3rd Global GLC meeting
World Health Organization, Geneva, Switzerland, 17-19 October 2012
Meeting report
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Welcome of participants
Dr Karin Weyer, Co-ordinator, LDR Unit, STB, WHO, and Aamir Khan, Chair, MDR-TB Working Group, Stop TB Partnership, welcomed all the members to the third gGLC meeting. The global discussions on MDR-TB have significantly moved forwards from the earlier ones on procedural issues to the crucial topic of how the global framework and partners are to support the countries in their efforts to scale-up MDR-TB services and management. To plan for the next steps on the moving forwards with global support to scale-up MDR-TB services and care, the members of the MDR-TB Working Group’s Core Group have been invited to attend the 3rd gGLC meeting and were welcomed to the meeting. On the morning of 19 October 2012, the plan is hold a joint gGLC and Core Group meeting to further discuss the way forward.

Members were reminded of the need during the meeting to focus on the important strategic issues such as: access to diagnostics; access to quality assured second line drugs (SLD) and the market dynamics related to SLDs; and issues with treatment regimens for R-resistant and MDR-TB cases. These and other issues were to be discussed during the meeting, and WHO is looking forward to the gGLC’s advice.

Declaration of Interests
Chuck Daley, Chair of the gGLC, thanked the speakers and all participants introduced themselves. Interests were declared and discussed. No conflict of interest was identified.

Meeting objectives
The objectives of the 3rd gGLC meeting were presented, namely:
• To provide an update on progress and achievements of the rGLCs in supporting MDR-TB management scale-up
• To provide an update on WHO Expert Group meetings, consultations and proposed new policies
• To provide an update on the Global Drug Facility and drug availability
• To provide advice on treatment regimens for R-resistant TB patients
• To provide an update on "short" regimens for MDR-TB treatment, and to present WHO’s position and action
• To discuss the "Moving Forwards" on global support to scale-up MDR-TB services and care

Session 1 – Report from the gGLC Secretariat
Objective: To follow up on recommendations made and action points agreed upon during the 2nd gGLC meeting

Dr Fraser Wares, gGLC Secretariat, presented the global position of MDR-TB and scale-up of services, and progress made in implementing the recommendations and action points from the 2nd gGLC meeting.
In 2010, the Stop TB Partnership launched its Global Plan to Stop TB (GPSTB), 2011-2015 having, as an ultimate focus, the elimination of TB in the world by 2050. The plan has important implications for the funding of MDR-TB activities to detect patients, notify them and place them on adequate treatment. The plan includes 6 objectives aimed at reducing the global burden of drug-resistant TB with intermediate targets to be reached by 2015.

In 2011, it was estimated that the global incidence of TB was 125 cases per 100,000 population, with most cases occurring in Asia (59%), and Africa (26%). Out of the 12 million (10-13 m) prevalent TB cases, around 630,000 were estimated to be multidrug-resistant, with over 60% of cases estimated to occur in Brazil, China, India, the Russian Federation and South Africa. When it comes to MDR-TB incidence, it is difficult to conclude on global or regional trends as a result of incomplete data on the frequency of MDR among TB cases. For some countries (e.g. Latvia and USA) and regions (e.g. Orel and Tomsk in the Russian Federation), time trends based on observations over several years indicate a decrease in MDR-TB frequency of late, while in others (e.g. Botswana and Swaziland) there appears to be an increase.

Another cause of concern is that the highest levels of MDR-TB ever reported occurred in recent years. In Belarus, parts of the Russian Federation, and in Uzbekistan, more than 1/5 of new TB cases now have MDR-TB. Swaziland reported the highest level of primary MDR-TB ever reported in Africa in 2009 (7.7%). While MDR-TB occurs in about 3.7% (95% CI 2.1%-5.2%) of new TB patients, levels are much higher in those previously treated – 20% (95% CI 13%-26%). There has been important progress in recent years in the global coverage of data on anti-TB drug resistance. To date, 135 countries have data from at least one representative survey or, in the case of 63 countries, from good-quality continuous surveillance systems. By early 2013, it is expected that all high TB and high MDR-TB burden countries will have baseline data on drug-resistance.

By 2011, 21 of the 36 countries with either a high burden of TB or MDR-TB had at least 1 laboratory capable of performing culture for tuberculosis per 5 million population. The Global Plan target for 2015 is that all 36 countries reach the minimum threshold. In most of the countries in Africa and the Indian subcontinent, the coverage is particularly low, while conversely many of the countries in eastern Europe are over-provided raising concerns about the quality of analyses performed. Of the 36 countries, 9 reported >1 laboratory / 5 million population using line probe assay to detect rifampicin and isoniazid resistance.

Globally 4% of new bacteriologically positive TB cases were reported to have tested for drug-susceptibility (DST) in 2011, far short of the 20% target set for 2015 by the Global Plan. The low score is partly due to a lack of sufficient access of TB patients to (DST). Another reason could be low capture of results from laboratories owing to inadequate TB information systems. DST coverage is higher among retreatment cases than among new cases but still distant from the 100% overall target of by 2015. In the European Region, while the coverage in new cases has exceeded the 20% level targeted by the Global Plan (56%), 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 (27%).

About 9% (6.7-11.2%) of MDR-TB cases in countries with representative surveillance data have additional resistance to a fluoroquinolone and a 2nd line injectable agent (extensively drug resistance; XDR-TB). The detection of XDR-TB is important for programme management and 2nd line DST is recommended for all confirmed MDR-TB patients. In 2010, only 23% of MDR-TB patients were reported with a test result. The high coverage in Africa drops to 9% without the data from South Africa. Under-reporting of test results accounts for a large degree of the low coverage in certain Regions. By October 2012, 84 countries had reported at least one case of XDR-TB. Coverage of testing for second-line DST among MDR-TB cases is particularly low in the African continent as a result of low capacity for testing.

A substantial increase in the notification of MDR-TB cases and their enrolment on treatment occurred between 2009 (30,485) and 2011 (55,597). Notifications in 2011 were however less than a half of what was aimed for in the Global Plan and represents less than a fifth of the estimated burden of cases which could have been detected had DST been accessible to all TB cases notified in the world. Regional variations are large and coverage is lowest in the regions where the large majority of TB cases occur.

The proportion of MDR-TB patients with a successful treatment outcome varied substantially between countries, and averaged to about 48% globally. Of the 107 countries reporting outcomes, only 30 achieved or exceeded the Global Plan target of 75% success.

In 2015, it is estimated that USD $2 billion will be required for the diagnosis and treatment of MDR-TB. Funding available for MDR-TB has increased from USD $0.5 billion in 2009 to USD $0.6 billion in 2011 in countries with data (representing 75% of estimated MDR-TB cases in the world). Costs for second-line drugs alone amount to USD $0.3 billion a year. Funding for MDR-TB has however been increasing in all country groups and is expected to total USD $0.7 billion in 2013, much of which is accounted for by the “BRICS” countries. Low- and lower middle-income countries estimate a funding gap of about one third of their MDR-TB budget in 2013. About 85% of available funding is currently concentrated in the 27 high MDR-TB burden countries. There is domestic capacity to fund the investments needed for basic TB care and control in the BRICS countries. An increase in domestic allocations for TB care and control in line with forecast growth in GDP per capita would be sufficient to mobilize the funding needed for diagnosis and treatment of MDR-TB in BRICS. In India, without growth in domestic allocations for TB above forecast growth in GDP per capita, about USD $0.1 billion per year is needed from donor sources. 14 countries not in the list of 22 HBCs but are in the list of 27 high MDR-TB burden countries are all European countries. 6 are UMICs and 1 is a HIC. Of the 7 LICs and LMICs, domestic funds may be adequate if rationalization of hospital care is done. The 17 non-BRICS HBCs need donor funding of USD $0.3-0.5 billion per year to reach the GPSTB targets. LICs need USD $0.2-0.3 billion per year, of which
USD $0.1-0.2 billion per year is in countries outside of the 22 HBCs. Additional investments are needed to scale-up rapid molecular diagnostics.

Progress and achievements made since the 2nd meeting was presented following the 6 points under the “Global Framework for Management of MDR-TB”, namely:

1. **Technical support**
i. 4 rGLCs are fully operational; the rGLCs in AFR and EMR are expected to be operational in the coming months (see **Session 2**).
   
   ii. From October 2011 to September 2012:
   
   • 75 monitoring and technical assistance (TA) missions for MDR-TB management capacity building to 67 countries were carried out;
   • TA was provided to 14 countries for the design and implementation of surveys and surveillance to monitor the magnitude of anti-TB drug resistance;
   • TA was provided to 8 countries to reinforce the recording and reporting of drug-resistant TB care;
   • TA was provided to 9 countries for the development, implementation or monitoring of infection control guidelines; and
   • TA was provided to 35 countries in relation to country-specific TB diagnostics capacity building needs.

   iii. Case study of 12 countries on-going to identify bottlenecks and delays in scale-up of MDR-TB services, and recommend solutions to tackle the identified bottlenecks and delays. Findings will be presented at the 4th gGLC meeting.

