Ending drug-resistant TB in WHO South-East Asia Region

Eleventh meeting of the Regional MDR-TB Advisory Committee (rGLC SEAR)

Dhaka, Bangladesh
25-26 FEBRUARY 2019
Contents

Acronyms ........................................................................................................................................ iii
Executive Summary ...................................................................................................................... iv
Background .................................................................................................................................. 1
Objectives of the meeting ............................................................................................................. 1
Inaugural session .......................................................................................................................... 2
Session 1: Background and introductions .................................................................................... 3
Session 2: Partners support in the SEA region ........................................................................... 6
Session 3: Planning transition to newer drugs and regimen ...................................................... 9
Session 4: Donor support for transitioning in the Region .......................................................... 13
Session 5: Plenary discussions on challenges faced by national programmes ....................... 15
Session 6: Community support in managing DR-TB ............................................................... 15
Session 7: Key advances in drug monitoring, research and management of MDR-TB .......... 17
Session 8: Planning for 2019 ................................................................................................... 20
Recommendations and actions to be taken ............................................................................... 21
Annex 1: Meeting agenda ......................................................................................................... 24
Annexure 2: List of Participants ............................................................................................... 26
Acronyms

aDSM active drug safety monitoring and management
Bdq bedaquiline
CDC Centers for Disease Control and Prevention, Atlanta
Cfz clofazimine
Dlm delamanid
DR-TB drug-resistant tuberculosis
DST drug susceptibility test
FQ fluoroquinolones
EQA external quality assessment
GF the Global Fund
GDF Stop TB Partnership's Global Drug Facility
GDI Global Drug-Resistant Tuberculosis Initiative
KNCV Royal Dutch Tuberculosis Association
Lzd linezolid
MDR-TB multidrug-resistant tuberculosis
MoH Ministry of Health
MoU memorandum of understanding
NSP National Strategic Plan
NTP National Tuberculosis Control Programme
NTRL national tuberculosis reference laboratory
PMDT programmatic management of drug-resistant tuberculosis
PPM public-private mix
PSM procurement and supply chain management
PV pharmacovigilance
rGLC Regional Green Light Committee
RR TB rifampicin-resistant tuberculosis
R&R recording & reporting
SEAR South-East Asia Region
SLD second-line drugs
SLI second-line injectable
SNRL supranational reference laboratory
STR shorter treatment regimen (for RR/MDR-TB)
TB tuberculosis
TWG technical working group
UHC universal health coverage
UN United Nations
XDR-TB extensively drug-resistant tuberculosis
Executive Summary

WHO Regional Office for South-East Asia organised a Regional MDR-TB Advisory Committee (rGLC) meeting on “Ending MDR-TB in the South-East Asia Region” from 25 to 26 February 2019. This was the 11th rGLC meeting and first of the reconstituted committee.

Participation was invited from 11 rGLC members, MDR-TB focal points from 6 High-burden countries, partners like Civil Society and affected communities’ representatives, the Global Fund, Stop TB Partnership’s Global Drug Facility (GDF), Stop TB Partnership and the US Agency for International Development (USAID). List of participants is attached at the end of the report along with the agenda of the meeting.

The objectives of the meeting included discussions on roles and responsibilities of the members, review of progress in DR-TB services in the Region and recommendations on way forward. Dr Fraser Wares was elected as Chair of the rGLC while Ms Paransarimita Winarni was elected as Vice Chair at the start of the meeting. The two-day meeting included sessions on background information, partner support in the Region, planning transition to new drugs and regimen, donor support, community support for ending TB, updates on research in the field and final session on planning activities.

Some of the key action points for rGLC members include development/ adoption of an OR protocol for standardised data collection on studies for all-oral shorter regimen; checklists to support rGLC consultants; review of mission reports as and when available; develop advocacy message to be shared with all member states for the introduction of new drugs and regimens, including transition to the 2019 WHO Guidelines on DR-TB treatment consider ‘data for action’ workshop to help countries use the available data in establishing strategic priorities.

Key action points for rGLC secretariat include development of an inventory of partners engaged in PMDT work in the SEA Member States; develop a summary of common areas of concern across the different Member States and proposed actions; organise a Webinar for all members once every two months; undertake a laboratory capacity assessment for Member States and share with rGLC members and share available information on aDSM status in countries, based on the workshop conducted last year. Organise a follow-up workshop to last year’s workshop to share experiences and develop/amend framework plans for the implementation of aDSM in member states.

The meeting concluded with a vote of thanks to the Chair and Vic-Chair of the meeting.
Background

The burden of tuberculosis (TB) remains disproportionately high in the WHO South-East Asia (SEA) Region, home to 26% of the world’s population. In 2017, an estimated 4.4 million people fell ill with TB in the SEA Region, representing 44% of the total TB incidence globally. SEA region is home to 6 high TB burden countries - Bangladesh, DPR Korea, India, Indonesia, Myanmar and Thailand\(^1\).

Although the Region experiences relatively low levels (2.7%) of multi drug resistant (MDR) and rifampicin-resistant (RR) forms of TB among newly detected cases, and 13% among previously treated cases, given the large number of TB cases in the Region, this translates into 99 000 estimated MDR/RR-TB cases among notified pulmonary TB cases each year.

The Regional Advisory Committee on MDR-TB in the WHO South-East Asia Region, also known as the Regional Green Light Committee (rGLC) was established in 2012 as an advisory body to the WHO Regional Director. The committee provides guidance on new policies and strategies and implementation of programmatic management of drug-resistant TB (PMDT). The members also actively engage in technical assistance activities.

