

NEW GLOBAL FRAMEWORK TO SUPPORT SCALE UP TO UNIVERSAL ACCESS TO QUALITY MANAGEMENT OF MDR-TB

A. Background

The WHO and the Stop TB Partnership currently support countries to manage multidrug-resistant TB (MDR-TB) through the Green Light Committee (GLC) Initiative. The GLC Initiative is comprised of the GLC Committee, the WHO/GLC Secretariat, the Global Drug Facility (GDF), and partners who provide financial and technical assistance.

There have been steady increases in the number of patients with MDR-TB approved each year for treatment by the GLC Committee (13,389 in 2009¹ and 42,033 in 2010²), and in those actually starting treatment (10,531 in 2009 and about 13,000 in 2010²). However the numbers remain small compared to the estimated annual incident 440,000 cases. This threatens the control of TB worldwide, potentially undermining the major advances made in detecting and treating TB in the past 15 years. The challenge now is how to re-structure the global organisation of the support to the expansion of MDR-TB care in such a way as to best accelerate the number of cases detected, enrolled on treatment and treated successfully, and hence achieve universal access by 2015.

The new Global Framework is the result of an inclusive and iterative process undertaken by all key stakeholders supporting the expansion of MDR-TB services and care over the past 20 months. This included two retreats in October 2009 and February 2010, several meetings of three Task Forces that were established to look at defined issues, and a meeting of key stakeholders on the "Way forward to achieve universal access to diagnosis, treatment and care of MDR-TB" held in Geneva, Switzerland in February 2011. The new Global Framework was reviewed at the 19th Stop TB Partnership Coordinating Board meeting in Johannesburg, South Africa in October 2010, at a special meeting of Board members in Berlin, Germany, on 11 November 2010, and endorsed at the 20th Coordinating Board in Washington DC, USA, on 1 April 2011.

B. Structure and functions of new framework to support scale up to universal access to quality MDR-TB management

Mission statement: To achieve a world free of drug resistant TB

Goal: To accelerate scale up to achieve universal access to prevention, early diagnosis and effective patient-centred treatment for drug resistant tuberculosis by 2015

To reach this goal, the new global framework will have to provide:

1. Increased level and diverse models of technical support from partners to assist countries to plan, implement, manage and monitor the required scale-up of MDR-TB services.
2. Increased access to high-quality, affordable second-line anti-TB drugs (SLDs) for the treatment of MDR-TB.
3. Strengthened advocacy for the accelerated scale up of the response to MDR-TB.
4. Regular and supportive monitoring and evaluation of country performance in accelerating access to MDR-TB treatment and care, to inform assessment of global progress, to propose improvements to the global, regional and national approaches, and to pursue advocacy activities tailored to country needs.
5. Regular updating of international policy and guidelines relating to programmatic management of drug-resistant TB (PMDT).

¹ GLC Annual Report 2009

² Data with GLC Secretariat, February 2011

6. Provision of advice to funding agencies, on their request, ensuring that the effective treatment of patients with MDR-TB is done in accordance with international standards.

C. Elements of the new framework to support scale up to universal access to quality MDR-TB management

1. Increased level and diverse models of technical support from partners to assist countries to plan, implement, manage and monitor the required scale-up of MDR-TB services

Scale-up has to take place at the country level and one of the main bottlenecks identified as hindering the scale-up is the lack of technical capacity and adequately developed health workforces in countries. Therefore the new framework will focus on capacity building at the country level and the provision of increased technical assistance (TA), including long term in-country TA, from all partners to develop the capacity to plan, implement, manage and monitor the required scale-up of MDR TB-services.

Technical assistance and monitoring activities will increasingly be decentralized to the regional and country levels. To further this aim, countries will be encouraged to develop their own national (or sub-national) technical assistance centres (TACs) to guide and support nationwide scale-up of PMDT, in collaboration with the regional GLC's (refer to page 3). National technical assistance centres can have regional functions; these TACs need to be maintained and supported.

The development of national TA plans will be prioritized and TBTEAM can play an important role in the development of these plans and in the co-ordination of the TA provided to countries by the different partners. Guidance and tools are being developed for assessing and planning the human resource requirements for country-wide management of MDR-TB.

2. Increased access to high-quality, affordable SLDs for the treatment of MDR-TB.

To ensure availability of quality-assured SLDs and other commodities in sufficient quantities at an affordable price and in a timely manner to all countries, a number of actions have been identified. GDF will continue to play an important role, with WHO PQ, in collaboration with ICH and other partners, needing to play an increasing role.