2. **Second-line anti-TB drugs**
i. Since July 2011, there has been direct access to GDF for procurement of QA SLDs. It is also possible to procure partial regimens through GDF, with the proviso that the SLDs supplied are used only in conjunction with QA drugs.

   ii. From September 2011 to October 2012, orders for SLDs were received by GDF from 72 countries. To date, almost 29,000 patient MDR-TB treatments have been supplied in 2012 (c.f. 2011: 19,605 supplied).

   iii. Updates on GDF and status on SLDs, and on clofazimine provided during **Session 5**.

3. **Advocacy**
i. There has been limited progress on the development of the comprehensive advocacy strategy to support the expansion of DR-TB management as supported by the gGLC. This was for further discussion in the **Sessions 9 and 10**.

   ii. Two chapters dedicated respectively to “Drug-resistant TB” and “Diagnostics and laboratory strengthening” were included in the 2012 WHO Annual TB Control Report. The report was launched in October 2012. For 2012, this replaced the request from the gGLC for WHO to produce annual MDR-TB progress reports until 2015.

4. **Monitoring and Evaluation**
In addition to the wealth of information and data included in the 2012 WHO Annual TB Control Report:
i. The respective rGLCs have planned and implemented annual monitoring missions for 2012. The 2013 plans will be developed in the coming months.
ii. Monitoring missions were undertaken to 51 countries from October 2011 to September 2012.
iii. A progress report on the WHA Resolution 62.15 was provided to the WHO Executive Board meeting (January 2012) and to the World Health Assembly (May 2012).
iv. The timeliness of submission of reports appears to be still a challenge, and the respective rGLCs were requested to comment further on this matter (Session 2). In view of the crucial role played by the Global Fund (TGF) in supporting much of the monitoring activities under the GLC Initiative, the timely submission of reports will become even more important with the signing of the new Memorandum of Understanding between TGF AND WHO, and the increased imperative of TGF to provide evidence for “value for money” of all funds disbursed.
v. In 2012, the LDR and TME Units, STB, have “systematised” the six-monthly collection of “early” data on three indicators: (i) notified MDR-TB cases; and enrolments on (ii) MDR-TB and (iii) XDR-TB treatment, from 32 priority countries. To date, 26 countries had reported.
vi. The development of plan for the evaluation of the Global Framework is pending. This needs further discussion and advice from the gGLC and rGLCs.

5. Policy and Guidelines
i. Acceleration in diagnostics:
   • The Guidance for Xpert MTB/RIF implementation is being refined based on the increasing evidence on the use of WHO-recommended diagnostic and clinical algorithms in different epidemiological and health care settings, following "Early Implementers" meeting, April 2012; and
   • Guidance on 2nd line DST from EGM, March 2012. (Session 4)
   • Increased access to new diagnostics and laboratory strengthening (GLI, and EXPAND-TB and TBxpert projects – Session 8).


iii. Treatment Guidelines:
   • A technical consultation on "TDR-TB" was held by WHO in March 2012 (Session 4).
   • A meeting of a small Working Group on “Duration of MDR-TB Treatment” (as per the WHO 2011 PMDT Update) was held by WHO in March 2012.
   • Position statement developed by WHO in relation to "Short" regimens for treatment of MDR-TB (Session 7).
   • The Task Force on “New drugs and their rationale introduction”, met in April and October 2012, with 2 gGLC members on the Task Force.

iv. Recording and reporting
   • Simplified definitions of cure and failure for DR-TB developed; pilot ongoing in 12 countries of these proposed new definitions.
   • e-R&R systems implemented in 5 countries.

v. Products planned in 2012-13
• “Companion handbook” to PMDT 2011 Update (Q4 2012)
• Modules for TOT on PMDT (Q3 2013)
• Meetings with countries and key stakeholders around UNION meeting in KL (November 2012) to review country plans, progress, and highlight bottlenecks and weaknesses (Session 10).
• Analytical and policy work on PPM-MDR TB, m-health and community based care for MDR-TB (supporting product developed by TBCARE II) (Q2 2013)

6. Advice to funding agencies
i. The provision of advice, particularly to TGF, is on-going on a regular basis. This forms an important role in TGF Phase 2 discussions prior to TGF Phase 2 Panel meetings.
ii. A proposal for SLD treatment to match the approved diagnostics proposal, was developed (led by TBP) and submitted to UNITAID in May 2012. Unfortunately the proposal was unsuccessful proposal (Session 5).

In conclusion, even if most TB patients globally are not drug-resistant, the burden of MDR-TB continues to represent a formidable challenge to global TB control; the coverage of DST for TB patients remains low and as a result only a minority of DR-TB patients are detected and notified; and that the treatment of MDR-TB is complicated and less effective than for drug-susceptible TB. Countries need to place more MDR-TB patients on adequate treatment and strive to attain the GPSTB Plan target of 75% success. The monitoring of the MDR-TB response needs to take advantage of modern technology to collect data efficiently and provide managers with indicators for timely action. To reach the GPSTB Plan targets, substantial resource mobilization will be needed, both from domestic and from external sources. SLD prices however remain a major barrier to scale-up. Finally, the Global Framework is now well established and working. The focus now needs to be on the rapid scale-up of DR-TB services, with focussed attention on capacity building in countries, introduction of rapid diagnostic tests, price reduction of SLDs, advocacy, etc.

Session 2 – Report from rGLCs
Objective: To provide an update on progress and achievements of the respective rGLCs in supporting MDR-TB management scale-up

The rGLCs for the American, European, South-East Asian and Western Pacific Regions are now fully operational. And the rGLCs for the African and Eastern Mediterranean Regions are expected to be operational by end Q4 2012. Dr Domingo Palmero, Chair AMR rGLC, Dr Askar Yedilbayev, representative EUR rGLC, Dr Rohit Sarin, Chair SEAR rGLC, and Dr Lee Reichman, Chair WPR rGLC, provided updates on the activities of the respective rGLCs.

AMR rGLC
The ad-hoc rGLC, set up in July 2011, has held regular meetings every 2 months during 2012 - 2 in person and the rest by teleconference. By the end of 2012, ad-hoc AMR rGLC will finish its task of continuation and adaptation of the “old” GLC
procedures and missions to the Americas countries, and that the call for applications of new members to replace the current ad-hoc rGLC, would be issued in October 2012. Although most countries now have MDR-TB expansion plans available, there is the continued need for the development of guidelines (e.g. DR-TB management, infection control). Case detection needs to be increased and this will require the introduction and wide implementation of the rapid molecular techniques. The timely supply of SLDs remains a challenge – first delay is from within the countries themselves, compounded by delays outside of the countries. There have been M&E and TA missions to 15 countries in 2012. A larger pool of experienced consultants are needed, alongside capacity building within the countries.

**EUR rGLC**

Monthly GLC-Europe meetings via WebEx, with one in person meeting, have been held. Monitoring missions are being conducted as far as possible jointly with TGF and GDF. A new format of the GLC-Europe report and new TOR for GLC-Europe experts have been developed. There have been 17 missions to countries in 2012. Workshops have been organised for the development/update of National M/XDR-TB Response Plans. The challenge of the high burden of M/XDR-TB in the region remains, with major issues related to early diagnosis and enrolment of cases, and poor treatment success rates. A concern was raised about the sustainability of programmes, including MDR-TB activities, after the support of TGF ends to many countries under the new funding mechanisms. A lot of work has been done on reviewing and revising the existing Health Services and Health Financing systems in the Member States. However much remains to be done. The provision of TA to Member States will continue, in particular to support the development and implementation of National M/XDR-TB Response Plans in the 18 high-burden countries. A number of Task Forces have been established and are working on MDR-TB related areas e.g. to prevent and control TB and MDR-TB among children; to document the role of surgery in TB and MDR-TB; to address the problem of TB and M/XDR-TB among vulnerable population (prisons, migrants); etc. As political commitment is crucial to the revision of health service and financing systems, high level advocacy will be needed.