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Objectives of the meeting

- Discuss roles and responsibilities of the advisory committee among the newly elected members;
- Follow-up on Regional meeting in December 2018 for planning transition to new regimen;
- Review status and progress of diagnostic capacity and treatment capacity in Member States specifically high burden countries keeping in view the new guidelines for treatment of RR/MDR-TB;
- Assess the technical support needs of the Member States in coming years and the role of rGLC members as well as other partners;
- Propose key activities of the rGLC for 2019 for enhanced support, and
- Make recommendations for the rGLC secretariat and Member States.

\(^1\) Global tuberculosis report 2018, World Health Organization, Geneva 2018
Inaugural session

The meeting was inaugurated by Mr. Mohammad Asadul Islam, Secretary, Department of Health Services, Bangladesh along with Dr Bardan Jung Rana, WHO Representative (WR) to the WHO Country Office, Dr Tjandra Yoga Aditama, Ag Director, Communicable Diseases Department, South-East Asia Regional Office (SEARO) of WHO and Prof. (Dr) Md. Shamiul Islam, Director, MBDC and Line Director TB, Lep & ASP, Bangladesh.

The WR welcomed the dignitaries and participants to the workshop. He highlighted the disproportionate burden of TB in the Region. He mentioned that the UN General Assembly High Level Meeting (UNHLM) on ending TB which took place in New York in September 2018, endorsed an action-oriented intergovernmental political declaration which embraced the advancing the response to TB through the 2030 agenda for Sustainable Development Goals, increasing multisectoral actions and intensifying innovative approaches for prevention, diagnosis, treatment and care. He emphasized the need for faster implementation of strategies and providing quality care to all those who need effective TB control.

Dr Aditama, talked about the disproportionately high burden of TB in the WHO SEA Region, home to 26% of the world’s population. In 2017, an estimated 4.4 million people fell ill with TB in the SEA Region, representing 44% of the total TB incidence globally. The performance of DR-TB control in region lags with only 51 788 MDR-TB and 2 755 XDR-TB notified in 2017, with 50% treatment success for MDR-TB and 28% for XDR-TB. Based on the five priority actions for MDR-TB control as advocated by WHO, the priority remains prevention of acquired drug resistance by ensuring high detection and cure rates through high quality services. In this context, addressing the high rate of missing cases faced by countries will be very important. It is equally important to treat RR/MDR-TB cases with high quality drugs and regimens. This becomes rather more important with the recent review of evidence on efficacy of drugs by WHO and the regrouping of the drugs used. In a nutshell, the DR-TB control programmes in the region need to strengthen existing services, introduce and scale-up new technologies, and update the policies and guidelines while garnering support from all stakeholders in the country.

The Secretary in his speech gave an overview of the TB control programme in Bangladesh. He stated that Bangladesh has a high burden of TB and an estimated 364 000 cases appeared in 2017. The total number of tuberculosis cases notified in the same year were 244 201. Bangladesh also had an estimated 8 400 RR/MDR-TB cases emerge in 2017. The country stands committed to attaining the SDGs for ending TB by 2030.

The Director, MBDC highlighted the programme achievements and efforts to reach out to all DR-TB patients. He informed the gathering that notification of DR-TB cases has gone up in the country. The country has also been a pioneer in testing a new shorter regimen that has been endorsed by WHO. He also mentioned the country’s interest in testing an all-oral shorter regimen around which work needs to be done. The programme has engaged with several partners and international organizations to improve access to services and it is expected that programme performance will improve further in coming years. The Director thanked rGLC for its continued support to the country.
Session 1: Background and introductions

All participants of the meeting were introduced, including the ex-rGLC chair, the incoming new rGLC members, community members, NTPs and partner representatives. The floor proposed Dr Fraser Wares (KNCV, The Netherlands) as the Chair and Ms Para Sarimita Winrani (PETA, Indonesia), as the Vice Chair for the committee. The chair reiterated the role of the rGLC and its members and how the committee needs to move forward differently in these new times – the committee members need to ask themselves what they can do better to assist the rGLC in moving forwards and how we can harness all available partnerships and resources. He asked members to think about what the rGLC could do, what it should do and what it can do over the next one year.

1. **rGLC MOU and activities conducted over the past years: Dr Rohit Sarin, NITRD, India**

   The ex-Chair of the outgoing rGLC presented on the new WHO/GF rGLC MoU 2017-2019, and the activities conducted in the last year. He emphasized the challenges of the Region with the highest burden of TB and with a view of ending TB in the region.

   He narrated a short history of rGLC and how during its evolution, it was realized that instead of just policing or monitoring, it should have a facilitator role to support the countries in expanding services and achieving the global End-TB targets. He stated that the reviewing the progress in the past may not have been up to the mark and a rethink is needed on how to improve moving forward as a new rGLC team. He raised a number of the challenges faced by the previous rGLC members in executing the roles and responsibilities of the rGLC.

   Capacity building should remain the main focus of country support in the context of PMDT. Focus of effort is on quality of DR TB management, revising and implementation of PMDT plan in alignment with the regional plan. The country’s need for support varies from country to country and technical assistance (TA) needs must be demand driven and contextualized to the respective country’s needs. The principles of the latest MoU are an enhanced package of services to be provided to the high burden countries and a core package of services to be provided to the other countries with at least one country visit annually and enhanced capacity building.

