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

27 October 2014, Barcelona, Spain

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Background

The first meeting of the Global Drug-resistant TB Initiative (GDI) Core Group (CG) was held in Geneva in May 2014, and this was the second GDI CG meeting coordinated by the GDI secretariat housed in the Laboratories, Diagnostics and Drug resistance (LDR) unit of the Global TB Programme (GTB)/WHO.

Welcome address

Dr Charles Daley, Chair of the CG welcomed the participants and informed them about the purpose of the meeting, along with an overview of the agenda. He reminded participants of the tasks that need to be accomplished by CG before the close of the meeting.

Meeting objectives and declaration of interests

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

- To follow up on recommendations and action points agreed upon during 1st GDI CG meeting and subsequent monthly teleconferences;
- To provide an update on progress in global scale up of MDR–TB services and care;
- To provide an update on the progress of the respective GDI Task Forces, and the request of the Infection Control (IC) sub–group;
- To strengthen communication within GDI, and between the GDI and partners including the GF; and
- To discuss the GDI "Business Plan" and the work plan for 2014–15.

Dr Wares also presented the summary of the interests declared by all CG members participating in the meeting. Of all CG members, 12 declared no interests as per the WHO 'declaration of interests' format, whilst 3 CG members declared interests which were considered no conflict of interest.

Report from the GDI secretariat

In the subsequent session, Dr Wares presented the actions taken by the GDI Secretariat on the recommendations made during the 1st CG meeting. The activities undertaken against each of the recommendation are as listed below:

1. Organise monthly GDI CG calls on the first Wednesday of each month
   - Monthly conference calls using WebEx have been regularly held since the 1st GDI CG meeting, with a total of 5 CG conference calls held to date.

2. Plan for the next GDI CG meeting on 27 October 2014 in Barcelona, close to Union conference. The meeting will also be an opportunity for task forces (TF) to present and discuss their action plan along with progress on the plan to the CG members
   - 2nd GDI CG meeting being held on 27 October as planned in Barcelona. TF leaders to present actions taken to date in subsequent sessions.

3. Publish a GDI newsletter in close coordination with the taskforce on advocacy
   - The 1st issue GDI newsletter was published in August 2014. This has been widely circulated electronically through the GDI listserv and hard copies are being distributed through the WHO booth at The Union conference.

4. Maintain GDI webpages on the Stop TB Partnership (TBP) website. Immediate action is to update it with a summary of the GDI CG meeting

- GDI webpages are being regularly maintained and updated. There are also plans to highlight progress of the 3 TFs and create a repository of tools developed by the TFs on the GDI webpages.

5. To circulate the MDR-TB burden estimates consensus document among GDI CG members for inputs prior to its presentation to WHO STAG for TB meeting in June 2014 for endorsement and subsequent dissemination.
   - Draft document was circulated to GDI CG and GDI members in late May 2014 for comments prior to submission to WHO STAG–TB in June 2014. All comments were incorporated into the subsequent versions of the document.

6. To prepare and circulate a concept note among CG members to seek innovative funding from the Global Fund (GF) and other agencies for MDR-TB scale-up activities.
   - Draft outline of the "GDI Business Plan" was circulated to CG members in early September 2014. The plan is to be discussed in 2nd GDI CG meeting.

7. To organise a webinar on QuanTB in coordination with the GDF.
   - A webinar presentation of QuanTB by MSH was organised during the CG conference call on 4 June 2014.

Other actions taken by the secretariat

- Maintained the GDI listserv which now has more than 300 subscribers. This is an open listserv and any interested person can subscribe to it.
- Oversaw administrative and contractual process for distribution of funding to the 3 GDI Task Forces on Advocacy, Patient Centred Care (PCC) and Research.
- Participated and coordinated with the rGLCs for the external evaluation of the 'GLC MoU' between the GF and WHO. The evaluation report is being discussed within the GF, and is expected to be presented to the GF Senior Management in November 2014 for decision on future arrangements of the GF to support PMDT activities. Decision of the GF will be communicated to all relevant stakeholders as soon as it is available.
- Drafted a proposal for FY 2014 USAID funding of the GDI. Any decision on funding mechanisms is pending due to the transition of the hosting of the TBP Secretariat from WHO to UNOPS as from 1 January 2015.
- Initiated preparations for the 2015 Annual GDI Forum (combined with the Annual GLI meeting and 3rd GDI CG meeting), during the week of 27 April-1 May 2015.
- Oversaw discussions of requested transition of the Infection Control sub–group from the TB/HIV WG to the GDI.
- Maintained coordination with the GLI Secretariat and GDF on relevant issues.
- Co–ordinated with the Sentinel Project for paediatric Drug–Resistant TB, and supported a training workshop on paediatric TB and DR–TB in PR of China, October 2014.
- Oversaw finalisation of WHO's training manuals of the "Management of DR–TB. Training for staff working at DR–TB treatment centres".