**SEAR rGLC**

The rGLC was established in April 2012 with 9 members and had its first meeting in May 2012. At the meeting, the chair and vice chair were elected, and the TOR were defined for the rGLC. The second meeting is planned in early Dec 2012. There have been 4 rGLC missions to countries in 2012. Less than 5% of the estimated MDR-TB cases are registered for treatment by NTPs. In addition to the huge numbers who are not getting treatment, a significant number of cases are being treated under unknown conditions with the high probability of the use of non-standardised regimens and drugs of unknown quality. There is poor drug regulation in many countries, with TB drugs (both 1st and 2nd line) available over the counter in several countries. Health infrastructures are often overburdened, specifically overcrowded hospitals with no or poor infection control policies. Several countries in the region face poor housing conditions and specifically overcrowding in urban areas (urban slums) that facilitate spread of
infections. In many countries, the supply of quality assured SLDs is a bottleneck, and except for India, 100% of SLD supply is supported by TGF as a single source. Laboratory capacity, appropriate models of care, capacity for clinical management and drug management is lacking in many countries, and capacity needs building on these components. This could include support to regional or national TA centres.

WPR rGLC
The rGLC has held 2 face to face and 3 teleconference meetings since the last gGLC meeting. Much progress is being seen across the Region. PMDT Expansion plans are now available for all high MDR-TB burden countries. Levels of reimbursement for MDR-TB services under the different Health Insurance Schemes in PR China is increasing. There has been progress in the detection of MDR-TB in 2011, but it is still far below the target with the number of MDR-TB cases notified in 2011 representing only 7% of the estimated of MDR-TB among reported TB patients with pulmonary TB and 44% of the planned by the countries. 46 GeneXpert machines are rolled out in all high priority countries in WPR. Of note is that an additional 2,020 R-resistant cases have been identified by GeneXpert. All (100%) of notified cases were enrolled on treatment. There have been M&E and TA missions to 10 countries. The first TB Clinical Collaboration Group Meeting between Papua New Guinea clinicians and their counterparts in Queensland, Australia has been held. The Regional SLD stockpile for Pacific Island countries and area (Cook Island, Tuvalu, Marshall Island) is functioning well. However funding gaps are seen in many countries, and there is heavy reliance on external donor funding (especially TGF). There is insufficient in-country human resource capacity, a lack of task analysis based HRD plan and training materials and methodology in many countries. There are common problems in delay in planned laboratory scale up, weak clinical management drug management capacity across countries. An advocacy framework is urgently required to mobilize internal and external resources. Capacity building activities, including training of trainers, development of diagnostic algorithms etc are needed. WPRO and the rGLC are supporting the development of frameworks and tools to assist countries. For example the development of a PPM framework, including PMDT, is ongoing (pilot in Philippines and Vietnam). A Regional PMDT Consultants training is planned for early Dec 2012, and a planning for a Regional drug management consultants training is on-going. The rGLC raised the issue of the flow of strategic information and the rGLCs’ role in gGLC meeting as issues that the gGLC meeting needs to discuss (refer to Session 3).

Updates from AFR and EMR were presented by Dr Daniel Kibuga, rGLC Secretariat, WHO AFRO, and Dr Aamir Khan, Chair, MDR-TB Working Group respectively.

AFR
The call for applications for rGLC members has been issued, and the selection of the members is ongoing. It is anticipated that the rGLC will be established before the end of 2012. MDR-TB cases have been notified by 42 countries in the region, and XDR-TB cases by 9. There have been M&E and TA missions to 14 countries in 2012. Common reported challenges to MDR-TB service scale-up across countries
were: lack of laboratory capacity for culture and DST, human resources for PMDT activities; poor infection control policies and poor implementation; need for community based programmes; and ensuring adequate supply of quality assured SLDs. There was a need to strengthen the basic TB control efforts, high level advocacy to create greater political support for PMDT activities, intensified technical support, and real time information gathering potentially via through the regional real time data collection initiative for priority diseases in AFRO. The gGLC was requested to strengthen the networking for consultants for PMDT and policy development, and support the development of early warning systems to detect problems/challenges in countries.

**EMR**

Currently the selection of the rGLC members is ongoing, and the first meeting of the EMR rGLC will be held in early December 2012. A regional MDR-TB training course on community based PMDT and ethical consideration has been held. Monitoring and TA missions were conducted to 5 countries. Five countries have been supported to finalize DRS surveys and 3 to finalize their National guidelines for MDR-TB management. The main challenges in the region to scale-up of MDR-TB services are: limited human resources both at regional level and at country level; limited laboratory capacity for culture and DST; security issues and displacement of populations in 3 countries; problems in drug procurement due to financial gaps and limited availability of certain SLDs; and anticipated financial gaps to support scaling up MDR-TB activities due to the reduced funding by TGF. Two meetings of the task force for new diagnostics are planned to finalize the regional road map to strengthen TB laboratory network. Continuous TA will be provided to countries to support the planned DRS surveys and for the establishment of proper MDR-TB management. The gGLC is requested: to examine closely the global issue of the scarce production of some SLDs (mainly the injectable agents); to advocate for financial resources to be made available to continue the support provided to countries for their MDR-TB activities; support further the regional MDR-TB course, consultancy training, and rGLCs both technically and financially.

**Discussion**

As highlighted by a number of presenters, the issue of the poor outcomes of treatment were discussed by the gGLC. The need to increase support to the patient during treatment was widely mentioned, including the use of enablers and/or incentives. A suggestion was made by AMR rGLC Chair that a new set of indicators could be introduced to better measure treatment outcomes, which may include aspects on social support/protection activities. The need for ancillary drugs for the treatment of adverse drug reactions (ADRs) and health care workers trained to manage the ADRs to be available was highlighted.

The gGLC commended the work of EUR rGLC in the revising of core documents and the Task Forces set up by EURO. It was suggested that all draft documents, for example on the role of surgery in MDR-TB care, be widely reviewed and especially by experts from outside of the Task Force and EUR, in order that any document be as evidence based as possible.
The need to improve TA mechanisms, to continue the “focus” on the “high MDR-TB countries” and support countries on how to decentralise services within their respective countries were also raised and discussed (see Session 8).

Conclusions and recommendations
The gGLC requests:
- the Secretariat to circulate the new monitoring mission reporting format developed by the EUR rGLC with the gGLC and all rGLCs; and
- that EUR rGLC present updates on the work of the relevant Task Forces established in the EUR at the next gGLC meeting.

Session 3 – gGLC administrative issues
Objective: To present an update on restructuring in the WHO STB Department, review the membership of the gGLC, and communications between gGLC and the respective rGLCs

Restructuring in the WHO STB Department
An update on the restructuring of the Units within the WHO Stop TB Department was presented by Dr Karin Weyer, Coordinator, Laboratories, Diagnostics and drug Resistance Unit (LDR). The new LDR Unit was created by the merger of the previous TB Laboratories and MDR-TB/GLC Operations Units. The LDR has 4 teams within it, looking respectively after: Diagnostics Policy & Laboratory Strengthening; Diagnostics & Treatment Alignment; MDR-TB Policy & Innovation; and PMDT Scale-up & Capacity Development. The members of the different teams and the Unit were presented, with their respective areas of work.

Review of the membership of the gGLC
The gGLC initially had 9 selected members who represented a range of technical areas and constituencies. In addition, there is 1 representative (rGLC Chair) from each of the 6 rGLCs, and the Chair of the MDR-TB Working Group, on the gGLC. The process of selection of the gGLC members was both lengthy and labour-intensive. Mr Neeraj Mohan (Drug management; Technical Partners & NGOs) resigned from the gGLC earlier in 2012, leaving a vacant position on the gGLC. Three options for filling the vacant position were presented to the gGLC for their discussion and advice: i. Call for applications specifically for the technical area left with reduced capacity due to vacancy (i.e. drug management); ii. Call for applications for other areas (e.g. nursing); or iii. “Wild card": Invitations of individuals with areas of expertise required for single meetings / series of meetings, and leave official gGLC position vacant.

Communications between gGLC and the respective rGLCs
In addition to the issues raised by the WPR rGLC Chair, the reality of having 6 monthly face to face meetings, with the limited time, is that not all topics can be covered during the meeting. Also how can the high level of engagement in-be maintained in between the face to face meetings, and also how to ensure that all important topics are covered? The gGLC was asked for advice on: i. Options for additional "meetings" (e.g. teleconferences, Web-ex conferences, other
communication methods); ii. Frequency of meetings; and iii. How is the gGLC meeting agenda or topics for discussion arrived at?

Conclusions and recommendations

Review of the membership of the gGLC
The gGLC acknowledges the need to replace the vacant committee member position in order to better able the committee to accomplish its terms of reference.

Furthermore, the gGLC recognizes the need to include an individual with experience in implementation of PMDT at a country level, particularly with a high burden country.

The gGLC recommends that the vacant gGLC committee member position be filled through a call for applications targeted to individuals with programmatic experience in implementation of PMDT country programs. Individuals from MDR-TB high burden countries will be given priority. Individuals with specific areas of expertise will continue to be invited as observers to the gGLC meetings as and when required.

Communications between gGLC and the respective rGLCs
1. The gGLC acknowledges the need to meet more frequently in order to be able to improve communication between the gGLC secretariat and committee members and between the gGLC and rGLCs.