2. **rGLC Global Perspective: Dr Medea Gegia, WHO HQ, Switzerland**

   DR-TB is a crucial issue and needs a global scale up of response given the 75% gap in diagnosis and unacceptably low treatment success rate of 55% globally. Significant global investment in PMDT and rGLC were being made in the past GF grant cycles to improve the situation. However, there is still a significant level of Lost to follow-up (LTFU) and not evaluated cases of DR-TB which remains to be improved.

   The key targets for impact of the UNHLM Political declaration 2018-2022 are: Treat 40 million TB affected people 2018-2022, including 3.5 million children and 1.5 million people with drug-resistant TB (including 115,000 children), and provide 30 million people with preventive treatment.

   The rGLC mechanism as a platform for bringing key stakeholders together with the principle of performance based, country driven, cost-sharing and mutual accountability plays an important role. The recent paradigm shift in rGLC operations from a monitoring to advisory and support mission means complementarity, country ownership, and value addition to local efforts which is consistent with the concept of demand driven TA that responds to respective country needs - an integral part of the current MOU with the GF.

   Currently 95 countries are benefitting from rGLC support based on country disease burden and receive enhanced or core service packages based on country demand and ownership to address the recommendations.
Progress in the provision of TA missions globally is very good and around 92% of the eligible countries were supported by the respective rGLC. The three-main areas of support were: PMDT TA missions (tailored to specific country needs); country capacity building; and capacity building for TA resource persons.

The framework of indicators for monitoring rGLC progress consist of Lab. diagnostic capacity, MDR-TB Diagnosis performance (DST coverage), MDR-TB detection performance (notifications), MDR-TB treatment performance (enrollment), aDSM (SAEs), PMDT plans & guidance tools, Technical Assistance and Country capacity building. These were chosen with the rationale of enabling systematic monitoring of rGLC activities and selected indicators focused on progress in the various areas of rGLC work streams and top 10 End TB strategy indicators.

The role of rGLC members to support quick transition and uptake of the new WHO recommendation on DR-TB treatment guideline were highlighted. The consolidated DR-TB treatment guideline will be available by the end of March 2019 and the Companion Handbook will be released by the end of the year. These documents will provide the core guidance to the countries as they transition to the new WHO recommended treatment regimens. Universal access to DST remains a critical factor here.

The rGLC mechanism provides a viable platform for effective coordination of stakeholders efforts in supporting regional and country level efforts to scale up global response to MDR-TB, plays a critical role in accelerating the scale up of new diagnostics, implementation of the shorter treatment regimen (STR) and uptake of the new TB drugs. The rGLCs are well-positioned to work with all stakeholders towards supporting country adaptation and implementation of the new DR-TB treatment guidelines.

rGLC members were reminded of the requirement of timely review and submission of mission reports, with recommendations being prioritized and an emphasis being given to the need for adaptation of the recent WHO

Key recommendations in the 2019 WHO consolidated guidelines on drug-resistant tuberculosis treatment

**Regimens for isoniazid-resistant tuberculosis (Hr-TB)**
- In patients with confirmed rifampicin-susceptible and isoniazid-resistant tuberculosis, treatment with rifampicin, ethambutol, pyrazinamide and levofloxacin is recommended for a duration of 6 months.

**The composition of longer MDR-TB regimens**
- In MDR/RR-TB patients on longer regimens, all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four TB agents likely to be effective. If only one or two Group A agents are used, both Group B agents are to be included. If the regimen cannot be composed with agents from Groups A and B alone, Group C agents are added to complete it.
- Kanamycin and capreomycin are not to be included in the treatment of MDR/RR-TB patients on longer regimens.
- Bedaquiline should be included in longer MDR-TB regimens for patients aged 18 years or more.
- Bedaquiline may also be included in longer MDR-TB regimens for patients aged 6–17 years.
- Linezolid should be included in the treatment of MDR/RR-TB patients on longer regimens.
- Clofazimine and cycloserine or terizidone may be included in the treatment of MDR/RR-TB patients on longer regimens.
- Amikacin may be included in the treatment of MDR/RR-TB patients aged 18 years or more on longer regimens when susceptibility has been demonstrated and adequate measures to monitor for adverse reactions can be ensured. If amikacin is not available, streptomycin may replace amikacin under the same conditions.

**Use of the standardized, shorter MDR-TB regimen**
- In MDR/RR-TB patients who have not been previously treated for more than 1 month with second line medicines used in the shorter MDR-TB regimen or in whom resistance to fluoroquinolones and second-line injectable agents has been excluded, a shorter MDR-TB regimen of 9–12 months may be used instead of the longer regimens.
recommendations, aligning national policies with the recommendations of the new WHO policy, and identification of the gaps in PMDT provision with linked proposed solutions.

3. Regional progress report: rGLC secretariat (Dr Vineet Bhatia, WHO SEARO, India)
There has been substantial improvement in the region in terms of trends in DR-TB screening. The screening proportion for drug resistance among TB patients in the Region is improving and is better than the global average reaching 27% for new cases and 85% for retreatment cases in 2017 against global average of 24% and 70% respectively for the same period. Case notification and treatment trend is improving but there is still gap between diagnosis and treatment. The low treatment success has to do with several operational reasons to ensure adherence and appropriate service package.

Significant increases in planned enrolment on new regimen as per the updated WHO guidelines on DR-TB treatment is expected by end-2019. Early adoption is expected in Bhutan, Indonesia, Nepal Sri Lanka, Thailand and Timor-Leste. Bangladesh will widely use Amikacin substitution in STR and OR on a modified STR will be carried out. India will use STR and all-oral regimen as back up, and Myanmar has already been using Am in place of Km in the STR.

