

First meeting of
the Core Group of
the Global Drug-
resistant TB
Initiative

1-2 May 2014

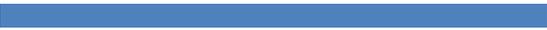


Table of Contents

Welcome address	1
Meeting objectives and declaration of interests	1
Session 2: To provide an update on progress in scale up of MDR–TB services and care, and updates on new policies	4
Progress versus targets in the Global Plan, updates from WHO 2013 Annual Global TB, and policies	4
Key areas of work in 2014 for Stop TB Partnership - Global Fund and Global Plan 2016-2020	4
Update on GDF Achievements & Strategic Framework Implementation.....	5
The Global Laboratory Initiative of the Stop TB Partnership.....	5
Updates on implementation of regional plans in response to M/XDR–TB, and activities and progress of the rGLCs.....	6
Session 3: To establish strategic priorities for the GDI	10
Session 4: To establish priority activities and method of work for the GDI	10
Session 5: To establish GDI workplan and timelines for 2014–15	10
Discussions and action points:	11
Annexure 1. List of Participants	16
Annexure 2. Agenda	18

Welcome address

Dr Mario Raviglione, Director, Global TB Programme (GTB), WHO, welcomed the participants to the first meeting of the Core Group (CG) of the Global Drug-resistant TB Initiative (GDI). Whilst noting the major achievements made in TB control over the last decade, he highlighted the fact that there are still 3 million missing TB cases each year that are not notified to the national TB control programmes. Nearly half a million new MDR-TB cases appear each year globally, but less than 20% are initiated on the appropriate second line drug treatment. There has been an impressive progress seen in the scale-up of MDR-TB services in some countries in recent years, but in other countries progress has been either slow or static. How the global community can support the rapid scale-up of MDR-TB services is the major challenge for this Core Group to deliberate on. Treatment success rates for MDR-TB also remain unsatisfactory at less than 50%. Dr Raviglione also highlighted that currently it is an interesting time in MDR-TB control as two new drugs have now become available for the treatment of drug-resistant forms of TB, namely Bedaquiline, for which WHO has already issued interim policy guidelines and Delamanid for which interim policy guidelines from WHO are expected soon. The ideas and recommendations of the CG can be taken to WHO's Strategic and Technical Advisory Group for TB (STAG-TB) in June 2014 for further consideration, and be the initial step towards informing WHO's decision making on future MDR-TB related policies.

Dr Suvanand Sahu, Deputy Executive Secretary, Stop TB Partnership (TBP) after welcoming the participants reminded the participants of the high expectations placed on the CG to create the situation whereby the rapid scale-up of MDR-TB services can be catalysed. There is a need for innovation in our approach to the problem. Country commitment needs to be improved through high level advocacy with the aim of increasing funding from domestic sources in order to reduce the current dependence on external resources.

Dr Chuck Daley, Chair of the CG thanked the speakers and also welcomed participants.

Meeting objectives and declaration of interests

The meeting objectives were presented by Dr Fraser Wares, GDI Secretariat, as follows:

- To orientate the Core Group (CG) members on the Global Drug-resistant TB Initiative (GDI):
 - role and function of the CG; and
 - Terms Of Reference
- To provide an update on:
 - progress in scale up of MDR-TB services and care;
 - new policies; and
 - Stop TB Partnership activities and plans
- To establish for the GDI:
 - strategic priorities;
 - priority activities; and
 - annual work plan for 2014-15

Dr Wares also presented the summary of the interests declared by all CG members participating in the meeting. No conflict of interest was identified. Members who as individuals or their institutions have received support in any form from a pharmaceutical company were requested to abstain from influencing discussions related to a product of the company

Session 1: To orientate the Core Group members on the Global Drug-resistant TB Initiative (GDI), and the role and function of the Core Group (CG) within the GDI

Dr Karin Weyer, Coordinator, Laboratories, Diagnostics and Drug Resistance (LDR) Unit, GTB, WHO, presented the timeline of key events that led up to the establishment of the GDI and the subsequent formation of the CG. Keeping in mind the need for rapid global wide scale up of programmatic management of drug-resistant TB (PMDT), way back in October 2010 it was acknowledged that there was a need for a change in the approach to this issue. A New Global Framework for MDR-TB support was agreed by partners in June 2011, which emphasised increased technical assistance (TA) from partners to countries, increased access to high-quality, affordable 2nd-line drugs, strengthened advocacy, decentralization of the global level Green Light Committee (GLC) Initiative to regional GLCs (rGLCs) and regular and supportive monitoring of country progress. Between January and September 2013, an evaluation of the TBP's Working Groups (WG) was carried out which recommended that an overhaul of the MDR-TB WG was urgently needed. There was an agreement to combine/merge/integrate the MDR-TB WG and the global GLC (gGLC), and to establish a new entity to replace the MDR-TB WG. This issue was further discussed at the Joint MDR-TB WG Core Group and gGLC meeting in April 2013. The meeting recommended that:

- The gGLC and MDR-TB WG CG members unanimously and strongly endorsed that the gGLC and MDR-TB WG Secretariats to proceed with the preparation a draft concept document, laying out the terms of reference and operating procedures and election process for a new body based on the Global Laboratory Initiative (GLI) model that will replace the existing gGLC and CG of the MDR-TB WG.
- Acknowledging the achievements of the decentralized MDR-TB support framework, recommend that the rGLCs continue as the mechanism for technical assistance, retaining their roles and responsibilities.