Therefore, the gGLC will work with the secretariat to establish quarterly gGLC meetings including two face-to-face meetings and two teleconference or web-based meetings.

2. The gGLC recognizes that time limitations during the 2-day face to face meetings held every 6 monthly prevents inclusion of all relevant topics in the agenda.

The gGLC requests the Secretariat to organize teleconference / Web-based meetings in between the six-monthly face to face meetings. These would enable focused discussions on specific topics. Frequency should be 3-monthly, although initially these meetings could be more frequent if felt appropriate.

3. The gGLC recognizes the need to improve communication between the gGLC and rGLCs.

The gGLC recommends that the secretariats of the gGLC and rGLCs develop a proposal to be presented at the next gGLC meeting to ensure better communication between the gGLC and rGLCs. The proposal should take into account the need to bidirectional and timely flow of information.
Session 4 – Update on technical consultations, and new policies

Objective: To provide an update on WHO Expert Group Meetings, global Consultations and proposed new policies

Updates were presented to the gGLC by the relevant focal point, WHO Stop TB Department, on the following WHO Expert Group Meetings, global Consultations and proposed new policies:

- WHO Strategic & Technical Advisory Group for TB meeting, June 2012.
- Expert Group Meeting on "2nd line probe assay and drug susceptibility testing for 2nd line drugs", March 2012.
- Guidance on the management of TB in children
- Guidelines on screening for active TB.

Session 5 – Availability of second line anti TB drugs and Group 5 drugs

Objective: To provide an update on the Global Drug Facility and drug availability

Update on GDF availability of SLDs and Group 5 drugs

An update on GDF and the availability of SLDs and Group 5 drugs was presented by Mr Tom Moore, acting Manager, GDF. A brief overview of the mandate of the GDF, and its impact were presented. In relation to SLDs, the GDF since inception has provided drugs for a cumulative total of 55,800 patients. The pricing of FLDs and SLDs has been consistently reduced over the years (inflation adjusted). And GDF has increased awareness at all levels of the importance of quality TB drugs.

GDF now proposes to shift from a “production to order” paradigm to “production to stock”. Currently manufacturers only order API and plan production, once they receive a firm order and prepayment - standard lead time is thus 4 and 6 months. Shifting the paradigm to “production to stock”, would allow building of stocks in anticipation of firm orders and lead times would be significantly lower. However GDF’s current strategic rotating stockpile (SRS) is unable to shift to the new paradigm due to its small size. Also currently the SRS is not creating income to cover operational costs. GDF will continue to promote its objectives through its pooling mechanism to continuously supply first line anti-TB drugs (FLDs) and SLDs. GDF can do much more through its pooling mechanism if supported by 2 new proposed initiatives: (1) Global Strategic stockpile and (2) Flexible Procurement Fund. These will allow GDF to: Greatly reduce lead times; Avoid unnecessary drug stockouts; Maintain quality and supplier base for the FLD and SLD market; and Sustain, then further reduce prices, gradually. The GDF/STP are working with the Global Fund and the U.S. Government to gain support for these two interventions.

The Global Strategic Stockpile (GSS) would be comprised of FLDs and SLDs which will: prevent the situation where patients wait unnecessarily for life saving medicines; flexibly manage the supply and demand challenges (eg. stock outs, long lead times, supply partial regimes or single products); and contribute
to stabilization of the market for SLDs (e.g. APIs and prices). The GSS will operate for at least 300,000 FLD patient treatments and up to 16,000 patient treatments for SLDs. The GDF would co-share this activity with TGF building on the existing stockpile (SRS), well-functioning since 2009 for 5,800 patient treatments.

The Flexible Procurement Fund (FPF) would mitigate funding delays on the demand side for both FLDs and SLDs, thereby: Increasing availability of drugs; Ensure procurement volume and commitment (advance purchase); Reducing threat of stock outs and patient treatment interruption; Promoting efficiency of the reordering process and stimulate interest for manufacturers wanting to supply GDF; and Bridging gaps caused by funding delays from GF to countries.

Currently there are now 2 suppliers for almost all SLDs and SLDs are available from GDF without any supply problems. In October 2012, GDF/IDA will conduct the next competitive bidding exercise for SLD’s, with invitations to bid being sent to all eligible manufacturers. New long term agreements (LTAs) will be valid from 1 January 2013. And currently GDF is finalizing the selection of a new Procurement agent. The LTAs will be transferred to the successful bidder if required.

**Linezolid:** Linezolid is marketed by Pfizer, and is patented in the USA and Europe until 2014/2016. GDF has received an offer letter from Pfizer for the price: USD $37 per tablet. However, the offer letter needs WHO legal review (pending) due to off-label use. However linezolid is not indicated for DR-TB and as such Pfizer is not able to discuss its use for DR-TB. Currently there are no requests to GDF from the countries for this drug.

**Imipinem /cilastatin:** Available as imipenem/cilastatin 500 mg + 500 mg i.v. from Labatec (Switzerland). The product is being qualified on the basis of the approval of an stringent regulatory authority. The shelf life is 36 months, with 10 vials in a carton. Currently there are no requests with GDF from the countries, thus no contractual arrangements have been made from this product at this time.

**Clofazimine:** Available for MDR-TB with specific requirements due to potential liability issue via Victoria Pharmacy in Zurich, as Lamprene 100mg, 100 capsules, CHF 105.48 ex-works Zurich (vs. 131.85 CHF public price). In order to process the order for this medicine, as requested by the manufacturer, GDF needs to receive in advance a list of patient names in the form of a prescription signed by a medical doctor, who is licensed to practice, duly signed and stamped, with applicable license number indicated. In addition, GDF requests the client to sign the disclaimer. GDF will initiate the order process upon receipt of scanned documents. However, the original prescription and disclaimer should be posted to GDF within 7 days.

Further information in relation to the availability of clofazimine was presented by Dr Ernesto Jaramillo, Stop TB Department. A brief background was presented, including that Novartis is the only quality assured manufacturer of clofazimine. However it is only registered by Novartis for the use in treatment of leprosy, in combination with rifampicin, although small supplies are available for off label
use only through Victoria Pharmacy, Zurich. The WHO Leprosy Programme had previously made available a limited quantity of the drug, free of charge, to the GLC approved programmes on a case per case basis until 2010. The increased demand for the drug however resulted in WHO Leprosy Programme stopping the supply in view of the conditions agreed with Novartis (drug is donated to WHO exclusively for use in leprosy patients).

Since the last gGLC meeting, an updated analysis of the evidence on the efficacy and safety of clofazimine for MDR-TB treatment has been published recently. GDF has continued to explore supply options via generic manufacturers meeting basic quality standards, in addition to establishing a supply line through Victoria Pharmacy, and streamlined according to Novartis requirements. Crucially, the WHO Stop TB Department and STP met with Novartis in August 2012 to discuss how to make adequate amounts of the drug available for use in M/XDR-TB cases. Follow-up on the issues raised during the August 2012 meeting is on-going.

**Discussion**
At the request of the gGLC, the complete GDF procurement process for SLDs was presented and discussed. The discussion looked at the average time for an order and whether there were any steps in the procurement process where action by technical agencies and partners could leverage a decrease in the required timelines. The gGLC was informed that the US Government agencies are working with TGF to see whether the procurement of commodities can be delinked from performance achievement, and hence remove the issues caused by the delay in release of the required funds.

The continued high cost of SLD and Group 5 drugs was highlighted and discussed, as were the proposed new initiatives. The need for countries to use the new funding model of TGF to scale-up MDR-TB services was reiterated – if countries do not use this opportunity, scale-up of services may well be at risk and even greater risk will be attached to the new initiatives. The gGLC was also requested by the STP to advice on what drugs should be sourced by GDF.

**Conclusions and recommendations**
The gGLC acknowledges the progress done to date by GDF to ensure a non-interrupted supply of QA SLDs, and the actions undertaken for including additional drugs from Group 4 and 5 in its portfolio. In particular, the gGLC acknowledges the pro-active work done to date by the STB Department and GDF with Novartis in moving forwards to having a sustainable supply of quality assured clofazimine.

The gGLC recognizes the challenge of developing generic WHO/ internationally approved suppliers for certain quality-assured second-line anti-TB drugs, including some of the Group five drugs. In particular, the gGLC recognizes that relying on the normal market dynamics (i.e. companies only deciding to develop quality-assured drugs if the numbers to treat will assure a profit) will not work for many of the drugs. The role of the Group 5 drugs’ linezolid and clofazimine are expanding. At present, these 2 Group 5 drugs are indicated in the treatment of XDR-TB and may have other roles in the near future, such as protecting
against resistance of newly developed agents in the treatment of XDR-TB.