The CG members were informed that whilst there are sufficient funds available for holding the 2015 Annual GDI Forum and two face to face GDI CG meetings in 2015, there is as yet no funding available for any activities of the GDI.

Progress in global scale up of MDR–TB services and care

An update on the progress in global scale-up of MDR–TB services and care was provided by Dr Dennis Falzon, LDR Unit, WHO/GTB. Key highlights were:

- In 2013, about 480,000 new MDR-TB cases were estimated to have emerged, whilst 210,000 MDR-TB patients died.
- The WHO/GLI SRL Network, now comprised of 33 laboratories, provides long-term technical assistance to countries. 152 countries and territories reported having a formal link with a partner SRL in 2013.
- Analysis of trends during 2008–2013 shows that, at the global level, the proportion of new cases with MDR-TB remains unchanged at about 3.5%. However, serious MDR-TB epidemics in some countries jeopardise progress.
- Globally, 8.5% of new bacteriologically positive and 17% of retreatment TB cases were reported to have had a drug-susceptibility test (DST) for rifampicin in 2013 – well short of the Global Plan targets of 20% and 100% respectively, set for 2015.
- In MDR-TB patients, the detection of resistance to fluoroquinolones and second-line injectable drugs has important implications for their treatment. In 2013, only 23% of MDR-TB patients had DST results reported for these two classes of drugs – again well short of the Global Plan target of 100% set for 2015.
- In 2013, the number of RR-/MDR-TB cases notified to WHO globally totalled >136,000 (compared to 111,000 in 2012) – an increase of 23% on 2012. However only about 97,000 TB cases were reported to have started MDR-TB treatment in 2013, or about 45% of the Global Plan target for that year. The ratio of enrolled to diagnosed cases was lower than 60% in 10 high MDR-TB burden countries in 2013 and lowest in Myanmar (34%), South Africa (41%), and Tajikistan (30%).
- In the 2011 cohort, the proportion of MDR-TB patients with a successful outcome averaged about 48% globally. Of the 126 countries reporting outcomes for 2011 cohorts, 29 achieved or exceeded the Global Plan target of 75% success.
- Among 1,269 XDR-TB patients in 40 countries for whom outcomes were reported in the 2011 cohort, overall 22% completed treatment successfully and 35% died, whilst 10% failed treatment and 33% were lost to follow up or their treatment outcome was not evaluated.
- By the end of 2013, at least 24 countries reported having used bedaquiline to treat a total of 186 patients as part of compassionate use, expanded access and under normal programmatic conditions. Three quarters of these patients were reported by Armenia, South Africa and Swaziland.

As per the report, key challenges to the MDR-TB response include growing gaps between the number of MDR-TB cases detected and numbers started on treatment, poor treatment outcomes due to health system weaknesses and inadequate drug regimens, and insufficient funding for care and research.

The CG members expressed reservations on the global funding gap (7.8%) for MDR-TB in 2014, based on data reported by countries this year. The CG members were of the view that the USD1.9 billion is a significant underestimation of the true total requirement for PMDT, and that the calculation may have included figures higher than actual contributions from

many countries and also may not have adequately factored in the added costs to increase detection and improve treatment success rates for MDR-TB patients.

Updates on recent WHO policies relating to MDR–TB

Dr Ernesto Jaramillo, LDR Unit, WHO/GTB, presented an overview of recent updates to WHO MDR-TB related polices and guidelines. Interim guidelines for use of bedaquiline were published in 2013, and interim guidelines for delamanid have also now been launched in October 2014. Another recent addition to WHO guidance documents has been the "Companion Handbook to WHO guidelines for the Programmatic Management of Drug-resistant Tuberculosis", that was launched in August 2014. Due to the release of the WHO interim guidelines for the use of delamanid, the Handbook is already under revision with 2nd next edition likely to be available in November 2014. The Handbook is meant to serve as a reference document for various levels of health care staff and programme managers.

WHO's PMDT training modules for staff working at DR-TB management centres will be published before the end of 2014. Additionally, a framework for engagement of all health care providers in MDR-TB care is being finalised after wide consultations with various partners, and is planned to be available before the end of 2014.

WHO guidance on the use of shorter regimens for the treatment of DR-TB cases has been available on WHO's website since 2012. Study protocols compliant with WHO's position statement are now being implemented in Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Côte d'Ivoire, DR Congo, Lao PDR, Niger, Rwanda, Swaziland and Uzbekistan.

The WHO handbook on pharmacovigilance for medicines used in the treatment of TB is now also available in French and Russian.

Next steps: updating of policies in 2015

Several updates to WHO guidelines and policies are planned in 2015, including updates to the 2011 WHO guidelines for PMDT. The guidelines are expected to include updated information on:

- Safety and efficacy of group 5 second-line drugs (SLDs);
- Re-grouping of SLDs;
- Treatment of XDR-TB;
- Treatment of mono/polyresistance;
- Models of care for patients without treatment options; and
- Social support to enhance treatment adherence and improve quality of life.