The Global Drug-resistant Initiative (GDI) was established in October 2013 following broad consultations, culminating in final discussions at the MDR-TB Stakeholders' meeting in Paris in October 2013, that was attended by nearly 170 participants from national TB control programmes, affected communities, civil society, technical agencies, funding agencies and professional associations. Key conclusions of the Stakeholders' meeting were that:

- Urgent acceleration and scale-up of MDR-TB care and control efforts are required;
- The current doubling time for enrolment on MDR treatment appears to be about 3 years, and ambitious plans for the scale up of services seem to be lacking in many countries;
- Rapid diagnostics is increasing MDR-TB diagnoses significantly, but a diagnostic/treatment gap is now a stark reality in many countries; and
- Treatment success rates urgently need to be improved.

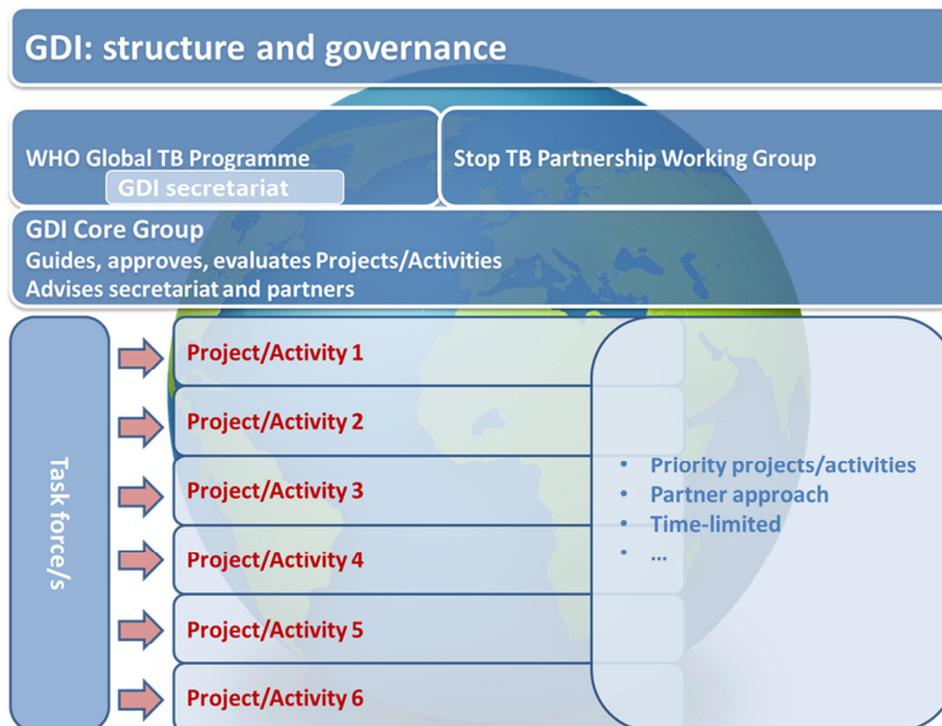
The GDI was formally launched in January 2014, with its mission being to serve as a multi-institutional, multi-disciplinary platform organizing and coordinating the efforts of stakeholders to assist countries to build capacity for PMDT in the public and private sectors, with an ultimate aim to ensure universal access to care and appropriate treatment for all drug-resistant patients.

As laid out in the governance document, the proposed strategic priorities for the GDI are:

- Build global consensus on management of DR-TB for patient centred care delivery;

- Promote strategies to facilitate patient access to high-quality DR-TB care, through a long-term, in-country capacity building approach targeting both the public and private sector;
- Facilitate integration and coordination of efforts to align diagnostic services for patients with access to high-quality care;
- Facilitate strengthening DR-TB reporting and monitoring systems to improve patient notification, drug management, patient records, and community-based care through public and private facilities;
- Facilitate effective knowledge sharing among partners and harmonise coordination with existing TA mechanisms to ensure quality support to PMDT;
- Strengthen regional frameworks and collaboration with rGLCs for support to country level PMDT expansion activities;
- Develop targeted advocacy strategies and resource mobilization for DR-TB management scale-up; and
- Support prioritization of research to generate evidence for PMDT scale-up.

It was emphasised that at this meeting the CG members needed to focus on finalising the key strategic priorities of the GDI, and decide on "project activities" that the GDI should undertake both in the short/medium and long terms. If needed, a "Task Force" could be established for undertaking any of the agreed activities. The task forces will be led by partner organisations that is willing to take the respective activity forward. The secretariat, hosted by WHO's GTB, will offer all the support needed for the work of the GDI CG and any Task Forces.



Session 2: To provide an update on progress in scale up of MDR–TB services and care, and updates on new policies

Progress versus targets in the Global Plan, updates from WHO 2013 Annual Global TB, and policies

Dr Dennis Falzon, LDR, GTB, provided a global overview of progress, along with consensus decisions from the MDR-TB Stakeholders' meeting in Paris, on use of the MDR–TB burden indicators for different specific purposes.

In relation to MDR-TB, the Global Plan to Stop TB 2011–2015 had targets set to:

- Increase in TB cases tested for R and H yearly from 0.8 million in 2011 to 1.9 million in 2015;
- 1 million multidrug-resistant TB (MDR-TB) patients detected and put on treatment over the 5 years; and
- USD 7.1 billion spent on MDR–TB services and care.