The gGLC further welcomes the 2 new interventions proposed by GDF to avoid stock-outs and reduce lead times for procuring MDR-TB medicines of Global Fund grants to countries, namely the Global Strategic Stockpile and the Flexible Procurement Fund.

The gGLC recommends:

- That the GDF continues to pursue additional avenues beyond depending on market dynamics to establish a stock of low-cost, quality-assured linezolid and clofazimine (and imipenim/cilastin and meropenem if possible) at the GDF. The gGLC requests that GDF actively seeks the inputs of the gGLC on the drugs to be included in future competitive bidding exercises and to regularly update (e.g. every 3 months), the gGLC on the GDF’s progress in establishing alternative solutions that go beyond the bidding exercises to identify suppliers of and establish the stocks of low-cost quality-assured clofazimine and linezolid; and
- That the Global Fund further investigates the possibility of providing funds to the Global Drug Facility to develop a stockpile of SLD and FLD medicines, building on the existing stockpile for SLDs which has allowed lead time for urgent orders to be reduced to a median of 30 days when counting elapsed time from GDF stock to country level. Likewise GDF should have access to the ECF (Emergency Commodities Fund) to back up advance purchase orders in emergency situations.

Session 6 – Treatment of patients with R-resistance

Objective: To provide advice on treatment regimens for R-resistant TB patients

The question of whether all TB patients infected with strains resistant to rifampicin (RR-TB) should be treated using a full MDR-TB regimen has been raised at a number of fora since the publication of the 2011 WHO Update of PMDT Guidelines. With the rolling out of GeneXpert, with its ability to rapidly detect R-resistance, there is an increasing need of clear guidance to be issued to countries. The background, guiding principles and proposed recommendation on this issue were presented by Dr Dennis Falzon, Stop TB Department.

The guiding principles are that: i. the risk of additional acquisition of resistance in RR-TB patients by the use of a weak regimen, must be avoided; ii. the start of MDR-TB treatment should not be delayed; iii. the patients are not deprived of H if this drug could be of benefit; iv. H has a known relatively good safety record; v. the global expansion in the use of rapid molecular tests will diagnose more RR-TB cases; and vi. any increased requirements in drugs to provide adequate treatment according to any revised recommendation needs to be considered.

The proposed recommendation is that “It is suggested that all TB patients infected with strains resistant to rifampicin are treated using a full MDR-TB regimen which also includes isoniazid until DST results to isoniazid are available and appropriate adjustments to the regimen can be made.” This implies that all
cases with RR-TB, with or without confirmed MDR-TB, be treated using a full MDR-TB regimen. In epidemiological settings where RR-TB is strongly associated with MDR-TB, rifampicin resistance detected on Xpert MTB/RIF is strongly correlated with MDR-TB.

RR-TB cases with confirmed mono-resistance would benefit from the addition of H to their MDR-TB regimen given the strong bactericidal properties of this drug. If H susceptibility is not known, as in the case of patients diagnosed using Xpert MTB/RIF alone, it is recommended to test for it using conventional phenotypic methods. If H susceptibility cannot be ascertained, the addition of H to the regimen may be considered in settings where mono-resistance to R is high or resistance to isoniazid is expected to be low-level and high-dose H may be of benefit. DST for other first and second-line drugs for which the methodology is known to be accurate and reproducible is also recommended to guide treatment.

The 2006 recommendation for treatment of patients with non-MDR RR-TB was based on expert opinion. No trial or observational data on non-MDR RR-TB cases outcomes were available to the panel when revising this recommendation again in 2012. The modification to the 2006 recommendation has been made after assessing the relative benefits and harms of prolonging the treatment by a few months and adding more drugs to the regimen.

The gGLC members were asked whether they agree with the proposed wording of the recommendation, and that it be included in the Companion Handbook.

Conclusions and recommendations
1. The gGLC acknowledges the importance of providing recommendations to programmes and providers regarding the treatment of R-resistant TB patients. Furthermore, the gGLC recognizes that the new molecular methods will increase the diagnosis of R-resistance.

Therefore, the gGLC recommends adoption of the proposed language, with minor editing, regarding treatment of R-resistant TB with a full MDR-TB regimen, with addition of isoniazid until DST results are available. The gGLC agrees that this language should be used in the PMDT “handbook” to accompany the current WHO PMDT Guidelines. The logic behind high or low dose of H, and the epidemic context in which this recommendation can be applied, should be discussed in the PMDT “handbook”.

The gGLC requests that in the systematic assessment of the literature during the next round of guidelines update the relevance of the current MDR- TB definition and whether it needs revising, and whether H should be included in the treatment of all MDR- TB cases, at least in the intensive phase, be explored.

Session 7 – Update on “short” regimens, and WHO’s position and action
Objective: To provide an update on “short” regimens for the treatment of MDR-TB, and to present WHO’s position and action
Evidence from Bangladesh for “short” MDR-TB treatment regimens
Dr Armand van Deun provided the gGLC with an update on the use of “short” regimens for the treatment of MDR-TB patients in Bangladesh. A standardised regimen of 4+ months intensive phase with 5 months continuation phase, is being used. Gatifloxacin (Gfx) is the core drug with clofazimine (Cfz), ethambutol (E), pyrazinamide (Z) throughout, plus in the intensive phase, kanamycin (Km), prothionamide (Pto), and isoniazid (high dose H). Patients are followed up for 2 years after cure, with 6-monthly smears and culture examination.

In relation to enrolment, patients are registered if at least 1 dose was taken. The treatment is free, with no incentives provided. Initial hospitalization of all patients was required until 2007. Patients with advanced disease were never excluded. A reserve regimen was used for those previously treated with SLDs: these patients were excluded from the analyses. The results presented were those from an extended patient cohort to that reported in 2010 in the American Journal of Respiratory and Critical Care Medicine. The same standard 9-month regimen was used, and 539 cases were enrolled for their first treatment. 63 cases were excluded from analysis, leaving 476 to be analysed.

Of the 476 patients analysed, 399 (83.8%) were cured, 11 (2.3%) completed treatment, 35 (7.4%) defaulted, 26 (5.5%) died and 5 (1.1%) failed. Just 3 relapses (0.6%) were observed, with a relapse-free treatment success rate of 85.5%. There were relatively few adverse side effects observed, with 320 (67%) patients having none recorded. Most were minor, with vomiting most common in 22%. Severe side effects were observed rarely: hyperglycemia in 8 (2%) patients (Gfx substituted by Ofx); hearing loss / ataxia in 25 / 8 patients (5% / 2%); and Km dose reduction for 6 patients and stopped in 1. Most deaths and defaults occurred early in treatment. The risk of failure was significantly increased if the patient had resistance at the start of treatment to either a second line injectable or fluoroquinolone (FQ), particularly if FQ resistant.

In conclusion, the earlier excellent results reported on appear largely maintained in the extended cohort. The presence of more extensive resistance limits the success rates, particularly FQ resistance (50% failure/relapse with high level Gfx resistance).

WHO’s position and action
Dr Ernesto Jaramillo, Stop TB Department, gave an overview of the action taken by Stop TB Department, WHO on the recommendations of the 1st gGLC meeting in October 2011 in relation to the “short” regimens for the treatment of MDR-TB.

In November 2011, a meeting was held with senior representatives of the UNION in Lille to discuss the way forwards in relation to the “short” MDR-TB regimens, and particularly in relation to the Cameroon project. A number of action points were agreed upon, including: Cameroon should officially request TGF to authorize the use of funds to buy the needed SLDs; A DSMB to be established, particularly because of the use of gatifloxacin; WHO will offer to the Cameroon project in due time a new assessment of the Good Clinical Practice (GCP) and the operations of the DSMB; and the UNION and the Cameroon government will
invite all concerned stakeholders to a conference in Cameroon in early March 2012 to further discuss the proposed project.

At the meeting in Yaounde, Cameroon, in March 2012, the criteria for WHO to support the use of “short” MDR-TB regimens were presented, namely:

• implementation of an operational research project to assess the safety and effectiveness of the regimen in patients enrolled;
• approval of the operational research project by a national ethics review committee, ahead of any patient enrolment; and
• the monitoring of the PMDT programme and the corresponding research project by an independent monitoring board set up by, and reporting to, WHO; and
• agreement on a plan for TA on PMDT (including pharmaco-vigilance and R&R), and research capacity building (GCP, ethics, etc).

By June 2012, these criteria had been presented to, discussed with, and endorsed, by the Secretariat of the WHO Guidelines Review Committee, the Secretariat of the WHO Ethics Review Committee, the gGLC, and the Chair of the WHO 2011 PMDT Guidelines development group.