A key achievement in 2019 was that nine of the ten eligible countries had an rGLC mission conducted, 2 workshops for capacity building were held (on i. molecular tests and ii. aDSM) in partnership with the Global Fund, USAID, GDF, KNCV, Challenge TB, FHI360, and other partners. ‘Community engagement tools for MDR-TB’ are being developed led by CSOs. And a country support for transition planning (and LTBI) workshop was held 12-14 December 2018, in which civil society, Global Fund, USAID, GDF, KNCV, The Union, FIND, CHAI, MSF, IFRC and other partners were involved. Five meetings of the advisory committee were held in 2018 – one face to face and 4 web-based. All rGLC country mission reports are now available on the website in public domain http://www.searo.who.int/tb/data/en/.

Progress against last year’s rGLC meeting recommendations

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<th>Recommendations for the committee</th>
<th>Progress</th>
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<tr>
<td>Create ‘how-to’ document/practical tips for providing care to DR-TB patients, specifically for nurses. Ms Sirinapha to take the lead in development of this document with support from interested partner organization/s</td>
<td>Pending</td>
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<tr>
<td>To enhance visibility of the rGLC mechanism; editorial/commentary to be considered for publication; Dr Patrick Moonan to take the lead along with the chair of rGLC</td>
<td>Pending</td>
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<tr>
<td>Further discussions are needed on role of rGLC in promoting support and rehabilitation for patients undergoing second-line treatment for drug-resistant TB. Ms Blessina Kumar will lead the discussions</td>
<td>Pending</td>
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<th>Recommendations for the secretariat</th>
<th>Progress</th>
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<tr>
<td>Create database of key partners actively supporting PMDT activities in the Region and update periodically to include any upcoming meetings/trainings/workshops within the Region.</td>
<td>Partly done. A list of key partners is available</td>
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<td>Continue video conferences and conference calls art frequency of about once in two months</td>
<td>5 Webinars were held in 2018 following this meeting</td>
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<td>Increase pool of consultants with different technical areas to address the emerging needs of PMDT, e.g. aDSM, Infection Control. Secretariat to</td>
<td>Regional aDSM capacity building workshop was held</td>
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http://www.searo.who.int/tb/data/en/
explore with USAID regarding tapping their pool of consultants for Regional needs

However Funding for training of consultants on whole range of subjects was not available.

Secretariat to initiate discussions with rGLC members on Centre of Excellence (CoE) for PMDT pertaining to the expectation from a CoE in terms of activities, expected basic/available capacity and infrastructure, possible support and certification process

Pending

Update PMDT monitoring format to adopt some of the key monitoring indicators being used in EURO

Some changes were done to align reporting format with GF requirements

Several operational challenges were also identified such as clustering of the missions in the second half of the year, limited availability of pool of consultants, coordination of mission between partners and DPRK’s uncertain future donors. There are financial challenges such as additional needs for capacity building workshops/training/mentoring for the consultants and funding for community engagement tools development and CSO capacity building.

During the discussions, Mohammed Yassin, the Global Fund, congratulated the progress made thus far. He said that based on the independent review of the rGLC in 2011/12, changes have been made to the support provided based on country needs. It needs to be remembered that as the money is coming from the country grant and hence the support provided needs to be accountable to the countries. At least one visit per annum should be made and all the support provided to the contributing countries needs to ensure capacity building of the respective country. He said that the rGLC in all regions contributed to increase coverage and scale up PMDT services. The funding from the GF to the rGLCs is provided under a cost sharing mechanism along with other partners e.g. USAID. The current MoU will be expiring end of 2019 and discussions are ongoing for renewal for the next three years in alignment with the GF grant cycle. He also mentioned that an rGLC can support countries other than those who receive GF funding where the rGLC feels the need to provide the required support, as long as the resources remain adequate for providing the mandated support to the countries that are contributing to the rGLC mechanism from their GF country grants.

Session 2: Partners support in the SEA region

1. **Technical support to DR-TB Programmes in the Region (Challenge TB experiences)** - Dr Fraser Wares, KNCV, The Netherlands:
   The Challenge TB project is a 5-year (2015-2019) flagship global TB project funded by the US Government, led by KNCV. The project supports 23 countries in Central Asia, South and South East Asia and Africa. The nature of support provided varies widely across the countries. In the SEA region, support is provided to Bangladesh, India, Indonesia and Myanmar. The support varied from assisting NTPs with STR introduction to revision of PMDT guidelines in Bangladesh to PMDT TA provision to Bdq CAP sites in India, PMDT expansion in Indonesia and TA support to NTP and FDA for establishment of an aDSM system in Myanmar.

   Lesson learnt were varied across the countries and challenges were country specific with some commonalities such as laboratory network, limited new drug and regimen experience, aDSM, etc. SAEs are reported from all four countries and national scale up of aDSM is needed. Countries continue to require TA, particularly in relation to the alignment of DR-TB treatment with the WHO 2019 guidelines.
Planned technical support in 2019 to the 4 countries in the Region include continuing support to the national coordination meetings, support FDA to become full member of WHO-IPDM, workshop on management of AEs related to the newer drugs and support aDSM implementation review meetings.