Globally in 2012, 5% of new bacteriologically positive and 9% of retreatment TB cases were reported with drug-susceptibility test (DST) results, well short of the 20% and 100% targets set respectively for 2015. This is partly due to a lack of sufficient access of TB patients to DST, and in some countries is due to the low capture of results from laboratories as a consequence of inadequate TB information systems. In 2011 and 2012, a total of 155,000 and 196,000 TB cases new and retreatment respectively were reported to have had DST results globally. In the European Region, while the coverage in new cases has exceeded the 20% target of the Global Plan (72%), incomplete reporting on certain categories of retreatment cases is common in the Russian Federation and elsewhere and, as a result, the overall coverage among retreatment cases is low (41%). About 9.6% (8.1-11.2%) of MDR-TB cases in countries with representative DST surveillance data have extensively drug resistant TB (XDR-TB). By October 2013, 92 countries had reported one or more cases of XDR-TB cases. In 2012, the number of rifampicin resistant (RR)/MDR-TB cases reported to WHO totalled 94,000, compared to 66,000 in 2011. However, only about 77,000 TB cases were reported to have started MDR-TB treatment in 2012, or about 45% of the target for that year according as per Global Plan. A number of countries are not able to place MDR-TB patients on appropriate treatment at the same pace at which they are diagnosed, which is a consequence of limitations in the curative services. And hence "waiting lists" for MDR treatment are a reality in many countries. With the introduction of rapid molecular diagnostic tests, these numbers are likely to grow.

Key areas of work in 2014 for Stop TB Partnership - Global Fund and Global Plan 2016-2020

In the subsequent presentation, Dr Sahu, Stop TB Partnership (TBP), reiterated the need for rapid scale-up of TB services as at current rate, the targets for TB control will be hard to reach in near future. Dr Sahu elaborated on the work of partnership, the making of new Global Plan to Stop TB, 2015–2020, and the TBP's work with the Global Fund (GF). The meeting was informed that the TBP now had a new operational strategy, a new structure and governance processes, and new Standard Operating Procedures (SOPs) for the WGs. He also agreed to share the presentation on recently developed Standard Operating Procedures for the Working Group.

Update on GDF Achievements & Strategic Framework Implementation

Ms Andrea de Lucia, Team Leader, Country Support, Global TB Drug Facility (GDF) presented the work of GDF and progress so far in ensuring uninterrupted supply of quality assured first and second line TB drugs. A total of 128 different countries have received the benefits from GDF procurement system. The support by volume includes > 23 million first line drugs (FLDs) patient treatments delivered, > 116,000 second line drugs (SLDs) patient treatments delivered, and > 1 billion USD of drugs and diagnostics procured since 2002 with a growing support from GDF to countries for diagnostics provision through projects like TB REACH, Expand TB and TB Expert.

To strengthen the GDF support, 3 Regional Support Officers (RSO) based in WHO Regional Offices have been recruited while another one is under the process of recruitment. The RSOs provide direct country support to all GDF clients, assist in the application for 1st line adult and paediatric grants, assist in the quantification of FLDs and SLDs for budgeting and ordering, facilitate order execution and delivery, assist in relieving financial bottlenecks, planning and conducting monitoring visits where possible, data collection for early warning system and in-country partner coordination. A total of 65 stock outs have been reported in GDF supported countries from 2007-2013. Out of these 54 were confirmed by different documents, 10 were confirmed as Non-stock-outs and 1 report was related with laboratory material - not to medicines procurement.

Key GDF achievements in recent years include:

- Merging of FLDs, SLDs, diagnostics procurement lines per country
- UNITAID Board approved GDF cost extension proposal to double the value of current Strategic Rotating Stockpile to the value of more than 14.5 M USD) for SLDs (including new TB Drugs) and FLDs
- GFATM Strategic collaboration on Rapid Supply Mechanism and closer working relationships with PSM Teams
- New Guarantee Fund with USAID implemented to avoid upfront payments
- Roll-out of new strategic tools like QuanTB and Early Warning Stock Out with partners for improved global forecasting
- On-going SLDs market review analysis with CHAI that will form the basis for operations re-modelling and the strategic discussions on innovative financing with Gates Foundation

The Global Laboratory Initiative of the Stop TB Partnership

Dr Tom Shinnick, Chair, Global Laboratory Initiative (GLI) presented the history and achievements of the GLI. The GLI had its beginnings in the WHO Supranational Reference Laboratory Network that later grew into the Subcommittee on Laboratory Capacity Strengthening of the DOTS Expansion Work Group. It was endorsed by TBP Coordinating Board in October 2007 and later elevated to a working group in June 2008. The GLI serve as a platform of coordination and communication for TB lab strengthening in the areas of:

- Global policy guidance
- Laboratory capacity development
- Interface with other laboratory networks, enabling integration
- Standardised lab quality assurance
- Coordination of technical assistance
- Effective knowledge sharing
- Advocacy and resource mobilisation

Dr Shinnick highlighted that lack of laboratory services continues to be a barrier to reaching global targets for TB control, as evidenced by the fact that only about 57% of all new pulmonary TB cases were bacteriologically confirmed in 2012. AFB smear-based testing is inadequate in high HIV settings and only about 19% of estimated 450,000 MDR TB cases were laboratory confirmed. Many XDR TB cases are not detected due to the lack of second-line DST

Some of the Guidance documents and Tools developed/ endorsed by the GLI include

- Roadmap for TB Lab Strengthening
- Tools for TB Laboratories – ‘GLI Tool Box’
- Roadmap for accrediting TB Labs and networks
- Roadmap for Incorporating Molecular Diagnostic Tests into TB Control
- Specifications for ventilated workstations
- Handbook for TB Laboratory Strategic Planning
- AFB Smear Microscopy Manual

These are available at <http://www.stoptb.org/wg/gli/documents.asp>

Some of the key priorities for GLI include:

1. Development of SLD DST capacity in countries to rapidly diagnose XDR cases and get them initiated on treatment
2. Establishment of regional GLIs on similar lines as the rGLCs. Both the mechanisms are expected to work in close collaboration on laboratory and treatment scale-up aspects.