An update is also expected on the emerging ethical issues in MDR-TB management to include:

- Caring for patients who are a source of infection but have no effective treatment alternatives;
- Forced repatriation of legal and illegal migrant TB patients;
- TB management in prisons;
- Advocacy for TB in the era of DR-TB;
- Ethics of preventive therapy in the context of TB elimination; and
- Management of MDR-TB in children.

WHO's current Infection Control guidelines were issued in 2009. Hence updating of WHO's policy guidelines on TB infection Control will start in 2015 following the well-established GRADE process used by WHO for policy development.

The CG members expressed interest in being actively involved during 2015 in the development of these various updated WHO guidelines.

Introduction of new drugs and regimen

Dr Christian Lienhardt, PSI Unit, WHO/GTB, presented the WHO policy and strategy for introduction of new drugs and regimen. The key principles stated in the WHO Strategic Plan for rational introduction of new TB drugs and regimens in countries are:

- Need for combination regimen(s);
- Adaptation to largely variable country settings (health and NTP infrastructure, geography, demography, TB epidemiology, level of preparedness, etc.);
- Ensure equitable access to safe and quality-assured new drugs for all patients in needs;
- Link with measures to prevent misuse of the drugs; and
- Multistage and pluri-partner process.

The 5 steps for introduction of drugs, as spelt out in the strategic plan are:

- Determination of the type of evidence & data to be required by WHO to recommend the use of new drug(s)/regimen(s) for the treatment of TB, and production of technical information notes;
- Development of a "*Policy Development Framework"* to establish recommendation for the introduction of new TB drugs/regimens in countries;
- Series of Expert consultations to evaluate new TB drugs/regimens coming out of the pipeline and revise/update treatment guidelines as appropriate;
- Recommendations and TA for introduction in countries; and
- Market introduction.

Further details on the subject are available at http://www.who.int/tb/new_drugs/en/index.html

Country preparedness is key to the introduction of new drugs, and it is important to have the necessary background information on the respective Health System and NTP infrastructures, and on the epidemiological data (*"know your epidemics")* for effective implementation. The main issues to be addressed include a working mechanism for delivery of drugs, assessment and understanding of risks to individuals (ADRs, DDIs) and implications, risk of resistance development, and feasibility of potential public health impact and cost-effectiveness.

WHO is launching a Policy Implementation Package (PIP) for the introduction of new drugs during the Union Conference in October 2014. The goal of the PIP is to support countries in preparing for their introduction of new TB drugs and/or regimens, based on WHO policy guidance, in order to better serve patients and communities in need. The PIP includes minimum requirements for country preparedness and planning, implementation plan for introduction of new TB drugs or regimens, pharmacovigilance and drug resistance surveillance, private sector engagement, systems approach for ensuring uninterrupted supply of quality-assured medicines and undertaking operational research.

Updates from the regional Green Light Committees (rGLCs)

All chairs of the rGLCs (except SEAR) presented the progress of the response to MDR-TB in their respective Regions, the challenges currently faced and possible solutions. Dr Hind Satti, Chair AFR rGLC, Dr Raimond Armengol, Chair AMR rGLC, Dr Essam Elmoghazy, Chair

EMR rGLC, Dr Andrey Maryandyshev, Chair EUR rGLC, and Dr Lee B Reichman, Chair WPR rGLC, provided updates on the activities of the respective rGLCs. Dr Rohit Sarin, Chair SEAR rGLC could not attend the meeting and hence no presentation from SEAR was made to the meeting.

AFR

To address the challenges in MDR-TB care in the region, the AFR rGLC has promoted human capacity strengthening for MDR-TB by supporting training courses in Ouidah – Benin and KEMRI-Kenya. Two training courses took place in 2013 where 46 participants from 18 countries received training in TB, TB/HIV and MDR-TB. A PMDT consultant training workshop for AFR will be conducted in late November 2014 in Durban.

In 2014 the rGLC secretariat received at least 30 requests from the GDF to review country's orders of 2nd line medicines. As a consequence of efforts, there have been less emergency requests and stock outs of drugs.

The rGLC is also working in coordination with laboratory experts to implement a well-functioning EQA Programme for National reference laboratories (NRLs) in Africa. The region plans to conduct a 'Stepwise Laboratory quality Implementation Process Towards Accreditation' (SLIPTA) and joint GLI assessment of NRLs in Africa and facilitate the accreditation of NRLs. The region also plans training of a pool of TB laboratory experts to provide services to TB laboratories in Africa, and hence decrease the reliance on external consultants.

In 2014, a total of 15 technical and monitoring missions were undertaken to countries with the aim of country support for DR-TB and DRS. However there is a significant backlog in conducting requested missions.

