and XDR-TB

In pursuit of Objective Three, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Develop a strategic, budgeted plan for strengthening laboratory services, including the deployment of rapid diagnostic tests led by the laboratory strengthening subgroup of the DOTS Expansion Working Group.
- b. Accelerate access to rapid rifampicin testing to improve case detection of all patients suspected of MDR-TB and XDR-TB, and in particular in high HIV prevalence settings, in collaboration with the Foundation for Innovative Diagnostics (FIND).
- c. Continue to expand the capacity for, and ensure the quality of, first- and second-line drug susceptibility testing (DST), mainly of the aminoglycosides and fluoroquinolones, since DST of most second-line anti-TB drugs is not yet standardized, through additional training courses, technical assistance and strategic laboratory network planning.
- d. Expand the annual WHO Supranational Reference Laboratory Network with additional laboratories particularly those in low-resource regions, and continue the annual meetings.

# 4. Expand surveillance of MDR-TB and XDR-TB to better understand the magnitude and trends of drug resistance and the links with HIV

In pursuit of Objective Four, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

a. Incorporate second-line DST (mainly of the aminoglycosides and the fluoroquinolones) into the ongoing round of routine drug resistance surveys

- by SRLs to obtain a better picture of the magnitude and trends of XDR-TB globally.
- b. Conduct rapid drug resistance surveys in priority countries of the Southern Africa Development Community (SADC) in collaboration with the SRLs in South Africa (Medical Research Council) and the United Kingdom (Health Protection Agency, Mycobacterium Reference Unit).
- c. Strengthen and expand the SRL network, particularly in the WHO African Region.
- d. WHO and the Union to publish the fourth drug resistance surveillance report by end-2007. Additionally, analyse and publish data from XDR-TB rapid surveys on failure cases and gather and analyse information on the epidemiological relationship between MDR-TB and HIV.
- e. Develop technical policy guidelines for the proper conduct of second-line DST through a meeting convened by WHO with technical partners.
- f. Accelerate efforts to conduct drug resistance surveys and surveillance particularly in African countries that have not yet reported data on drug resistance trends, and countries where standardized second line regimens have been implemented.
- 5. Foster sound infection control measures to avoid MDR-TB and XDR-TB transmission to protect patients, health workers, others working in congregate settings, and the broader community, especially in high HIV prevalence settings

In pursuit of Objective Five, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. CDC to assist WHO with updating the WHO *Guidelines for the prevention of tuberculosis in health care facilities in resource-limited settings* published in 1999.
- b. Ensure publication and wide dissemination of the guidelines *Tuberculosis* infection control in the era of expanding HIV care and treatment.
- c. WHO to develop, through a global consultation of appropriate experts, guidance for programme managers of NTPs and NACPs to implement infection control measures nationwide. This then needs to be followed by a plan to support implementation of the infection control guidelines at country level, with appropriate indicators, and mechanisms to monitor it over time. This work to be coordinated by the subgroup on infection control, recently established under the TB/HIV Working Group of the Stop TB Partnership.
- d. Expand the pool of infection control consultants by organizing training sessions and on-the-job training of potential consultants.
- 6. Strengthen advocacy, communication and social mobilization for sustained political commitment and a patient centred approach to treatment

In pursuit of Objective Six, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Encourage all health-care providers to follow the *International standards for tuberculosis care*<sup>5</sup> to curb further development of MDR-TB and XDR-TB.
- b. Update the WHO and Stop TB Partnership web sites on XDR-TB to contain monthly activity updates, frequently asked questions, press releases, articles and meeting reports.
- c. Prepare a generic advocacy pack containing information materials for patients, health care workers, employers, donors and civil society, which promotes health education and communication activities that help to reduce stigma attached to TB, coordinated by the advocacy and resource mobilization sub-group of the MDR Working Group of the Stop TB Partnership.
- d. Strengthen communication with key country and global advocacy groups on XDR-TB, develop and distribute treatment literacy materials and the *Patient's Charter*.
- e. Deliver technical assistance to countries aimed at improving their communications on TB, MDR-TB and XDR-TB.
- f. Add an XDR-TB component to the current ACSM training materials for consultants.
- g. Advocate for the XDR-TB emergency and response needs at the following important events:
  - i. World TB Day, 24 March
  - ii. Release of the Global Drug Resistance Report containing data on XDR-TB and MDR-TB/HIV, October 2007.
  - iii. Meeting of the Stop TB Working Group on MDR-TB, Tbilisi, Georgia, 20-22 September 2007.
  - iv. European High Level Ministerial Forum on TB Control, Berlin, 22 October 2007
  - v. Union World Conference on Lung Health, Cape Town, South Africa, November 2007.
  - vi. International AIDS Society conferences in Sydney (2007) and Mexico (2008)

## 7. Pursue resource mobilization at global, regional and country levels to ensure that necessary resources are available

In pursuit of Objective Seven, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Assist countries with developing plans for activities in response to MDR-TB and XDR-TB, in particular through assistance, where needed, in preparing proposals for the Global Fund.
- b. Seek funding for a sustainable approach at the global level to control MDR-TB and XDR-TB.

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<sup>&</sup>lt;sup>5</sup> Available at http://www.who.int/tb/publications/2006/istc\_report\_shortversion.pdf

c. Initiate scale-up of access to second-line anti-TB drugs to countries approved by the GLC by negotiating financial support from UNITAID, the new innovative financing mechanism for TB, HIV and malaria drugs that is based primarily on tax contribution on air tickets.

# 8. Promote research and development into new diagnostics, drugs, vaccines, and operational research on MDR-TB management to shorten treatment,

In pursuit of Objective Eight, WHO and members of the Stop TB Partnership will seek to carry out the following activities:

- a. Encourage the private sector and academia to commit more human and financial resources into research, in collaboration with the Stop TB Partnership secretariat and Working Groups on new tools.
- b. Advocate for additional funding for clinical trials and for a policy on rapid access to new drugs, once approved by stringent drug regulatory authorities.
- c. Define priority operational research areas for MDR-TB and XDR-TB, encourage research activities at country level and coordinate partners to avoid duplication of work and ensure use of resources according to WHO Guidelines through the subgroup on research of the Stop TB Working Group on MDR-TB. Strengthening of the recording and reporting system for MDR-TB is a must for operational research to deliver (See 2.d. above).
- d. Responsible bodies for drug trials of new anti-TB drugs should consider the evaluation in parallel of new drugs for both susceptible and resistant TB cases.