Updates on implementation of regional plans in response to M/XDR-TB, and activities and progress of the rGLCs

The next session included presentations from the respective rGLCs on progress made in respective regions. Dr Hind Satti, Chair AFR rGLC, Dr Raimond Armengol, Chair AMR rGLC, Dr Essam Elmoghazy, Chair EMR rGLC, Dr Andrey Maryandyshev, Chair EUR rGLC, Dr Rohit Sarin, Chair SEAR rGLC and Dr Lee B Reichman, Chair WPR rGLC, provided updates on the activities of the respective rGLCs.

AFR rGLC

The WHO Africa Regional Office established the rGLC in February 2013, and the committee had its first meeting in Brazzaville from 17-19 July 2013. A second meeting took place during the UNION conference in Paris in November 2013. Country support for MDR-TB includes monitoring missions, remote support for access to second line medicines through the GDF and also support for programme implementation by advising during regular programme reviews. This has been undertaken either by WHO inter-country support teams (IST) or by the Regional Office staff. The rGLC has promoted human capacity strengthening for MDR-TB by supporting two 6 week training courses held in Ouidah, Benin and KEMRI, Kenya. In 2013, the rGLC secretariat received at least 20 requests from the GDF) to review country’s orders of 2nd line medicines. There has also been development of regional Global Laboratory Initiative (rGLI) for the African Region, called GLI-AFR. This is aimed at bringing closer to member states oversight functions, including quality assurance mechanisms and operational models. In 2013, a total of 18 technical and monitoring missions were undertaken to countries with the aim of country support for DR-TB and DRS.

A total of 83,574 MDR-TB cases have been notified from 44 of the 47 countries in the Region between 2004 and 2012. Significant increases in case notifications have been observed since rapid molecular tests were endorsed by WHO in 2010. The number of MDR-TB cases reported by year has increased from 3,501 in 2004 to 18,129 in 2012. A total of 3,487 XDR-TB cases have also been notified.

Key issues:

- Inadequate supply of consultants for PMDT in the African Region.
- Language barrier which limits the performance of some of the consultants in some countries.
- Staffing compliment in the WHO Offices for coordination of the activities.

AMR rGLC

A renewed r-GLC-AMR, with a mix of old and new members, started activities in 2013. The rGLC has 7 members including a patient representative and one NTP manager as a country representative. There were 5 rGLC meetings in 2013, including 2 face to face meetings and 3 conference calls. Country support included: Monitoring missions to 12 countries with GF grants and another non-grant country. 3 Country Expansion Plans were reviewed, 2 MDR-TB and Infection Control (IC) guidelines update reviewed and 33 SLD requests were also reviewed by the rGLC secretariat. Technical assistance to countries is continuously provided by internet and during M&E missions.

The implementation of DST diagnostic capacity has been increasing slowly in the Region in last five years with Culture and DST for FLD available in 24 countries and DST for SLD available for 15 countries. Xpert MTB/Rif was rolled out and as of 2013 68 units were in place in 15 countries. Line Probe Assay (LPA) is available in 10 countries. In 2012, 2,976 MDR-TB cases were notified in the Americas in 2012, 43% of the 6,962 estimated cases and 500 less cases than the previous year. The reduced notified numbers were mainly from Peru and Ecuador despite the increased number of DST performed in those countries in that year. 98 cases of extensively drug-resistant TB (XDR-TB) were notified that year

Key issues:

rGLC and Secretariat

- Limited budget for carrying out activities
- Decreasing number of countries eligible for GF support under the NFM mechanism
- Slow implementation of recommendations provided by rGLC monitoring missions

Countries:

- Limited political commitment
- Budgetary limitations to fund all the activities to accelerate the expansion of PMDT.
- Most of the countries depend on funds coming from the Global Fund
- Limitations of trained human resources
- Limited laboratory capacity.
- Slow implementation of new technology (Xpert, LPA..)
- Information system still based on paper, with parallel systems for TB program, MDR-TB and laboratory information

EMR rGLC

The first EMR-rGLC committee meeting was held in December 2012, with the election of chair and co-chair of the EMR-GLC in February 2013. The 2nd EMR rGLC meeting was held in Cairo in May 2013. During 2013, the WHO RO supported the countries to plan for MDR-TB management and adopt ambulatory model. A workshop for MDR-TB management planning was held in March 2013. The workshop was based on the MDR planning tool kit. There were also seven monitoring and TA missions to Djibouti, Egypt, Iran, Pakistan and Sudan in 2013. A regional plan 2014-2015 is going to be developed during the 3rd rGLC meeting proposed from 7-9 April 2014, with main strategic directions of the work being improving planning for PMDT (update the regional plan and support planning at country level); developing regional high standard ambulatory based model (guidance

document, training, monitoring and evaluation) based on global documents and country experience; and scaling up R&R for MDR (standardized tools and reports preferably on line, data quality and analysis) and scaling up infection control at all levels.