2. Support to Bangladesh and other countries-Damien Foundation experiences- Dr Aung Kya Jai Maug, Damien Foundation, Bangladesh

In Bangladesh, Damien foundation (DF) had been involved in TB services since 1991 and its MDR-TB project since 1997. DF works in 13 districts covering 28 million population, 103 sub districts, 3 hospitals and 150 microscopy centres, 5 EQA central laboratories and 1 reference laboratory for AFB culture and DST. DF delivers services through the existing government health service structures. The organisation works with government, other partners and private sectors with coordination at different levels. They work extensively with the community ensuring community awareness that includes planned health education sessions; NGO, School, Community group health education and education during absentee visit, DOT visit, Drug delivery. Clinic health education is carried out in OPD (twice daily) and Indoor (twice weekly). There is also involvement of community groups such as TB Club at upazila & at unions involving local elites, religious leaders, school teachers, village doctor’s orientation and pharmacy holders and GP orientation. Coordination at various levels is held at NTP through TB partners coordination meeting, TB Technical Working Committee, M&E Working Group, Child TB Working Group; with PR BRAC through Quarterly performance review meeting, SR supervision & monitoring; with Leprosy & TB Coordination Committee (NGOs); and District level monitoring meetings, trainings etc.

DF played important role in design and implementation and scale up of STR in Bangladesh and supported in training on STR in Pakistan, Myanmar and Indonesia.

3. Laboratory strengthening needs in the Region- FIND experience – Mr Sanjay Sarin, FIND India, India

FIND India is a key implementing partner of the Revised National TB Control Programme (RNTCP) in India for TB laboratory strengthening. FIND supports delivery of lab services through upgradation of lab infrastructure, procurement of lab. supplies, equipment maintenance, HR and training support at national level. Through donors like UNITAID & Global Fund, FIND also supported development of lab infrastructure in Bangladesh, Indonesia and Myanmar, 61 C-DST laboratories established for the RNTCP, supported sustaining service delivery in 61 labs through management of laboratory equipment, consumables and maintenance of equipment that led to, 1.3M patients tested for TB/DR TB in these labs and 114,813 cases of MDR TB detected. They trained >3000 personnel, established Six Genome sequencing labs. heralding latest in diagnostic technologies and 45 mobiles vans provided with diagnostic capability to support active TB case finding efforts by the RNTCP.

Adoption and use of diagnostics connectivity solutions are monitored as core indicators for laboratory strengthening under the End TB Strategy. However, healthcare in LMICs remains hampered by poor quality, availability & use of diagnostic data. A data-centred initiative can knit together various aspects of interconnected networks.

Major underutilization of Xpert machines is observed in many settings. Often machines are incorrectly placed with sites of low burden, with a lack of focus on “need” during the planning of machine placement.
SIMplicity: enables low-cost, secure and dependable mobile data capabilities in low-resource settings. A global SIM digital connectivity service to support diagnostics and other connected healthcare devices and expert consultations on diagnostics and clinical connectivity offered to global health partners, from small-scale trials to regional programmes. Such technology can enhance real time use of data to improve linkage to treatment, inventory, systems and quality management.

Key point for the TB laboratory system strengthening are planning for implementation of diagnostic services, developing lab infrastructure, plans for maintenance & implementation of biosafety measures establishing systems for managing laboratory commodities and supplies, ensuring appropriate strategies and methodologies for training and capacity building of lab. HR, developing systems for lab data collection & management and optimizing lab networks to ensure access as per demand and ensuring optimal utilization

4. **Xpert MTB/RIF external quality assurance (EQA): Christine Ho, CDC, USA**

WHO-recommended rapid TB diagnostics (WRDs) should be available to all persons with signs or symptoms of TB, all bacteriologically confirmed TB patients should receive drug susceptibility testing (DST) at least for rifampicin (RIF) and all patients with RIF-resistant TB should receive DST at least for fluoroquinolones and second-line injectable drugs.

The potential gains of the Xpert MTB/RIF are significant decrease in diagnostic delays, increase in detection of drug resistance and impact on transmission. But, quality assurance of the diagnostic system is critical in optimizing use of the TB diagnostics including Xpert MTB/RIF.

Continuous quality improving (CQI) is critical for ensuring timely, accurate and reliable Xpert MTB/RIF test results and CQI implementation has struggled to keep pace with the rapid expansion of Xpert MTB/RIF testing.

CQI can be done at two levels: National and Supervisory Levels focusing on establishing or integrating Xpert MTB/RIF QA activities into the TB diagnostic network in a country or region and QA at Xpert MTB/RIF Testing sites addressing key activities to be carried out at the testing sites to ensure quality Xpert MTB/RIF results. However, challenges for the Xpert MTB/RIF proficiency testing are availability of affordable proficiency testing (PT) and lack of validated procedures for PT panel manufacture.

The Xpert MTB/RIF Performance Evaluation Program (XMPEP) was first piloted in 2013 to fill the gap in PT availability. This was piloted at 600 sites in India this year. The results are varying, and experiences show that there is room for improvement and provides a window of how things are happening when real samples are tested at the field site. It highlights the challenges of diagnostics when practiced in actual sites with real patient samples. Hence newer diagnostics such as Xpert is not a magic bullet solution to diagnostics problem. The PT results leads to action needed to fix the problem as the cost of poor quality testing results in under-diagnosis which can lead to worsening of disease and can contribute to the spread of TB (including drug-resistant TB) in the community and over-diagnosis which results in unnecessary patient treatment and stigma.
Session 3: Planning transition to newer drugs and regimen

1. Supporting quantification and forecasting for transition to new regimen: Alessio Mola, GDF

The speaker provided an overview of the services available through the Stop TB Partnership’s Global Drug Facility. Initiative of the Stop TB Partnership, housed in UNOPS, GDF has changed the landscape of TB care since its creation in 2001 by increasing access to high quality and affordable TB treatments & diagnostics to population in need. By the end of 2017, GDF delivered more than 30 million treatment courses to 139 countries. GDF is the largest global provider of quality-assured tuberculosis medicines, diagnostics, and laboratory supplies to the public sector.