The 1st face to face meeting of the rGLC committee was in Brazzaville in July 2013. A 2nd informal meeting took place during the Union Conference in Paris last November. The committee members have been reviewing the reports from country missions and providing advice in addition to taking part in some of the missions that have taken place in the countries. The next rGLC face to face meeting is proposed in December 2014.

The African (AFR) region notified more than 18,000 RR/MDR-TB cases in 2012, whilst the number fell to just over 13,500 in 2013. The MDR-TB treatment success has marginally improved from 46% for 2010 cohort to 47% for the 2011 cohort.

Despite large balance in funds (around USD 1m), a major challenge faced by the AFR rGLC is the lack of a full time dedicated staff to support r-GLC. There is also an inadequate supply of consultants for MDR-TB in the African Region. Recently countries have been busy with their GF Concept Notes leaving little time for monitoring missions. It was also stated that there is only one laboratory focal person at WHO Regional Office to support 47 countries. The recent Ebola epidemic has also increased pressure on the already limited staff at AFRO.

The CG members expressed their severe concerns over the unacceptable delay in hiring of the rGLC focal point in the Region. A number of CG members raised the issue of whether alternative or interim solutions could be found outside of AFRO to bridge this gap. The members also urged the rGLC secretariat to utilise all available human resources with the various partners working in the Region to assist in the provision of the required TA to the countries in the region.

AMR

AMR rGLC has held 5 meetings in 2014 (2 face to face, and 3 via conference calls). Monitoring missions were conducted to 16 countries, and country support was provided for SLD requests.

The AMR rGLC has supported the expansion of DST capacity in the region. As of now, there are culture facilities in 24 countries and DST for FLD in 22 countries. DST for SLD is now available in 16 countries, with an additional 8 countries utilising facilities outside their respective countries. Rapid molecular test are also expanding with Xpert MTB/Rif now available in 17 countries (101 units in 2014) and Line Probe Assay (LPA) in 11 countries.

The Committee coordinates international transfers of MDR-TB patients specifically to ensure that transferred patients reach the correct destination in order to continue the proper treatment in the country of arrival. Technical assistance is provided continuously by internet and during the monitoring missions. To boost the HR capacity for TA, a tutoring programme for 16 professionals was organised during the year. There have also been training courses in PMDT - 1 international MDR-TB programmatic management course and several other national courses.

The Region faces challenges with limited funds for carrying out the rGLC activities as there is a decreasing number of countries eligible for GF support under the NFM mechanism. The Committee has also noticed slow implementation of the recommendations provided during the rGLC monitoring missions. There is a limited political commitment in many countries, including budgetary limitations at country level for PMDT. Most of the countries supported by the GF depend almost exclusively on this grant for PMDT activities.

EMR

The EMR rGLC held its 3rd meeting in April 2014, with the 4th meeting planned for November 2014. The committee also held a teleconference during September 2014 to follow up on the implementation of the action plan 2014-2015. Continuous communication online is extended between countries, rGLC secretariat and members of the committee.

Based on regional situation analysis and update of the regional strategic plan the following priority activities were selected for the 2014-2015 work plan of the committee:

- Strengthen planning for expansion of PMDT;
- Strengthen HR capacity;
- Strengthen laboratory capacity;
- Drug management;
- Filling financing gap; and
- Monitoring and OR.

Overall technical support was provided in the region in the form of revising and updating plans for PMDT for 4 countries. A training course was held in September 2014, with three courses on Clinical management, Consultants and Palliative Care respectively are planned in 2015.

To strengthen the laboratory capacity, an inter-country laboratory quality management training was held in Islamabad, Pakistan in October 2014. A report on regional laboratory network situational analysis is also being produced. Drug management support is being provided to the countries in close coordination with the GDF focal point. Countries are also being supported in resource mobilisation to overcome financial gaps, specifically by

supporting preparations of the Concept Notes under the GF's NFM.

In 2013, a total of 4,365 RR/MDR TB cases were diagnosed in the region out of which 393 were from new cases and 3,972 from previously treated cases. About 65% of these cases were initiated on treatment.

EUR

The EUR rGLC has produced the 'Consolidated Action Plan to Prevent and Combat M/XDR-TB in the WHO European Region, 2011-2015'. A follow-up plan is under development, in line with the global End TB Strategy. The strategies included in the plan are:

- Prevent the development of M/XDR-TB;
- Scale up access to effective treatment;
- Scale up access to early diagnosis;
- Improve infection control;
- Strengthen surveillance;
- Expand management capacity of the programmes; and
- Address the needs of special populations.

It is estimated that the absolute number of MDR-TB cases are decreasing in the Region with about 8.4 cases/100,000 population estimated in 2013. However, the percentage of MDR-TB is still on the rise at 16.9% amongst new TB cases and 48.3% amongst the retreatment cases. Information relating to SLD DST remains limited as only a few countries provided data, altogether accounting for just 21% of all notified MDR-TB cases. Coverage of SL DST among the reporting countries was 52%. In total, 525 XDR–TB cases were detected, equating to 12.8% XDR amongst the MDR-TB cases with a SL DST result.