In 2012, only 1,602 MDR-TB cases, out of 2,236 notified cases were put on treatment, which means that only 72% of confirmed cases at NTP received treatment. However the waiting list gap was closing by the end of 2012 and the reported number on the waiting list in the last month of 2012 were only around 126 cases from 9 countries.

Key issues:

- Unstable situation in many countries in the region, namely Afghanistan, Egypt, Lebanon, Iraq, Pakistan, Somalia, Syria, Tunisia and Yemen.
 - Huge population movement across the region
 - Huge staff turn over
 - Destruction of infrastructure
 - Limited movement in the field
 - Sever loss of drugs and equipment
- Limited lab capacity
 - Culture and DST are not available in Somalia and South Sudan. DST is not available in Afghanistan.
 - Most of the countries in the region did not widely apply the new diagnostics.
- DR survey and surveillance:
 - Updated survey is ongoing in Iraq, Iran, Pakistan, Sudan, and needed in Syria.
 - There is a need to document/report results of DR surveillance that is ongoing in GCC countries, and expand the continuous surveillance in the remaining 15 countries.
 - Libya is still the only country in the region without proper management of MDR-TB management.
- Expected financial gap to support scaling up MDR-TB activities in most countries- Djibouti, Egypt, Lebanon, Jordan, Iran, Pakistan and Syria.
- Limited human resources at country level - MDR local support on continuous basis is needed in Afghanistan, Iraq, Pakistan and Sudan.
- Limited consultancy capacity in the region in general - a team of 5 consultants was established last year to support countries.

EUR rGLC

The EUR rGLC was established in 2011 and has been conducting regular meetings both in person and virtual (via WebEx). Key achievements in 2013 include continuing the provision of state of the art TA to Member States on MDR-TB, improved collaboration with other related technical entities, such as the European TB Laboratory Initiative (ELI) to scale up quality diagnosis and complementing the scale-up packages and activities in the field of PMDT and the Global Drug Facility (GDF).

A compendium of best practice examples from the WHO European Member States in TB prevention, control and care has been developed, input to and review of which was also provided by European rGLC members. Additionally, important consensus documents on the role of surgery in TB and MDR-TB and on cross-border TB control and care, including X/MDR-TB aspects, have been developed, with input of the rGLC members. A workshop on pharmacovigilance was recently held in March 2014, with significant involvement of the European rGLC. Twenty two monitoring and TA missions were conducted in 2013 for 18 different countries supported by the GF. GLC-Europe monitoring missions are commonly jointly organized with GF and/or GDF. The GLC TA is often embedded in NTP review missions. Coverage of DST among all notified TB cases confirmed by culture was 86.6% while coverage of DST among bacteriologically confirmed new TB cases in the WHO European Region was

87.5% and among bacteriologically confirmed previously treated TB cases 85.9%. The target is that in 2015 all new cases will be tested to H and R

Of the estimated 76,400 MDR-TB cases in the European Region in 2012, 33 373 (43.7%) had been detected that year (up from 38% in 2011). The proportion of MDR amounted to 47.1% among previously treated cases in 2012, representing a slight improvement of the related figures from previous years regarding retreatment cases (47.5% in 2011 and 48.2% in 2010)

Key issues:

- Need for guidance to countries that intend to introduce Bedaquiline.
- Insufficient political commitment, outdated guidelines, weak HR planning and management, IC, insufficient patient-centeredness, rise of TB/DR-TB-HIV, access to care of vulnerable groups and demographic shifts
- Treatment success rate remains low at 49%
- Sustainability of programmes after TGF support ends, particularly in the upper-middle income countries

SEAR rGLC

The SEAR rGLC was constituted in April 2012. The 3rd meeting of SEAR rGLC was held from 29-30 April 2013, with the 4th meeting was held on 21-22 November 2013 in Jakarta, Indonesia. The 4th meeting reviewed progress made based on the recommendations of the 3rd meeting and recommended that the SEAR MDR-TB Advisory Committee and the WHO Secretariat should actively support countries. Also regular monitoring of country PMDT, preferably every 6 months by r-GLC was recommended based on matrix to be developed by the committee. Exploring potential Centres of Excellence in MDR-TB clinical management at the regional level was also recommended. In 2013, there were nine monitoring and TA missions undertaken in the region under the overall guidance of the rGLC. In addition the rGLC supported development of PMDT Expansion Plan for Bangladesh and helped organise PMDT Training in Timor Leste and Thailand. A workshop on Training of Trainers for PMDT was organised in collaboration with WHO and CDC Atlanta in March 2014.

In 2012, about 20,000 MDR-TB and 4,000 RR-TB cases have been reported, and almost 16,000 patients with MDR-TB had been registered for treatment in the Region. Data available from the first semester of 2013 (from 5 countries, including India) show a continuation of the increasing trend as almost 12, 000 cases were reported to have been enrolled on treatment.