The facilitator informed that similar to the paediatric-friendly formulations for Drug Sensitive TB, for the first time ever GDF can supply pediatric formulations of the second-line drugs used in the treatment of drug-resistant tuberculosis (DR-TB); these new formulations will be most beneficial in children who are 25kg and below.

More than 500 TB diagnostic products and laboratory supplies are currently in the GDF Catalogue to equip and maintain all levels of laboratories, from microscopy/GeneXpert centers to reference labs with culture/DST; the facilitator updated also on availability of pure drug substances for DST in line with new WHO DR-TB guidelines.

GDF offers a value-adding package of services, comprehensive technical assistance and capacity building to countries on quantification, forecasting, procurement and supply chain management of TB medicines - managed by regional technical advisors and pool of trained consultants; these services are focused on:

- Developing different scenarios for transition plans;
- Working with the NTP, in-country partners and Global Fund in the procurement and supply planning (PSP)
- Capacitating country teams on PSP and establishing fully functional quantification and early warning system

GDF also works in close coordination with the rGLC secretariat. Procurement and Request Forms for SLDs orders placed through GDF are shared with the GLC secretariat to:

- ensure number of cases are accurate based on NSP/targets and
- treatment regimens are aligned with WHO, country guidelines and recommendations from latest GLC country mission

GDF organizes technical missions to countries, participates in regional rGLG meetings, facilitates PSM sessions during trainings of new consultants.

GDF ensures access to all WHO recommended medicines and diagnostics in one place; through managing the Strategic rotating stockpile, GDF can reduce delivery lead times to countries and achieve price reduction for SLDs, while smoothing production cycles, accelerate orders and scale-up access. GDF also offers a unique tool, the Flexible procurement fund, to bridge procurement costs and speed up order placement when funds are not readily available in countries.

During the session, countries were also informed that Janssen-USAID Bedaquiline Donation Program ends on 5 March, 2019. The last date to submit procurement request forms to GDF is 5 March, 2019. The J&J post-donation bedaquiline price is USD 400 for a bottle of 188 tablets; this price is available to all countries who can purchase medicines via GDF.
As final key messages, the speaker highlighted some solutions to address the most common challenges while transitioning to new WHO recommended regimens:

- Accurate processes for quantification and supply planning and careful step-wise preparation and implementation along with proper procurement frequency - prerequisite for continued access to TB pharmaceuticals and diagnostics;
- Regularly updated quantification files from all countries to produce accurate global forecasts for GDF suppliers to smoothen production planning and to ensure that GDF medicines are provided at lowest-possible, sustainable prices.

Pooled procurement via GDF continues to be a solution:

- All quality assured TB pharmaceuticals and diagnostics recommended by WHO are available from GDF
- There are no anticipated supply limitations for all reclassified medicines on new DR/RR-TB regimens
- TA and capacity strengthening for the introduction of new recommendations are available through GDF and USAID-funded projects

During the discussion, countries asked whether orders already placed based on previous recommendations can be cancelled or modified. The speaker explained that this will depend on how far the order has been processed, on other medicines included in the same order and on country programmatic needs (e.g., risk of stock outs). For confirmed orders where NTPs wish to cancel, please contact GDF, who will do its best to find a solution on a case-by-case basis. Orders for which purchasers have given the green light for packing typically cannot be modified or cancelled; it is therefore important for the purchaser to be sure that the products will be used before giving the green light for packing.

Wastage endorsement should be considered and transition plans with scenarios for estimation of volumes/values of obsolete medicines for withdrawal and/or increased demand of medicines could be developed.

The Global Fund facilitator informed that The Global Fund is willing to absorb the cost of any wastage of non-recommended drugs.

Global Fund clarified that it would follow WHO recommendations in principle. However, country specific discussion and justifications may be considered to ensure there is no disruption of services.

2. Private sector engagement for transitioning to new WHO guidelines for MDR-TB: Dr Ye Tun, Myanmar

While presenting on the necessity to engage the private sector, Dr Ye Tun dwelled on the consequence of non-engagement of private sector. These include:

- Increased transmission as a result of delayed diagnosis and treatment.
- Excess mortality and morbidity as a result of inappropriate treatment.
- Increased drug resistance as a result of incomplete treatment.
- Catastrophic costs to patients and their families as a result of out-of-pocket expenditures for private care.
- Incomplete monitoring and evaluation of TB services.

Some of the ways of engagement of private sector include:

- Identifying patients with presumptive DR-TB and referring them to PMDT sites
- Promote and support patient care, and provide DOT, including identification and reporting of side-effects of SLDs
- Provide DR-TB patients and their family members with TB health education (infection control, and early case detection of TB disease among contacts)
- Participate in advocacy and communication activities at community level to support TB and DR-TB control

Introduction of new TB drugs requires a set of best practice regulations by ministries of health to provide rational access to and protection of the new drugs against development of resistance. Collaboration with the private sector is also crucial to determine the pathway for access and use of the new drugs. There is also need for dissemination of knowledge about SAEs to private sector to meaningfully engage with the private sector for MDR TB patient care. Laboratories or health-care facilities in the private sector with DST capacity can diagnose DR-TB and refer DR-TB patients to a PMDT site. It is necessary for the private sector however to comply with the national policy on diagnostic algorithms for DR-TB and meet the required national quality assurance (QA) standards and use of the NTP’s recommended diagnostics for the diagnosis of DR-TB. It is also necessary to take on board and engage private sector NGOs who are involved in direct DOT to DR TB patients.