Under the new framework, all countries will be eligible to approach GDF directly for the procurement and supply of quality assured SLDs, with no prior GLC application nor approval process. The GDF is undergoing restructuring, including proposed regionalization of activities, to meet the new needs. (Included in the proposed re-organization is a decentralization of activities with the establishment of eight Regional Support Officers positions, based at the global (1) and regional levels (7).) All those ordering via GDF, are accountable for proper patient management and are expected to participate in a regular monitoring system through the regional GLC's, and receive TA as required.

In order to optimize the current supply system, countries need to improve their planning. To assist them in this, appropriate TA in drug management needs to be delivered and the developed forecasting tool needs to be piloted as soon as possible. Advance purchase commitment may be further explored as a novel way to increase access to quality assured SLDs. Partners will continue efforts to provide TA to suppliers in order to facilitate the prequalification process for SLDs, specifically the United States Pharmacopeia and WHO's Prequalification of Medicines Programme.

To place the issue of lack of access to adequate supplies of quality assured SLDs as a real humanitarian emergency, discussions need to take place at the highest political levels which brings key players around the same table to create a solution to the issue.

3. Strengthened advocacy for the accelerated scale up of the response to MDR-TB.

Advocacy for greater investment and increased political commitment is needed to accelerate scale up of effective strategies and tools to achieve universal access to DR-TB management. STP must ensure that advocacy related to PMDT is integrated into a broader TB advocacy strategy, in order to take the MDR-TB agenda forward by all partners. To support PMDT advocacy activities, a "DR-TB advocacy manual" will be needed to support activities of country-level as the new GLC framework is scaled up.

4. Regular and supportive monitoring and evaluation of country performance in accelerating access to MDR-TB treatment and care, to inform assessment of global progress, to propose improvements to the global, regional and national approaches, and to pursue advocacy activities tailored to country needs.

Assessment of country progress and performance will be undertaken by the Global and Regional GLCs utilizing information from monitoring and technical missions with the support of the respective secretariats, and data collected from the countries and from in-country partners. Country performance will be monitored and evaluated annually through an expanded collection of national data by WHO and the results will be published in the WHO Annual Global TB Control Report.

5. Regular updating of international policy and guidelines relating to PMDT.

As and when required, GLC members may be invited to attend meetings called by WHO for the review and/or development of new PMDT related Policy and Guideline documents. The members of the Global and Regional GLCs will contribute to the updating of the evidence base, and WHO policy and guidelines relating to PMDT.

6. Provision of advice to funding agencies, on their request, ensuring that the effective treatment of patients with MDR-TB is done in accordance with international standards.

To improve the efficiency of the assistance provided to countries and the Global Fund (GF) in relation to both application to the GF for funding support and implementation of activities of grantees, it is proposed that the provision of TA will occur earlier than currently occurs under the existing mechanism. TA will be provided to assist countries develop or update their national MDR-TB scale-up plans, and also to support countries and the GF during the grant negotiation period.

D. Structure of the new framework to support scale up to universal access to quality MDR-TB management

Global and Regional GLC Committees

To support the activities and implementation of the new global framework, GLC Committees will be established at the global and regional levels. It is proposed that they will be known as the Global GLC at the global level and generically at the regional level as the Regional GLCs. The term "GLC" is however now to be seen as a brand name and not as an abbreviation of a specific longer form of notation. Regional GLCs will be identified by their respective geographical location e.g. EURO - GLC for the European Region. The regional secretariats may be based, but not mandatorily, in the WHO Regional Offices. The rationale of decentralization is to bring GLC activities closer to the countries and benefit from the greater involvement of key national and international partners in the scale-up of MDR-TB services and care in the respective Region. Hosting Regional GLCs in the regions would also ensure coordination of activities with other on-going TB, HIV and health system strengthening related interventions from the Regional level.

The overall objective of the Global and Regional GLCs is to provide advice to WHO, Partners and

countries on strategic issues related to scaling up DR-TB care in order for countries to achieve universal access to management of drug-resistant TB (WHA 62.15).

Global GLC Committee (hereafter referred to as "gGLC")

Role of the gGLC Committee

The global level strategic gGLC should have the dual role of advising WHO and Partners, that is it should be both i. an advisory committee to WHO, and ii. a sub-group of the MDR-TB Working Group of the Stop TB Partnership.