Key issues:

- Limited laboratory capacity and networking
- Limited national and sub- national capacity to improve and maintain quality services for DR-TB cases
- Low case detection due to weak networking and referral between PMDT services and other TB service providers
- Lack of clinical management skill
- Inadequate implementation of TB-IC measures
- Inadequate supervision of and support to PMDT sites due to lack of sufficient human resources
- Limited implementation of PPM and community involvement
- Limited capacity of drug regulatory authority for ensuring adequate quantities of quality assured FLD and SLD

WPR rGLC

After being established in 2011, the rGLC has had several face to face and teleconference to discuss the PMDT situation in the region and scale-up related issues. The 4th rGLC meeting was held from 10-13 April, in Ha Noi, Viet Nam while the 5th rGLC meeting and Programme Managers meeting were held together from 20-23 August in Manila, Philippines. Additionally four online meetings were held to review reports and SOPs of MDR-TB management. An important outcome of the rGLC mechanism has been the development of a regional pool of experts for PMDT scale-up and drug management support. Research initiated by the rGLC Secretariat provided a unique analysis of the private sector contributions in the Philippines. Monitoring and technical assistance were undertaken for 9 countries and in 3 cases coordinated with other events such as joint programme reviews. In addition, clinical consultations for Pacific Island countries, in-country training for China and Cambodia, DRS data analysis workshop for Philippines, Vietnam and PNG, Drug management courses for Cambodia, Mongolia Philippines, Vietnam and PNG were also held. A Training-of-trainers workshop for PMDT was held in Manila in May 2013 in collaboration with HQ and CDC - USA with participation of 5 countries.

Alignment of notification (laboratory capacity) and enrolment (treatment capacity) is a growing concern, especially after introduction of the rapid diagnostic technology (Xpert MTB/Rif). This alignment of diagnostic and treatment capacity needs to follow the same geographic distribution. In 2011 and 2012, enrolment is more than notified cases to cover up previous back log. There were 6,342 MDR/RR-TB cases enrolled on treatment against 5,749 notified.

The WPRO chair emphasised that factors that help in success of rGLC are visibility, advocacy and the strong support of the rGLC secretariat.

Key issues:

- Financial sustainability
 - The GF allocation for MDR-TB is insufficient to sustain, let alone expand, PMDT services. For the rGLC secretariat function there is an approximate need for USD 220,000, for meeting organization approximate need USD 60,000 and activities approximate need USD 100,000. However the current flow from GF is only USD 200,000/ year
 - Scale up plan depends on the resource availability
- Alignment of diagnostic and treatment capacity is improving but needs to be monitored
- Cure rates among MDR-TB patients remains low
- PPM-PMDT – collaboration with the private sector needs to be expanded and sustained
- Pharmacovigilance in the Region needs to be strengthened

Session 3: To establish strategic priorities for the GDI

Session 4: To establish priority activities and method of work for the GDI

Session 5: To establish GDI workplan and timelines for 2014–15

Since there was continuity and overlap in Sessions 3, 4 and 5, they are being reported together under 'Discussions and action points'.

Discussions and action points:

The following areas were discussed by the core group members:

In relation to the global scale-up of MDR-TB and envisaged role of the GDI

1. There is a need to improve capacity to treat MDR-TB patients in alignment with the diagnostics expansion. As is obvious from the global reports, there is a growing gap between number of RR/MDR-TB patients being diagnosed in the countries and those put on treatment.
2. Global treatment success rate among MDR-TB patients remain very low at 48%. It was evident from presentations of the rGLCs that high loss to follow-up and not evaluated are major contributors to the low treatment success rates observed. Some of the areas that need to be looked into to reduce the high loss to follow-up rate are:
 - a. Social issues leading to high rates of loss to follow-up need to be addressed
 - b. Treatment duration could be made patient friendly using shorter regimen and/or introduction of new drugs
 - c. Focus on vulnerable groups
 - d. Addressing side effects of medicines at the earliest
 - e. Apply frequent interim cohort analysis for early diagnosis system failures (and addressing these)
3. Advocacy for MDR-TB needs to be strengthened for increasing resources. There are several opportunities and renewed interest in anti-microbial resistance, which can be utilised to raise the visibility of MDR-TB and the GDI.
4. The members also emphasised the need for rapid scale-up of SLDST to treat XDR-TB. Ignoring XDR-TB at this stage could lead to a propagation of the infection and spread, in absence of clear policy guidelines for control. This may need a multi-pronged strategy including scaling up second-line DST, new drugs complimented with palliative care.
5. There is a clear need to decide on what disease burden indicators need to be used for which purpose. The WHO STAG for TB in its meeting in July 2013 had recommended WHO to hold a broad consultation on the subject. A consensus document has been developed following the MDR-TB Stakeholders' meeting in Paris in October 2013 incorporating the views of the participants. The CG members expressed a desire to provide inputs on the document prior to its finalisation and dissemination.
6. Strengthening supply chain systems and access to quality assured second-line drugs through GDF support. The members requested GDF representative clarifications on:
 - a. Availability of USAID supported guarantee for purchase of SLDs. The mechanism allows rapid procurement of SLDs by cutting down on lead time involving transfer of funds to supplier. However the current scope and funding availability is limited and hence the mechanism can only be used by a small number of countries.

- b. Access to rotating stock-pile. The stock-pile is currently only available for a relatively small number of second-line treatments and can be used only for emergency situations.
- c. CG members wanted to know the costs and availability of Bedaquiline (BDQ) through GDF, how the GDF plans to monitor the use of BDQ and whether it will face registration issues in countries
- d. Availability of group 5 drugs, especially Clofazimine also remains a challenge for countries.
- e. It was felt that coordination of GDF visits with the GLC monitoring missions and other joint missions (GLI) is important to reduce the burden of monitoring visits in the host country.