All high priority countries in the Region except Romania, reported use of Xpert MTB/RIF in 2013.

41 Member states maintain an electronic case-based data management system at least for MDR-TB patients at the national level.

Key contributions by rGLC Europe include:

- All High Priority Countries have country adapted M/XDR-TB plans;
- Inputs to workshop on efficient management tools in TB prevention and care;
- Assessing possible causes of loss-to-follow up within ongoing health care reforms;
- Inputs to country adapted infection control plans;
- Assessing underlying causes of lack to access of second line drugs;
- Contribution to the rational introduction of bedaquiline at country level through the consilium approach;
- Continue regional and country PMDT mentorship programme; and
- Close linkage and collaboration with other regional and global initiatives, such as GDI, GDF, ELI, childhood TB taskforce, GFATM and TBTEAM, thus strengthening synergies and effectiveness.

CG members expressed the wish to explore whether the GDI can communicate with the drug regulatory authorities of the respective countries the request that they establish CU or EA programmes, or give waivers, for the introduction of new drugs.

WPR

WPR rGLC held its 1st meeting for 2014 in April in Malaysia to discuss treatment of XDR-TB,

updates on the shorter regimen and also to hold a workshop on PMDT for Malaysian stakeholders. The 2nd meeting is planned in December in Philippines, back to back with the Technical Advisory Group and NTP managers' meeting. During this meeting, there will be working group discussions with countries to identify their priority TA needs. Additionally, regular teleconferences have also been held.

Focused missions have been held in 6 countries in 2014. This includes PCC in Viet Nam, XDR – TB management in Mongolia, Clinical Audit in Cambodia, Pharmacovigilance in Laos and Xpert roll-out in Philippines. The annual mission to PR of China is planned for December 2014.

Other activities in the region include:

- Workshop on strengthening drug regulation in March 2014 where the drug regulatory authorities and NTP had joint discussions and identified priority actions;
- Workshop on Childhood TB Action Plans where Maternal and Child Health staff, Paediatricians, and NTP came together to discuss and develop the action plans;
- New drugs introduction in the Philippines and Viet Nam;
- Shorter regimen preparation workshop in Laos, the Philippines, and Viet Nam;
- Z-Mfx resistance surveillance in the Philippines; and
- Stock pile management for the Pacific Island countries and areas.

Papua and New Guinea (PNG) has been a recent focus country for the rGLC because of the reported high proportions of MDR– and XDR–TB cases. The emergence of resistance is being ascribed to a poorly performing NTP. The WPR rGLC was approached in July 2014 regarding management of 7 XDR–TB and 2 "pre–XDR-TB" cases. The rGLC reviewed all the available patient data and reports and expressed its deep concern on the current situation of MDR-TB management (and overall NTP performance) in PNG. With the current condition of the NTP, the rGLC is not in a position to recommend PMDT or individualized treatment on a national scale.

Joint GDI and GLI CG session

A combined session of the Global Laboratory Initiative (GLI) CG and the GDI CG was held to discuss the issue of growing gaps between the number of MDR-TB cases detected and the numbers started on treatment. The session was addressed by Dr Mario Raviglione, Director WHO/GTB, who highlighted the five priority actions recommended by WHO to address the problem of MDR-TB, namely:

- Prevent the development of drug resistance through high quality treatment of drug-susceptible TB;
- Expand rapid testing and detection of drug-resistant TB cases;
- Provide immediate access to effective treatment and proper care;
- Prevent transmission through infection control; and
- Increase political commitment with financing.

Dr Thomas Shinnick, GLI Chair, presented a summary of activities undertaken by the GLI taskforces in the last year. He presented the GLI structure and governance process, which are very similar to those of the GDI. Regarding the formation and functioning of taskforces under the GLI, Dr Shinnick mentioned that all taskforces have adequate partner representation and defined deliverables with an established timeline. A project review process is always established and lead partner identified. He also presented the proposed priorities for GLI. The importance of alignment of the national strategic plan (NSP) with the national laboratory plan was highlighted in the presentation and that the Concept Note

developed by countries for GF support has to reflect country diagnostic needs among other PMDT issues.