Overall, successful PPM initiatives would need:
- Political commitment or mandate for the role of private sector care providers (PSCP) in the care and management of MDR-TB patients.
- Care providers from the Private sector need to be made aware of MDR-TB diagnosis and treatment processes.
- Advocacy for current MDR-TB diagnosis and treatment with possible forthcoming changes in regimen should be conducted to PSCP (including awareness of potential drug side effects of regimen changes).
- Preparedness for orientation of changing regimen for private sector care provider is important.
- Private sector collaboration and coordination needed to pay attention for policy maker level for MDR TB detection and seeking proper management.

Dr Ye Tun also made a short presentation on Myanmar experience with use of Amikacin. He said that Myanmar had used kanamycin widely for the previous 40 years to treat various infections, including gonorrhea. This means kanamycin was widely used by general practitioners and hence the possibility of baseline Km resistance is high. Thus, the National Expert DR-TB committee guided NTP to use amikacin (Am) when the DOTS-plus pilot project was launched in mid-2009. Hence the country has used Am for almost 9 years. The treatment success rate has been 80% or more for past 3 years’ patient cohorts. Myanmar uses Am and Eto in STR (instead of Km and Pto) as in the conventional regimen.

3. Challenges in implementing new MDR-TB guidelines: Dr Wipa Reechaipichitkul, Thailand

Dr Wipa first highlighted the current and new regimen to treat RR/MDR-TB. Group of drugs to treat MDR-/RR-TB now include Gr. A (Core drugs), B, C. For most cases starting with 4 drugs and dropping to 3 once Bdq is stopped seems to be sufficient. But this is a conditional recommendation and countries may opt to start with 5 agents instead of 4 to avoid the need to replace a medicine into treatment, namely:
- 2 of the 4 agents are likely to be stopped before the end of treatment, for instance Bdq stopped at month 6 and Lzd stopped early because of toxicity;
- Reliable DST is not available for one or more of the agents on the regimen but background resistance to the agent is known to be high;
- The agents included in the regimen are unlikely to cure the patient (e.g. only total of 2 of the agents from Group A and Group B are included in the regimen)

Rapid diagnostic tests, e.g. line probe assay, to detect resistance to second-line anti-TB drugs (SL-LPA) are essential specifically when using the shorter MDR-TB regimen (9-12 months). The SL-LPA produces results in just 24-48 hr. It allows quick triage of confirmed MDR-TB patients into the shorter MDR-TB regimen (9-12 months):
  - RR (Xpert MTB/RIF) or MDR-TB (LPA),
  - No previously treated with second-line drugs > 1 month,
  - Excluded XDR-TB (resistance to fluoroquinolones and second-line injectable drugs)

**Figure 1: Exclusion/Inclusion criteria for shorter regimen**

![Diagram showing exclusion and inclusion criteria for shorter regimen]

Thailand has a plan for reducing TB incidence by 12.5% per year by 2021 as per the national strategic plan. This would also mean adequately addressing the problem of RR/MDR-TB. The presenter also quoted the examples with adoption of new regimen from Thailand which has achieved wide coverage for patients under health schemes.

1. Universal Coverage (UC): 75% (47 million people)
2. Social Security Scheme (SSS): 16%
3. Civil Servant Medical Benefit Scheme (CSMCS): 9%
4. Others: Private Insurance: Out-of-Pocket (OOP)

Challenges to implementing new DR-TB guidelines include:
  - Lack of capacity for SL DST and/or Whole genome sequence
  - Low awareness leading to shortage of drug supply for new MDR-TB regimen
  - For Private hospital: How to access Bdq based regimen
  - How to prevent drug resistance to new longer regimen
  - Administration of treatment for migrant MDR-TB patients specifically those not covered under insurance schemes

During discussions, Dr Wipa clarified that many hospitals in the country have introduced the STR and there is an intention to continue the STR as it is found to be effective. Next week, there is the
national expert committee meeting for shorter regimen v/s longer regimen in Thailand that would review the decisions.

Session 4: Donor support for transitioning in the Region

1. **Global fund perspective on PMDT expansion in light of the new WHO recommendation:**
   **Dr Mohammed Yassin, the Global Fund, Switzerland**

The Global Fund (GF) allocates funding to eligible countries to support HIV, TB and malaria programs and to build resilient and sustainable systems for health. These allocations are made every three years at the beginning of a new funding round. The GF adopted a refined methodology to calculate the country allocations during the 2017-2019 funding cycle. The 2017-2019 allocation methodology drives an increased proportion of funding to higher burden, lower income countries, and specifically accounts for HIV epidemics among key populations, the threat of MDR-TB and for malaria elimination efforts.

Globally, the GF is supporting scale up of responses to DR-TB especially to the scale up of diagnostic e.g. GeneXpert, STR and new drugs. GF also supported the strengthening of DR-TB services in the countries through the rGLC mechanism and providing support for the transitioning to the new WHO recommended MDR-/RR-TB regimens,. However gaps in coverage and quality remain. The MOU between the GF and WHO for rGLC support has been revised several times since the first MOU in 2007. The current MoU period is from 2017 to 2019.