Improving access to quality assured drugs also needs to identify and address obstacles in regulating drug use. These are mainly around accessibility issues and implementing the policy related to drug regulations specifically in large countries

The members were also informed about the QuanTB tool. To promote a systems-strengthening approach to TB medicines management, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program developed QuanTB—a downloadable, desktop tool that transforms complicated calculations into a user-friendly dashboard displaying key quantification and supply planning information. By alerting users to risks of stock outs, QuanTB operates as an early warning mechanism. QuanTB allows users to forecast needs of tuberculosis medicines and treatment regimens for any period of time.

Forecasting can be done by:

- The number of enrolled and expected cases per month or by percentage of use of each medicine
 - Either multi-drug or single-drug regimens
7. The CG members also felt that there is need for coordination of technical assistance (TA) being provided through various funding agencies and technical partners. Some of the important partners/mechanisms involved in providing TA are:
 - a. rGLCs through GF grants
 - b. TBCARE
 - c. USAID supported regional grant
 - d. The Union supporting 9 Francophone countries in AFR for shorter regimens
 - e. Technical partners directly involved in TA on PMDT – KNCV, The Union, PIH and WHO
 8. Private sector involvement in PMDT is considered essential and as yet has not received much attention. The members were informed that WHO will be organising a consultation meeting in June 2014 to finalise framework for PPM for PMDT. The framework will be then discussed in next GDI CG meeting.

In relation to functioning of the GDI CG

1. The members discussed whether future GDI CG meetings should always be closed or open. There is the possibility of organising a GDI wide meeting either along with the Union Annual Global World Lung Health Conference in October 2014 or with the 2015 Annual GDI meeting in early 2015. Members felt that given the funding constraints and that this year's Union conference is only about 6 months away, it may be too soon to hold a large meeting involving all stakeholders. Instead the CG members were of the opinion that additional invitees such as the rGLC secretariats, GF representative and some technical experts could be invited as observers, subject to funding availability, to a wider CG meeting in October 2014 at the time of the Union meeting. The lead partners to the Task Forces that are to be established would also be invited to the meeting and present a progress report to the CG. It was also felt that future GDI CG meetings could be held at different locations, linked to respective rGLC meetings, which would enable the involvement of host country's Ministry staff as observers in the meeting.
2. Coordination and communication were of particular interest, particularly with the GDI being a new working group which needs to establish its respective credibility and visibility. There is also a need to develop and maintain relations and good communications with the broader GDI group, other working groups and their sub-groups (e.g. the PPM and Childhood TB sub-groups). A first step is the nomination of a GDI CG representative to the CG of GDI to act as a liaison person (Daniella Cirillo was nominated for this task and accepted). She will circulate the agenda of the monthly call among the GDI members and when specific topics of interest will be discussed, other members of the Core Group could be invited to join the call. There is also need for an advocacy strategy for the GDI.

Based on the discussions, the following strategic priorities and activities were agreed by the CG members:

1. **Develop targeted advocacy strategies and resource mobilization** for DR-TB management scale-up
 - An advocacy task-force to be formed led by Dalene von Delft, TB Proof and Gini Williams, International Council of Nurses (ICN), to develop a concept note for advocacy for DR-TB management scale-up and to raise the visibility of the GDI. Areas for action include:
 - GDI newsletter – structure and contents
 - Use of social media
 - Activities around launch/ re-launch of GDI
 - Tagging to other advocacy activities like the AMR activities. However this may be taken up after the World Health Assembly this year
 - The work will need to be coordinated with the Advocacy Team within the TBP Secretariat.
2. **Facilitate integration and coordination of efforts** to align diagnostic services for patients with access to high-quality care;
 - Formation of a task force that will involve rGLCs, GDF, GDI Core Group and GDI Core Group members, to identify the barriers to enrolment, and the barriers to the linkages

between diagnostic and treatment services. Information systems linking laboratory and patient treatment registers are crucial.

- Map activities currently on-going to address this

3. Build global consensus on the management of DR-TB for patient centred care delivery ("care for cure")

- Task force, to be led by Gini Williams, ICN, will be formed that will
 - Compile a repository of best practices and experience s;
 - During the 4th Q of 2014 a document will be available from a joint assessment by KNCV, WHO, MSH and PIH of different effective models of patients support, with a focus on sustainability of the model.
 - Review available tools;
 - Identify the existing gaps; and
 - Prepare a 'How to' document to assist programmes and projects in implementing patient centres care.
 - Collaborate with existing consultant training mechanisms to train nurse consultants to provide technical assistance regarding patient-centred care

4. Promote strategies to facilitate patient access to high-quality DR-TB care, through a long-term, in-country capacity building approach targeting both the public and private sector.

- A Task force will be established to map, with the rGLCs, needs for capacity building and best practices.
 - Map the gaps - Optimise TA for PMDT in countries
- The International Standards of TB Care (ISTC) to be promoted. Work with the ISTC Steering Committee on MDR-TB related issues; disseminate the ISTC document through the GDI website.
- Explore possibility of a GDI workshop or a GDI approved training for PMDT
- Establishment of Centres of Excellence (COE) for PMDT. This could be at the Regional and/or country level. However the decision on whether the COE is required at Regional or country level can be taken by respective rGLCs depending on the regional needs, resources available and DR-TB burden in countries. Sustainable models are already available in some regions, which could be replicated.
- Routine monitoring interim treatment outcomes. KNCV will share the exercise that they have been doing on cohort analyses and its implication on improving treatment outcomes among MDR-TB patients.
- Promote Public-Private Mix (PPM) for PMDT
 - Map best practices, and finalise and disseminate the WHO Framework for PPM for PMDT.
 - Promote ISTC among all care providers including the private providers
- Mapping best practices
- Finalisation of framework for PPM for PMDT