Progress on this area of work was presented to the 12th Meeting of the WHO Strategic and Technical Advisory Group for TB (STAG-TB) in June 2012 (Session 4c: “Short-Course” Regimen for MDR-TB). STAG-TB acknowledged that: current evidence for safety and efficacy of the short “Bangladesh” regimen is limited; additional high-quality data to further inform future evidence-based recommendations is needed; and use of the short “Bangladesh” regimen needs proper attention to regulatory and ethical issues to facilitate the gathering of evidence that can be used in future updates of current WHO policy development. STAG recommended that WHO: provide TA to countries wishing to implement the regimen and define a set of prerequisites and recommendations for implementation; facilitate the development of adequate laboratory capacity to support patient management; facilitate the gathering of evidence that meets the requirements of WHO guidelines for policy development, including ethics; and facilitate access to funding sources, including TGF, required to implement the regimen and conduct the operational research needed for further policy update.

The next steps were outlined, including: briefing to TGF (done in July 2012); information to countries and WHO R/CO (note up on the WHO web-site as from 10 August 2012); meeting of WHO with technical partners of West Africa (planned in Q4 2012, Ouagadougou, Burkina Faso); briefing to the 3rd gGLC meeting; participation in a symposium at the UNION Annual World Conference (Nov 2012); conducting of cost-effectiveness assessments.

Discussion
The ensuing discussions, recognizing the sense of urgency around the need for shorter regimens for the treatment of MDR-TB, focused on whether there was sufficient data available to enable WHO to review the “short” regimen. That the study results presented come from just the one specific geographical setting, with limited numbers of HIV-infected patients and minimal use of SLDs, was
highlighted by gGLC members. The need for patient support even with a 9 month regimen was also highlighted.

**Conclusions and recommendations**
1. The gGLC recognizes the excellent outcomes that have been reported to date with the 9-month "Bangladesh" regimen and the potential benefits to the treatment of MDR-TB patients.

The gGLC also recognizes that the regimen has been studied in a relatively small population and thus, the results may not be generalizable to all patients with MDR-TB outside of this specific setting.

Therefore, the gGLC continues to recommend that shortened treatment regimens for MDR-TB patients, including the so-called “Bangladesh” regimen, be evaluated in different populations and different settings following WHO recommendations.

Furthermore, the gGLC recommends that the members of the gGLC, rGLCs, and the Research subgroup work with the planned ad hoc Working Group (as recommended during the “consultation on TDR-TB” in March 2012, footnote 1) in order to develop “indicators” and standards that can assist countries to identify the potential benefit of using such regimens. This will assist also countries identify what resources are necessary to begin using the “Bangladesh” regimen (and potentially other shortened regimens for MDR-TB patients) under appropriate operational research conditions, as well as how to monitor and evaluate newly introduced shortened regimens.

**Session 8 – Moving Forwards on global support to scale-up of MDR-TB services and care**

**Objective:** To provide introduction on how to move forwards on the global support to scale-up of MDR-TB services and care

As an introduction to the session, four presentations were made on: feedback from the informal consultation, June 2012; aligning diagnosis and treatment; innovations for PMDT capacity building; and building momentum for technical assistance.

**Feedback from the informal consultation, June 2012**
The informal consultation in June 2012 was attended by a wide range of representatives from many partners. Participants felt that galvanizing the global community around two or three specific activities would be a good way forward to kick-start and accelerate PMDT scale-up. While the cost of second-line drugs continues to be prohibitive and will seriously restrict the urgently needed scale up if it cannot be brought down, the system issues need to be addressed and the capacity for laboratory capacity, treatment delivery and drug management need

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1 The meeting recommended that WHO set up an ad-hoc Working Group to develop and publish guidance on what observational studies of the treatment for drug resistant TB should do better to ensure the best possible evidence.
to be built in tandem. A close link allowing for concerted action of all players, including the MDR TB Working Group, GLI, gGLC and rGLCs, regional/country centres of excellence, SLDAII etc., will be crucial. It was recommended that a session on “the way forward” be included in the 3rd gGLC meeting, with representatives from the rGLCs and the MDR-TB Working Group invited.

**Aligning diagnosis and treatment**

The presentation on “Acceleration in TB diagnostics scale-up and need for alignment with treatment” provided the background and impressive achievements made in recent years in scaling up of diagnostic services and the introduction of new and more rapid diagnostics. The EXPAND TB Initiative was presented, and its activities and successes highlighted. To date: 58 out of the planned 100 laboratories have been established and are providing rapid, WHO endorsed laboratory services for the diagnosis of TB and MDR-TB; 19 countries are now routinely reporting MDR-TB cases detected in these laboratories; and cumulatively over 21,000 MDR-TB cases have already been diagnosed by these laboratories, with almost 50% of them being detected from January to June 2012.

The outline and objectives of the TB EXPERT Project were provided. This is a USD $25.9 million UNITAID-funded project for the procurement of GeneXpert machines and Xpert MTB/RIF cartridges, to be undertaken by a consortium of agencies, led by the WHO Stop TB Department and Stop TB Partnership. The project aims to: reduce the cartridge price from USD $16.86 to $9.98 to generate demand and create a sustainable market; rapidly scale-up implementation of Xpert MTB/RIF in target countries using effective diagnostic algorithms; and develop and establish innovative PPM models to accelerate uptake and increase demand. Under the project, over 200 GeneXpert machines and 1.4 million Xpert MTB/RIF cartridges are to be supplied to 21 countries from 2013-2015.

Finally an update on the impressive roll-out of GeneXpert was presented. In the 18 months following WHO endorsement in December 2010, from a baseline of 99 GeneXpert machines (524 modules) in the public sector in 23 countries, there has been an increase to 749 GeneXpert machines (3,602 modules) in the public sector in 67 countries. As of June 2012, over 1.1 million cartridges have been procured by the public sector in eligible countries. The impact of this will be the rapid case detection of TB and RR-TB cases, and a reduced (but not eliminated) need for conventional laboratory services.

All of these initiatives to scale-up laboratory diagnostics will rapidly increase the detection of MDR-TB cases, with the urgent need for this to be matched by a similar rapid increase in the capacity for treatment and care delivery.

**Innovations for PMDT capacity building**

Dr Aamir Khan, Chair of the MDR-TB Working Group, presented a number of innovative initiatives that are being undertaken by partners to build PMDT capacity within countries. These initiatives are harnessing the power of modern information technology to strengthen various components of PMDT in many different settings. These include automatic transfer of GeneXpert results via laptop computers with GPS SIM cards to the Central NTP Unit, attending doctor
Building momentum for technical assistance
The final presentation reminded the gGLC of the Global Framework for Management of MDR-TB objective of “Increased level of technical support to countries.” This was to be aimed at building in-country capacity to scale-up PMDT, would be dependent on the situation in each country, and would require different skill sets by the technical assistance (TA) providers to meet the various stages of PMDT development in respective countries and the wide range of technical areas.

The expanded approach to TA, including decentralization of the TA functions, was to be based on:
1. Building countries’ capacity for guidance and facilitation of PMDT scale-up. This requires well informed NTP managers and PMDT focal points at all levels, collaborating with National PMDT “Technical Assistance Centre(s)” (TACs) that provide TA, training, technical updates, opportunities for study visits etc. for PMDT in their country. The innovative usage of modern communication systems will be important.
2. Increasing numbers of “qualified” (local and international) consultants. To learn from past activities, an assessment of TA needs, present practices of TA provision, coordination, gaps and funding levels, is needed. The response by the international partners will be based on the results of the assessment. However a plan will be needed on how to address any identified gaps in TA capacity, and to establish systems to monitor effectiveness of TA and funding.
3. Duration and intensity of TA provision, TA modality mix. Based on the situational assessment, the present mix of TA modalities applied may well need to change, with increased recognition of need for long term in-country TA provision. The required funds for the identified TA needed, will require identifying.
4. TA coordination required at the global, regional, and national level.

The gGLC was reminded that the transition plan developed in 2011, had an indicative budget attached to it, including a USD $35 million 2-year TA component. Only a small fraction of the indicative amount for TA has been made available by the global community for this activity.

Discussion
The discussion focused on firstly recognizing that with the introduction of new rapid diagnostics, the landscape in relation to the detection of MDR-TB and RR-TB is fast changing. However will the treatment and management services scale-up at the same pace to ensure that diagnosis and treatment are aligned. The need to provide “intensified TA” was unanimously agreed. However much discussion ensued in relation to what is meant by this statement and how it is to be acted upon. The issue of whether this should be implemented across all countries, or in a smaller number of “prioritized” countries was discussed. It was
recognized that what each country may require in relation to TA, will differ and hence any action needs to be tailored to the respective country.

**Conclusions and recommendations**
The gGLC recognizes the critical importance of aligning diagnosis of drug resistant tuberculosis with treatment and the need to build country capacity.