In relation to the growing gap between the diagnosed and enrolled RR/MDR-TB cases, the joint group stated that some of the common identified challenges include:

- Unequal resource allocation for diagnosis and care of MDR-TB patients because of laboratory and programme planning in isolation;
- Diagnostic and treatment algorithms are not always clear to the treating clinicians and they are often not relying on Xpert/MTB Rif results even when the patient is found to be Rif resistant and wait for the culture & DST results before making any clinical decisions. Often the patients' selection criteria are not developed properly resulting in different interpretation of the final findings;
- Policy of hospitalisation in some countries at the start of treatment, but not with enough bed capacity to ensure prompt patient enrolment on treatment;
- Laboratory networking issues because of different location of microscopy, GeneXpert and culture & DST facilities; and
- Other health system issues, such as the disconnect between laboratory and NTP information systems

Ideas for joint GDI/GLI action discussed during the meeting included:

- Ensuring that National TB laboratory plans are incorporated in NSPs;
- Development of a training module for Clinicians and nurses on the utility and interpretation of Xpert MTB/RIF results;
- Development of guidance on forecasting diagnostic and treatment needs;
- Development of mHealth solutions to ensure laboratory results are linked with patient records including HIV status; and
- Establish updated diagnostic algorithms and specimen referral mechanisms.

The members had extensive discussions on field experiences and the possible reasons for the growing gap and suggested a few ideas. The joint action plan based on these ideas will be crystallised in coming weeks over e-mail, including possible formation of a task-force specifically for addressing this issue. The GDI and GLI core group members agreed that a joint advocacy strategy is needed to reduce the growing gap between diagnosis and treatment.

Progress of the respective GDI task forces

Presentations were made by the 3 GDI taskforces on Advocacy, Patient Centred Care (PCC) and Research, regarding their accomplishment to date and possible future work. The task forces were formed after the discussions during the 1st GDI CG meeting and became operational in August/September 2014.

1. The GDI taskforce for PCC is being led by Ms Gini Williams, ICN. The taskforce was established with the objectives of identifying gaps and priorities for development of additional practical tools for operationalising patient-centred PMDT. The taskforce will also look into ways and means to address urgent concerns regarding access to diagnosis and enrolment on treatment once diagnosed, high rates of loss to follow up and unknown treatment outcomes, and assist programmes in moving from hospital-based to community-based care. The taskforce will put together a repository of information and guidance on PCC.

The taskforce issued a call for membership through the GDI listserv in August 2014 and held its first teleconference in September. Requisite tools and materials have been gathered and it is expected that the repository will be created by the end of November 2014.

A nurse consultant training is planned in Manila from 17 – 21 November 2014 in coordination with the WPR rGLC. The training will include practical exercises and site visits organised in collaboration with the Philippines NTP.

Subject to availability of funds, the PCC taskforce intends to organise following activities in 2015:

- Management of repository plus development of practical tools for assessment, planning and implementation of patient-centred PMDT;
- Advocacy to ensure patient-centred PMDT is properly planned and funded within scale-up activities; and
- Nurse consultant training in all remaining regions, starting with AFRO and EURO.

2. The advocacy taskforce being led by Dr Dalene von Delft presented the work and plans of the Human Spirit Project being undertaken by the taskforce. The Human Spirit Project aims to promote a world with zero deaths, zero disease, and zero suffering due to tuberculosis and drug-resistant tuberculosis and reducing burden of disease in the patient, family, and community. It aims to accomplish this by messaging through the use of online short films, a comprehensive and informative website, and using the social media and screenings

The project has developed a key message line – 'PSsssssssssT! It's an emergency!' based on the principles of Prevent DR-TB, Swifter diagnosis, Stronger, Safer, Simpler, Shorter, Scalable Systematic, Sustainable, Stigma free, Socio-economically supported Treatment. The advocacy task force has also produced a short advocacy film for screening. The film will be screened for the first time at a meeting immediately after the CG meeting.

Based on the current work, potential future projects for the taskforce include:

- Unmask stigma;
- TB in health care workers/ infection control;
- Human spirit project expansion – screenings, stories;
- Kick TB & HIV – Russia FIFA 2018; and
- Ask?
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3. The GDI Taskforce on Research is led by Dr Agnes Gebhard, KNCV and Dr Chen Yuan Chiang, The Union. Three priority tasks were decided upon by the Research task force and the update on progress to date is as below:

Task 1 - Develop a prioritized research agenda related to PMDT scale-up. The task force is building on the work done by the former MDR-TB research subgroup, led by Carol Mitnick and Susan van den Hof. Through an announcement on the GDI listserv, a wider range of interested members were recruited to the current work. This was followed by creation of an inventory of the information yielded by the global consultation for the new global PMDT research agenda conducted from the end of 2013 to early 2014 under the leadership of "Resist TB". A wide range of resources were consulted including relevant documents produced by CDC, ECDC, MSF, NIAID, Stop TB Partnership and WHO,

The list was circulated to the TF members who were asked to select and rank the top 5 within:

- Laboratory support (10 questions);
- Treatment strategy (7 questions);
- Programmatically relevant research (18 questions);

- Epidemiology (13 questions); and
- Management of contacts (8 questions).

Next steps for the draft prioritised agenda:

- Disseminate among the CG and the wider TF membership for comments;
- Revise the draft;
- Present final draft prioritized research agenda to the GDI GC for endorsement; and
- Submit for publication in a peer reviewed journal.