5. Facilitate effective knowledge sharing among partners and harmonise coordination with existing TA mechanisms to ensure quality support to PMDT;

- Harmonising TA from different partners through TBTEAM
- Review the PMDT consultants list available on TBTEAM website, rGLCs to add
- Ensure engagement of all major partners in PMDT through the rGLC mechanism

- 6. Support prioritization of research** to generate evidence for PMDT scale-up.
- Develop a standardised generic Operational Research (OR) protocol for shorter DR-TB regimens that could be used by countries for quick initiation of OR activities related to the shorter regimens
 - Create a research task force involving the former research sub-group to make a prioritised research agenda.
 - The task force will also prepare a living document collating information on on-going DR-TB research activities which will then subsequently be maintained by the GDI secretariat.
 - The task force will be led by Agnes Gebhard from KNCV and CY Chiang from The Union

All Task Forces will be led by an identified GDI partner and progress in its work will be monitored by the Core Group on a regular basis.

Action points for GDI secretariat:

- Organise monthly GDI CG calls on the first Wednesday of each month.
- Plan for the next GDI CG meeting on 27 October 2014 in Barcelona, close to The Union conference. The meeting will also be an opportunity for task forces to present and discuss their action plan along with progress on the plan to the CG members.
- Publish a GDI newsletter in close coordination with the taskforce on advocacy
- Maintain GDI webpages on the Stop TB website. Immediate action is to update it with a summary of the GDI CG meeting.
- To circulate the MDR-TB burden estimates consensus document among GDI CG members for inputs prior to its presentation to the WHO STAG for TB meeting in June 2014 for endorsement and subsequent dissemination. To initiate a discussion within GTB, WHO on whether a similar exercise should be done on XDR-TB.
- To prepare and circulate a concept note among CG members to seek innovative funding from the GF and other agencies for MDR-TB scale-up activities.
- To organise a webinar on QuanTB in coordination with the GDF.

Annexure 1. List of Participants

GDI Core Group

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20. Vineet Bhatia, GDI Secretariat, GTB/LDR
21. Dennis Falzon, GTB/LDR
22. Linh Nhat Nguyen, GTB/LDR
23. Ernesto Jaramillo, GTB/LDR
24. Fraser Wares, GDI Secretariat, GTB/LDR

Stop TB Partnership Secretariat

- 25. Suvanand Sahu,** Deputy Executive Secretary
26. Andrea de Lucia, Team Leader, Country Support, GDF

Annexure 2. Agenda

Day 1 (1 May 2014)
M.205, WHO/HQ Switzerland, Geneva
Chair: Charles Daley

09.00 – 09.15	Welcome Meeting objectives and declaration of interests	M Raviglione, S Sahu GDI Secretariat (FW)
Session 1 09.15 – 10.30	Objective: To orientate the Core Group members on the Global Drug-resistant TB Initiative (GDI), and the role and function of the Core Group (CG) within the GDI <ul style="list-style-type: none"> • Video • Introductions • Overview of the establishment of the GDI, presentation of the TORs, operating procedures and financing of the GDI and its CG • Nomination of Vice-Chair 	ALL GDI Secretariat (KW) CD
10.30 – 11.00 Coffee		
Session 1 ctd 11.00 – 11.30	Discussions	ALL
Session 2 11.30 – 13.00	Objective: To provide an update on progress in scale up of MDR-TB services and care, and updates on new policies <ul style="list-style-type: none"> • Progress versus targets in the Global Plan, updates from WHO 2013 Annual Global TB, and policies • Key areas of work in 2014 for Stop TB Partnership - Global Fund and Global Plan 2016-2020 • Updates on implementation of regional plans in response to M/XDR-TB, and activities and progress of the rGLCs Discussions	GTB/LDR (DF) GLI (TS) TBP (SS) / GDF (AL) Chairs of the 6 rGLCs ALL
13.00 - 14.00 Lunch		
Session 2 ctd 14.00 – 15.30	Discussions	ALL
15.30 – 16.00 Coffee		
Session 3 16.00 – 17.30	Objective: To establish strategic priorities for the GDI <ul style="list-style-type: none"> • Presentation of proposed strategic priorities Discussions	CD ALL
17.30 – 18.00	Wrap up of Day 1	Chair (CD)

Day 2 (2 May 2014)
M.105, WHO/HQ Switzerland, Geneva
Chair: Charles Daley

09.00 – 09.30	Review of Day 1 discussions and decisions	Chair (CD from Day 1)
Session 4 09.30 – 10.30	Objective: To establish priority activities and method of work for the GDI <ul style="list-style-type: none"> • Presentation of proposed activities and work structure Discussions	Designated CG member ALL
10.30 - 11.00 Coffee		
Session 4 ctd 11.00 – 13.00	Discussions continued	ALL
13.00 – 14.00 Lunch		
Session 5 14.00 – 15.30	Objective: To establish GDI workplan and timelines for 2014-15 <ul style="list-style-type: none"> • Presentation of agreed strategic priorities, activities and method of work Discussions	Designated CG member ALL
15.30 – 16.00 Coffee		
16.00 -16.30	Wrap up and next steps Other business	CG Chair

FW Fraser Wares
CD Charles Daley (CG Chair)
TS Tom Shinnick
AL Andrea de Lucia

KW Karin Weyer
DF Dennis Falzon
SS Suvanand Sahu