Furthermore, the gGLC recognizes the importance of providing high quality long term technical assistance to countries with high rates of MDR-TB.

The gGLC strongly endorses the restructuring in the Stop TB Department in relation to the establishment of the LDR Unit, which will strengthen WHO’s support to the efforts of countries to align diagnosis capacity of drug resistant tuberculosis with treatment and to build in-country capacity.

The gGLC recommends:
- that WHO work with the gGLC, rGLCs and Partnership to facilitate the implementation of intensified technical assistance, including the use of innovative approaches, in a limited number of identified countries to serve as both a starting point for increasing the rate of scale-up in a particular country and as examples of the impact of intensified technical assistance.
- working with the rGLCs and EXPAND TB in order to identify countries where the rollout of rapid molecular drug susceptibility testing is occurring and thus, there is likely to be a rapid increase in the detection of drug resistant tuberculosis.
- prioritizing long-term technical assistance, preferably with in-country technical teams and/or “technical assistance networks”. The rGLCs should work with countries in identifying which require long-term technical assistance.

**Other business**
- The next gGLC meeting will be held 18-19 April 2013 (linked to the GLI meetings in Annecy, 15-17 April 2013).

The sessions 9 and 10 on day 3 (19 October 2012) were a joint meeting of the gGLC members and the members of the Core Group of the MDR-TB Working Group (WG).

**Session 9 – Looking Forward**
The participants were welcomed to the meeting on behalf of the gGLC by Dr Charles Daley, gGLC Chair, and Dr Aamir Khan, MDR-TB WGChair. Updates from the Stop TB Partnership, WHO STB Department, GLC and the Core Group of the MDR-TB WG, and discussions on “The Way Forward” continued.

*Stop TB Partnership - Update on Strategic Plan and future direction*
Dr Lucica Ditiu, Executive Secretary, Stop TB Partnership (STP), presented an
update on the strategic plan and future direction of the TBP. Three areas have been focused on in the on-going review of the TBP: future strategic direction of the STP; re-organisation of the STP Secretariat; and governance reform. Agreed core activities of the STP include: to facilitate/catalyse work of the partners; and advocacy, communication and resource mobilization for TB control work globally. A 3-year strategic plan to support the implementation of the Global Plan to Stop TB, 2011-15, has been drafted and will be presented to the Co-ordinating Board meeting in November 2012. Once the strategic plan is approved, there will be a re-structuring of the STP Secretariat to implement the new plan. Governance reform will be aiming to revise the structure and functions of the STP Co-ordinating Board and the Working Groups. These three issues will be discussed at the Board meeting in November 2012.

**WHO - New organizational structures**
As the restructuring of the WHO Stop TB Department had been presented in detail to the gGLC meeting on day 1 (17 October 2012), at which session virtually all participants were in attendance, Dr Karin Weyer, Co-ordinator LDR Unit, Stop TB Department, provided a very brief reminder of the new structure of the WHO Stop TB Department (refer to Session 3. gGLC Administrative issues).

**GLC - Update**
Dr Charles Daley, gGLC Chair, provided an update on the GLC Initiative. A brief overview of the process taken in 2010-11 leading up to the agreement of the new global framework to support scale-up of MDR-TB, the mission, goal and objectives of the new framework, and the respective roles of the global and regional GLCs, was presented.

**MDR – TB Core Group - Update**
Dr Salmaan Keshavjee, member CG Core Group, presented an update from the MDR-TB WG Core Group. Dr Keshavjee reviewed the 2001 TOR of the STP, the details of the WG’s TOR, and the WG structure and its sub-groups. The work of the gGLC and the Research sub-group fit nicely within the mandate of the WG. In many settings, scale-up of MDR-TB diagnosis and treatment is not happening at an optimal pace. Given the WG’s mandate, is there something that it can and should be doing to: draw from the activities of its subgroups; and bring the partners together to help with scale-up and optimize care delivery?

To answer these questions, Dr Keshavjee presented a number of gaps and possible options on how the WG and its subgroups can engage on the issues:

i. Scale-up of MDR-TB services and care: The WG could engage with countries in a phased approach to support scale-up. In phase 1, two or three countries with on-going EXPAND-TB or TBxpert activities with a gap between diagnosis and treatment, could be intensively supported to scale-up services (via in-depth situational analyses, where available using existing historical data, and with WHO ROs and key stakeholders develop an “solution” plan and implement the “solutions”). The outcomes of interest should focus on increase of patients on treatment, less deaths and higher success rates, and hence less suffering. In phase 2, based on the outcomes of phase 1, the support could be extended to
additional countries. This will provide an alternative mechanism to bring together stakeholders, allow for the dissemination of innovative ideas, and for tying activities directly with advocacy by the STP.

ii. Optimizing MDR-TB care: The WG via the partners can work to implement “shorter” regimens and build the evidence base for them; document and disseminate the findings of the TB REACH projects as it relates to MDR-TB; and working with partners to learn how better to engage with the private sector for PMDT.

iii. Advocacy: The Core Group/WG should use the country interventions as a basis for working with the Stop TB Partnership and the partners to: engage local civil society and advocacy groups around MDR-TB; and hone advocacy messages in different settings.

The above proposed activities will require the necessary funding and human resources to be available to implement. The Core Group will need to map out the resources required: funds for secretariat; funds for independent assessment missions and stakeholder consultations; funds for monitoring and evaluation of progress; enhancement of the Core Group; mapping of what will be needed from the sub-groups (e.g. advice from the gGLC and rGLCs) and WG members; and better communication with the WG members.

Discussion
Participants raised the issue of whether it was time to review the TOR of the gGLC, and possible realign or modify them either in content or priority. The issue of better engagement of the gGLC with the research sub-group was also discussed. A strong view was presented that the advocacy and resource mobilization roles as laid out in the current TOR’s of the gGLC appear better suited as the role of the STP, particularly in view of the presentation of Dr Ditiu of the future direction of the STP. It was also discussed that if this is the case, then the STP Secretariat should present in future an update on its advocacy activities at each of the gGLC meetings.

There was general agreement on the areas of work as proposed for the WG/CG. There were a number of countries mentioned where many of the required “pieces” and “players” were present in-country, and yet progress was slow. There was however much discussion, and some unease, in relation to how countries would be “identified” for the proposed intensive support. This was felt to require careful consideration/analyses and development of a set of criteria for selection. This will need the input of all key stakeholders, not least the countries themselves. The natural forum for further discussion on this matter was felt to be the MDR-TB Stakeholders Meeting planned to be held in Kuala Lumpur, Malaysia, from 11 to 12 November 2012 (refer to Session 10).

Session 10 – Planning for the MDR-TB Stakeholders Meeting, Kuala Lumpur, Malaysia, 11-12 November 2012
Session 10 focused on the planning for the MDR-TB Stakeholders Meeting to be held in Kuala Lumpur, Malaysia, 11-12 November 2012. It was clarified that the afternoon of 11 November and the morning of 12 November 2012 will be
dedicated to the members of the MDR-TB WG and country participants. The afternoon of 12 November 2012 was a combined meeting of the MDR-TB WG and UNITAID, during which the focus will be on drug related issues. Suggestions for the agenda were made and discussed. Following on from the discussions in Session 9, it was asked whether the final “listing” of countries to be supported with intensified TA could be made at the Kuala Lumpur meeting. It was agreed that this would require criteria and a matrix of how to “identify” countries for support. A crucial criteria is that a country wishes to be intensively supported, and that the benefit to the country is clear. The draft agenda will be further discussed and finalised during the meeting of the Core Group on the afternoon of 19 October 2012.