Terms of reference of the gGLC Committee

1. Provide advice to WHO and Partners on strategic issues related to scaling up MDR-TB care;
2. Strengthen advocacy for increasing commitment of countries, donors and technical agencies to achieve universal access to patient-centered MDR-TB management according to WHO guidelines;
3. Monitor and evaluate global and regional scale-up of MDR-TB management to optimize regional and country strategies;
4. Promote access to high-quality, affordable second-line anti-TB drugs and other commodities;
5. Liaise with global partners in support of scale-up of PMDT for harmonization and streamlining of efforts and identification of research needs;
6. Ensure collaboration among Global and Regional GLCs to ensure consistency and communication across regions to address technical issues, programmatic challenges, and strategic planning;
7. Contribute to regular updating the evidence base, WHO policy and guidelines relating to the programmatic management of drug-resistant tuberculosis, including the rapid uptake of new tools to improve PMDT; and
8. Provide opinions to donors/funding agencies at their request on country PMDT scale-up plans and subsequent TA needs addressing identified gaps, via the global GLC secretariat.

The secretariat of the gGLC will be housed in WHO, Geneva.

Reporting structures and accountability

In its role as a WHO advisory committee, the Global GLC will report and be accountable to the Director of the STOP TB Department, WHO. In its role as sub-group of the MDR-TB Working Group, it will report and be accountable to the Chair of the MDR-TB Working Group. Regular updates will be provided to the Stop TB Partnership Coordinating Board and the WHO Strategic and Technical Advisory Group for Tuberculosis. An annual GLC report will be published.

Regional GLC Committees (hereafter referred to as "rGLC")

Decentralization to the regions will happen in a phased manner. Regions that requested to start in the first year are AMRO/PAHO, EURO and WPRO.

Terms of reference of the rGLCs

- Review and provide inputs to the regional strategies and/or action plans for scale up of PMDT;
- Review and analyze GLC monitoring mission reports and surveillance data:
 - Identify programmatic issues that need to be addressed and recommend actions, including the provision of technical assistance and prioritization of resources.
 - Monitor scale-up progress - Programmes that have gone through this process will be considered "GLC Reviewed Programmes.";

- Provide an opinion to donors/funding agencies on their request on country PMDT scale-up plans and the subsequent TA needs addressing identified gaps, via the gGLC Secretariat;
- Oversee the provision of supportive monitoring missions and technical assistance missions to countries;
- Liaise with the gGLC and exchange information on plans of rGLC activities, seek inputs and advice as and when required, and inform the gGLC of technical and political issues relevant to TB and MDR-TB prevention and control.
- In collaboration with WHO Regional Office and Partners, to convene advocacy efforts for PMDT scale up, access to and rational use of quality medicines, and coordinate and report on progress related to data collection in respective regions.

During the first year, regional committees will be established in AMRO, EURO and WPRO, with the secretariats of the rGLCs housed in the respective WHO Regional Office. In the first year, the global level will perform certain required activities, in collaboration with the WHO Regional Offices and other regional partners, to ensure that countries in the three other Regions (AFRO, EMRO and SEARO) receive the support required for MDR-TB management to be scaled up. However during the first year, activities should be undertaken in preparation for the time when these regions will take up all activities under the new framework.

E. Resources needed for the implementation of the new framework

Indicative budget estimates show that a 3-4 fold increase in the current level of funding is needed to meet the "bottom-line" requirements for the establishment and functioning of the new global framework i.e. an increase from the current annual investment of USD \$5-6 million currently flowing through the GLC secretariat to approximately USD \$23 million annually flowing to the most appropriate partners. It must be noted that for comprehensive scale-up to universal access of DR-TB management, additional activities are required that are not addressed in these estimates. The estimates do not include those funds currently available for supporting other aspects of scale-up of MDR-TB services, such as laboratory strengthening, infection control, etc, provided through different channels and agencies both involved and not involved in the current GLC Initiative, or future requirements. Thus the estimates should be seen as a "bottom-line" requirement for the implementation of the new framework.

Without the availability of new and additional funding, support to the global scale-up of MDR-TB services will continue. However it will be at a much reduced level than hoped for and will reduce the likelihood of achieving universal access to diagnosis and treatment of MDR-TB by 2015.

To conclude, the final goal of this framework is to enable countries to accelerate the scale-up of MDR-TB management in order to be on track towards the target of universal access to diagnosis and treatment by 2015. Realigning the process of coordination between partners to support countries is one focus of the new framework described here, and ensuring an efficient transition from the previous model of work. The funding requested for the framework, if achieved, will enable WHO and partners to coordinate more effectively the support needed by countries.