The CG members requested the TF to have another look at the research categories as they appear to be too broad and hence may miss some of the relevant topics.

Task 2: Preparation of information on ongoing DR-TB research activities. An e-mail group was made of members of the Resist-TB research group (derived from the former research subgroup of the Stop-TB MDR WG) and all GDI members who expressed interest to the GDI secretariat and/or the TF that they would like to be a member of this task force, and of individuals suggested by GDI CG members of being involved in PMDT-relevant research. A questionnaire was sent out to the people on the list to request information on ongoing research related to PMDT, and asking for more contacts of people / groups doing relevant research for the overview. Mails were also sent to RESIST-TB research group (former research subgroup of MDR-TB WG), TB Alliance, ACTG, LSHTM, MRC, TBPANNET/TBNET, EDCTP, Otsuka, Janssen and others. The TF members also cross-checked the results with trial group websites: RESIST-TB, TB Alliance, TBTC, ACTG.

5 broad categories of research were identified: Laboratory Support, Treatment Strategy, Programmatically Relevant Research, Epidemiology and Management of Contacts.

Next step: adjustments to be made following the upcoming Clinical Trials meeting in December 2014.

Task 3: Develop a generic operational research protocol for shorter DR-TB regimens
The first draft of the protocol was developed by Chiang Chen-Yuan and Arnaud Trébucq. The draft was reviewed by colleagues from MSF, KNCV, WHO and a number of other independent experts.

The protocol is now being shared with GDI CG members with the specific question of whether the protocol is sufficiently generic to allow for local adaptation, and to encourage harmonization of study methodology, for comparability of the primary and secondary study results. It was clarified that the protocol is not meant to be a handbook or recommendation on shorter regimens, but rather a guidance note with reference to relevant documents.

TB Infection Prevention and Control (IC) sub-group discussions and request to GDI

Dr Carrie Tudor, vice-chair of the IC sub-group, presented the outcomes of the latest IC sub–group CG meeting and the background to its request to move under the GDI umbrella. At its recent meeting, the IC sub–group had identified its mission and strategic priority areas, and has now begun to develop a strategy focusing on global TB transmission prevention and control measures.

There was unanimous agreement amongst the GDI CG members to the request of the IC

sub–group to move under the GDI umbrella and to provide a seat to the IC sub-group on the CG. The operational modalities and future functioning of the IC sub-group need to be discussed at a later date.

Strengthening communications within and outside the GDI

This session discussed the strengthening of communications within and outside the GDI. The issue had been highlighted in the recent evaluation report of the GLC MoU undertaken by the Global Fund. The members were reminded that the Secretariat is maintaining the GDI website (http://www.stoptb.org/wg/mdrtb/), is regularly sharing information through the GDI listserv with over 300 subscribers, has published the 1st newsletter, and maintains close links with the GLI Secretariat.

However web-space needs to be provided for the taskforces on the GDI website to share documents and tools, reporting from the rGLCs on their activities to the GDI Secretariat needs to be improved for donor reporting, increased interaction between the rGLCs and Regional partners and funding agencies, and strengthening communication with the other TBP working groups.

The CG members agreed to work on this aspect after reviewing the GLC MOU evaluation report that is expected to be available for dissemination by the end of November 2014.

Development of GDI business plan

The final session discussed the GDI "Business Plan". It was proposed by the Secretariat that rather than a "Business Plan" it could be called a "costed Global Framework for scale-up of MDR-TB services". The majority of CG members felt that the plan needed to spell out where we want to be with regard to PMDT expansion both in the short term and the long term (10 year period) i.e. have a big vision for diagnosis, treatment and all elements of care, what resources will be required, and how all partners can be brought into the envisaged required activities. The envisaged activities should not be limited just to what the CG members can do, but that the agreed activities can be layered to what the CG members can do and also what can be done by the various other stakeholders. GDI CG members could chose to lead specific work areas, but the actual taskforce lead could be outside the CG members. The plan should include innovative and strategic activities that all partners can buy into.

It was agreed that the global transition framework developed in 2010/11 needs to be reviewed, and any lessons learnt can be utilised to inform a concrete action plan for the GDI. It was proposed that a small group of GDI CG members could meet in early 2015 to provide shape to the proposed GDI plan.

Recommendations and follow-up action points

1. Convene in early 2015 a small group of CG members to develop a draft of the GDI "costed Framework" document.
2. GDI CG to seek representation on the taskforce working on the next Global Plan to Stop TB development to ensure adequate inclusion of MDR-TB activities and budget calculations after having produced the global framework as discussed above.
3. GDI secretariat to discuss with relevant staff in WHO GTB about the funding gap calculations for global MDR-TB scale-up, and to share the concerns of the CG members and revert to the CG with clarifications.
4. The GDI and GLI Chairs, and respective Secretariats to coordinate the finalisation of a set of proposed joint GDI/GLI activities. These are then to be shared with the respective CGs for further discussion, inputs and agreement.