**Recommendation**
1. A small group, comprising of 3 gGLC members (Daniella Cirillo, Chuck Daley, Joel Keravec), 2 MDR-TB WG CG members (Salmaan Keshavjee, Aamir Khan), the gGLC and MDR-TB WG Secretariats (Fraser Wares, Fuad Mirzayev), to be set up to draft criteria and a matrix for “identifying” countries for intensified support. The draft criteria and matrix to be shared with the gGLC and CG members for comment, and the final draft, if ready, to be presented at the meeting in Kuala Lumpur.
### 3rd Meeting of the Global GLC Committee
17 -19 October 2012, World Health Organization, Geneva, Switzerland

### Agenda

#### Day 1 (17 October 2012)

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>09.00 – 09.30</td>
<td>Welcome</td>
<td>K Weyer, L Ditiu, A Khan</td>
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<tr>
<td></td>
<td>Declarations of Interest</td>
<td>Secretariat (FW)</td>
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<tr>
<td></td>
<td>Meeting objectives</td>
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<tr>
<td>09.30 – 10.30</td>
<td>Objective: To follow up on recommendations made and action points agreed upon during the 2nd gGLC meeting</td>
<td>Secretariat (FW)</td>
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<tr>
<td></td>
<td>• Report from the gGLC Secretariat</td>
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<tr>
<td>10.30 – 11.00</td>
<td>Coffee</td>
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<tr>
<td>11.00 – 13.00</td>
<td>Objective: To provide an update on progress and achievements of the respective rGLCs in supporting MDR-TB management scale-up</td>
<td>Chairs: AMR rGLC (DP), EUR rGLC (AY), SEA rGLC (RS), WPR rGLC (LR)</td>
</tr>
<tr>
<td></td>
<td>• AMR, EUR, SEAR and WPR rGLCs</td>
<td>Representatives: AFR (DK), EMR (AK)</td>
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<tr>
<td></td>
<td>• AFR and EMR related issues</td>
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<tr>
<td></td>
<td>Discussions</td>
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<tr>
<td>13.00 – 14.00</td>
<td>Lunch</td>
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</tr>
<tr>
<td>14.00 – 14.45</td>
<td>Objective: gGLC administrative issues</td>
<td>STB/LDR (KW), Secretariat (FW)</td>
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<tr>
<td></td>
<td>• WHO/STB/LDR restructuring</td>
<td>Chair (CD)</td>
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<td></td>
<td>• Ensuring representation of all “technical areas” and “constituencies” on the gGLC</td>
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<td>• gGLC communications</td>
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<tr>
<td>14.45 – 15.30</td>
<td>Objective: To provide an update on WHO Expert Group Meetings, global Consultations and proposed new policies</td>
<td>STB/LDR (KW), STB/LDR (CG)</td>
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<tr>
<td></td>
<td>• WHO Strategic &amp; Technical Advisory Group for TB</td>
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<td></td>
<td>• 2nd line line probe assay and drug susceptibility testing for 2nd line drugs</td>
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<tr>
<td>15.30 – 16.00</td>
<td>Coffee</td>
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<tr>
<td>16.00 – 17.00</td>
<td>“Totally Drug-Resistant TB: definition and treatment options”</td>
<td>STB/LDR (DF), STB/TSC (MG), STB/PSI (KL), STB/PSI (CL)</td>
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<td>• Guidance on the management of TB in children</td>
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<td>• Guidelines on screening for active TB</td>
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<td>• New drugs and their rationale introduction</td>
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<td></td>
<td>Questions and discussions</td>
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<tr>
<td>17.00 – 17.30</td>
<td>Wrap up Day 1</td>
<td>Chair (CD)</td>
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</tbody>
</table>
### Day 2 (18 October 2012)

<table>
<thead>
<tr>
<th>Session 5</th>
<th>09.00 – 10.30</th>
<th>Objective: To provide an update on the Global Drug Facility and drug availability</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>- Update on GDF</td>
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<td>- Update on availability of SLDs and Group 5 drugs</td>
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<td>- Update on clofazimine</td>
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<td>Discussions</td>
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<td>GDF (TM)</td>
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<td>STB/LDR (EJ)</td>
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| 10.30 - 11.00 Coffee |

<table>
<thead>
<tr>
<th>Session 6</th>
<th>11.00 – 11.45</th>
<th>Objective: To provide advice on treatment regimens for R-resistant TB patients</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>- Should all patients with R-resistant TB be treated with a full MDR-TB regimen?</td>
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<td></td>
<td>Discussions</td>
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<td>STB/LDR (DF)</td>
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<table>
<thead>
<tr>
<th>Session 7</th>
<th>11.45 – 13.00</th>
<th>Objective: To provide an update on “short” regimens for the treatment of MDR-TB, and to present WHO’s position and action</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>- Evidence from Bangladesh for “short” MDR-TB treatment regimens</td>
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<td></td>
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<td>- WHO’s position and action</td>
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<td>Discussions</td>
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<td>The Union (AvD)</td>
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<td>STB/LDR (EJ)</td>
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| 13.00 – 14.00 Lunch |

<table>
<thead>
<tr>
<th>Session 8</th>
<th>14.00 – 15.30</th>
<th>Moving forward on global support to scale-up of MDR-TB services and care (brief introductions, followed by discussion)</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>- Feedback from informal consultation, June 2012</td>
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<td></td>
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<td>- Aligning diagnosis and treatment</td>
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<td>- Building momentum for technical assistance</td>
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<td>- Innovations for PMDT capacity building</td>
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<td></td>
<td>Discussions</td>
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<td>STB/LDR (KW)</td>
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<td>STB/LDR (FM, WvG)</td>
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<td>STB/LDR (FW)</td>
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| 15.30 – 16.00 Coffee |

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<tr>
<th>Session 8 ctd</th>
<th>16.00 - 17.30</th>
<th>Discussions continued</th>
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<thead>
<tr>
<th>17.30 -18.00</th>
<th>Wrap up Day 2</th>
<th>Chair (CD)</th>
</tr>
</thead>
</table>

| 18.00 – 19.00 | Cocktail reception, D Building Cafeteria |
### Day 3 (19 October 2012)

**Session 9**
08.30 – 10.30

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Chairs:</th>
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<tbody>
<tr>
<td>08.30</td>
<td>I. GLC and MDR Core Group - Looking Forward</td>
<td>gGLC (CD) and MDR-TB WG (AK)</td>
</tr>
<tr>
<td>09.30</td>
<td>1. Welcome and Introductions</td>
<td>CD and AK</td>
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<tr>
<td>10.00</td>
<td>2. Stop TB Partnership - Update on Strategic Plan and future direction</td>
<td>LD</td>
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<tr>
<td>10.30</td>
<td>4. WHO - New organizational structures</td>
<td>KW</td>
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<tr>
<td>10.45</td>
<td>5. GLC - Update</td>
<td>CD</td>
</tr>
<tr>
<td>11.00</td>
<td>6. MDR - Core Group - Update</td>
<td>AK</td>
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<tr>
<td>11.15</td>
<td>Open Discussion - The Way Forward</td>
<td>ALL</td>
</tr>
</tbody>
</table>

**Coffee**
10.30 – 11.00

**Session 10**
11.00 – 12.00

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Chairs:</th>
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<tbody>
<tr>
<td>11.00</td>
<td>Planning for the MDR-TB Stakeholders Meeting, Kuala Lumpur, Malaysia, 11-12 November 2012</td>
<td>MDR-TB WG (AK) and gGLC (CD), and MDR-TB WG Secretariat (FM)</td>
</tr>
<tr>
<td>12.00</td>
<td>Wrap up and other business</td>
<td>Chair (CD)</td>
</tr>
</tbody>
</table>

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CD Charles Daley        FW Fraser Wares
KW Karin Weyer         DP Domingo Palmero
AY Askar Yedilbayev   RS Rohit Sarin
LR Lee Reichman        DK Daniel Kibuga
AK Aamir Khan          MG Malgosia Grzemska
KL Knut Lönnroth      CL Christian Lienhardt
CG Chris Gilpin        DF Dennis Falzon
TM Tom Moore           EJ Ernesto Jaramillo
AvD Armand van Deun    FM Fuad Mirzayev
WVG Wayne Van Gemert   LD Lucica Ditiu
List of participants

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   Ambassador Court, Block A 5
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2. **Chen-Yuan Chiang**
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6. **Aamir Khan**
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8. **Andrey Olegorich Maryandyshev (Unable to attend)**
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   Head of the Phthisiopulmonology Department
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9. **Domingo J Palmero**
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   Buenos Aires
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10. **Michael Rich**
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3rd Meeting of the Global GLC Committee
17 -19 October 2012, World Health Organization, Geneva, Switzerland

11. Lee B. Reichman
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12. Rohit Sarin
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13. Hind Satti
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   LESOTHO

14. Askar Yedilbayev
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   Almaty 050013
   KAZAKHSTAN

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17. Patrizia Carlevaro (Unable to attend)
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   Otsuka SA
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   Switzerland

18. Paula Fujiwara (Unable to attend)
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   NIGERIA

22. Paul Thorn
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   4 Golf Drive
   BN1 7H7 - Brighton
   UNITED KINGDOM
23. Catharina Lambregts van Weezenbeek (Unable to attend)
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   Geneva 27
   Switzerland

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   Geneva

29. Ernesto Jaramillo, STB/LDR, WHO
   Geneva

30. Daniel Kibuga, rGLC Secretariat,
    WHO AFRO, Brazzaville

31. Fuad Mirazayev, STB/LDR, WHO
    Geneva

32. Fraser Wares, STB/LDR, WHO
    Geneva

33. Karin Weyer, Coordinator, STB/LDR, WHO Geneva

Stop TB Partnership Staff

34. Lucica Ditiu, Executive Secretary
35. Kaspars Lunte, Team Leader MDR
    TB supply GDF

36. Thomas Moore, Manager, GDF