5. Further discussion is needed on the following documents/tools which may be useful to align diagnostic and treatment services:
    a. Checklist of criteria to evaluate NSPs for linkage between the laboratory and programme;
    b. Laboratory network development guide;
    c. The TB laboratory consultants guide being developed by the GLI could have sections on alignment;
    d. Case studies providing rationale for alignment;
    e. Clear guidance on how to deal with discordant results and their dissemination;
    f. Joint advocacy with message that no diagnosis should go without treatment;
    g. Working with relevant experts for mHealth solution to ensure lab results are linked with patient records including HIV status; and
    h. GDI supporting the development of Clinicians and Nurses modules for interpretation and use of Xpert MTB/RIF results.
6. To explore with the TBP Secretariat the administrative processes that need to be completed for the IC subgroup to move under the GDI umbrella and to provide the IC sub-group with a seat on the GDI CG;
7. To start preparations for the 2015 Annual GDI Forum in late April 2015;
8. Start preparations for the 2nd newsletter of the GDI. All GDI CG members to send ideas and stories for the next newsletter;
9. Consider allocating time for one rGLC during each of the CG teleconference to discuss their specific issues in details and how the GDI can support the respective rGLCs;
10. GDI Chair to seek clarification of the future of the Working Groups and funding for 2015 GDI activities from TBP Secretariat;
11. Invite CG members to contribute to WHO's guideline development processes to be undertaken in 2015; and
12. GDI CG members to provide feedback within one month on:
    a. Draft generic protocol for introduction of shorter regimen for MDR-TB;
    b. Draft prioritized research agenda; and
    c. Overview of the ongoing research.

Annex 1: Agenda

Chair: Charles Daley

08.30 – 08.45	Welcome Meeting objectives and declaration of interests	GDI Secretariat (FW)
Session 1 08.45 – 09.15	Objective: To follow up on recommendations made and action points agreed upon during 1st GDI CG meeting in May 2014, and subsequent monthly teleconferences • Report from the GDI Secretariat • Discussions	GDI Secretariat (FW) ALL
Session 2 09.15 – 10.30	Objective: To provide an update on progress in scale up of MDR-TB services and care, and updates on new policies • Updates from WHO 2014 Annual Global TB and on new policies, including introduction of new drugs • Updates on implementation of regional plans, and activities and progress of the rGLCs	GTB/LDR & PSI (DF / EJ / CL) Chairs of the 6 rGLCs
10.30 – 11.00 Coffee		
Session 2 ctd 11.00 – 11.30	• Updates on implementation of regional plans, and activities and progress of the rGLCs ctd • Discussions	Chairs of the 6 rGLCs ALL
Session 3 11.30 – 13.00	**Combined GLI and GDI meeting** • GLI experience on operationalizing taskforce/s work plan and lessons learned • Joint activities to align diagnostics and treatment • Discussions	GLI (TS) GLI (TS) / GDI (CD) ALL
13.00 - 14.00 Lunch		
Session 4 14.00 – 15.30	Objective: To provide an update on the progress of the respective GDI Task Forces, and the request of the Infection Control (IC) sub-group • Progress of the respective GDI Task Forces • Request of IC sub-group to move to the GDI • Discussions	Task Force Leaders Co-Chair, IC sub-group ALL
15.30 – 16.00 Coffee		
Session 5 16.00 – 16.45	Objective: To strengthen communication within GDI (including rGLCs), and between the GDI and partners including the GF • Issues with communication between the various components of the GDI • Discussion	GDI Secretariat (VB) GDI members
Session 6 16.45 – 17.30	Objective: To discuss the GDI "Business Plan" and GDI work plan for 2014–15 • Potential scope and audience of the GDI "Business Plan" and GDI work plan for 2014–15 • Discussions	Chair (CD) ALL
17.30 – 18.00	Wrap up and next steps Other business	Chair (CD)

FW	Fraser Wares	DF	Dennis Falzon
EJ	Ernesto Jaramillo	CL	Christian Lienhardt
TS	Tom Shinnick	CD	Charles Daley
VB	Vineet Bhatia		

Annex 2: List of Participants

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21. **Carole Mitnick,** GDI DR-TB Research Task Force
22. **Tom Shinnick,** Chair, GLI
23. **Carrie Tudor,** Vice-Chair, IC sub-group
24. **Mohammed Yassin,** TB Advisor, GF

WHO Geneva

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26. **Dennis Falzon,** GTB/LDR
27. **Ernesto Jaramillo,** GTB/LDR
28. **Christian Lienhardt,** GTB/PSI
29. **Linh Nguyen,** GTB/LDR
30. **Fraser Wares,** GDI Secretariat, GTB/LDR
31. **Diana Weil,** GTB/PSI