He also informed that responses to the new recommendation for DR-TB treatment demonstrates GF’s flexibility/willingness to adapt quickly by the country to best standards/practices. GF participated in different discussions with WHO/partners before and after the rapid communication including participation in the development of FAQs and there was a positive discussion within GF internal team to support countries who are willing to transition. He said that there are many opportunities to mobilize additional resources to support implementation of new recommendation. Countries can reprogram the existing grants in view to adapt the new recommendation and submit to GF for approval. He also informed that GF is supporting 7 countries for transition with USD $17 million under the Wave 2 portfolio optimization (PO) process. Wave 3 will be coming soon.

Participants said that drug support is not enough and supportive measures to improve diagnostics and other programmatic components will be critical. Patient-centred support for treatment adherence and aDSM are essential. GF will support as per available resource and encourage to leveraging support from other sources including domestic and other donors. In addition to funding TA through grants, Global Fund provides support for the six rGLCs as part of the MOU with WHO and will support countries for transition plan through rGLC mechanism. rGLC reports are used to for advocacy and decisions making and prioritize supporting countries to transition to the new guidelines. GF promotes capacity building at country and regional level to have a pool of experts to implement and support national programs.

2. **Donor perspective and support available for transition to new regimen: Dr Viktoriya Livchits, USAID, USA**

Dr Livchits presented USAID’s perspective and support available for transition to new WHO recommended RR-/MDR-TB treatment. TB is a top priority for the United States Government. USAID’s new TB business model, the "Global Accelerator to End Tuberculosis," will catalyse investments across multiple countries and sectors to end the epidemic while building self-reliance.
In response to the persistent challenges related to TB, including drug-resistant TB, the U.N. General Assembly held its first-ever high-level meeting on TB in 2018 to discuss these challenges and examine progress toward global goals, including ending the epidemic by 2030. The U.S. government (U.S.) involvement in global TB efforts was relatively limited until the late 1990s (1998 -- $10 million). Since that time, its efforts to address TB have grown, and now the U.S. is one of the largest donors to global TB control. U.S. funding for bilateral TB efforts through USAID was $261 million in FY 2018, up from $64 million in FY 2001. In February 2019, the US Congress passed the FY 2019 appropriations bill with an additional $41 million dedicated to international TB effort with total of $302 million. Additionally, the U.S. is the largest donor to the GF. U.S. TB activities reach more than 50 countries including at least 20 of the 30 high burden countries where most new cases are occurring, and focus on preventing, detecting, and treating TB, including drug-resistant

The National Action Plan for Combating Multidrug-Resistant Tuberculosis (National Action Plan/NAP) is a five-year plan that builds on, and contributes to, the U.S. Government’s domestic and global TB strategies, as well as the End TB Strategy of the WHO and the Stop TB Partnership’s Global Plan.

She said that new guidelines offer an opportunity to revisit and revamp global effort to reach all with DR-TB ensuring best care and treatment to obtain better treatment outcomes. She also mentioned that introduction of new guidelines will require a significant amount of TA to adapt guidelines to local context including translation guidelines into SOPs and to build local capacity. Countries will need TA to adapt drug and commodity procurement to implement the new guidelines.

She informed that at present USAID is supporting 23 countries (4 in the SEA region: Bangladesh, India, Indonesia and Myanmar) through the Challenge TB project, which is one of the flagship global TB USAID project. USAID also supports countries through another TA approach working via the Global Fund/MDR-TB Advisors towards 16 countries (2 in the SEA region: Bangladesh and Myanmar). These TB In-Country Advisors focus on improving the effectiveness of NTPs around the world by developing and strengthening the institutional capacity of NTPs and their staff. Another TA approach USAID is via the hiring of MDR-TB consultants through The United Nations Office for Project Services (UNOPS) to provide support to countries to review and finalization of guidelines or protocols, development of aDSM plans, guidelines and reporting algorithms, clinical management of patients on new drugs or regimens and capacity building of healthcare workers on clinical management of patients on BDQ/DLM and aDSM. At present, more than 11 countries have requested this TA.

In response to queries about USAID support for the new guidelines on MDR/RR-TB, she informed that USAID has two targeted areas for TA as per country situation. Countries that have already introduced the STR, USAID will support to both the longer and shorter regimen, including strengthening of laboratory services required for implementation of new guidelines. The countries that have not introduced the STR, USAID will support the introduction of the all oral longer regimen and operational research (OR) of a modified shorter treatment regimen (mSTR).

USAID is supporting the evaluation of a mSTR through the use of the DESTROY TB (Discovering Evidences Supporting the effectiveness of new Treatment for drug Resistant Tuberculosis) project. This is an open-label single-arm study to assess the country-specific feasibility and to measure the effectiveness of a new treatment regimen of 40 weeks (9 months) duration in patients with pulmonary RR-/MDR-TB. She presented the design of the DESTROY TB protocol and the proposed regimens.
The presenter assured the continuation of USAID global support for a successful DR TB program at all level and will promotion of the WHO treatment change through organizing webinars, and informative sessions with USAID country mission.

Session 5: Plenary discussions on challenges faced by national programmes

This session was an open discussion between the NTP representatives attending the meeting and rGLC members, along with the representatives of the other partners at the meeting. The overall objective of the session was to hear from the programmes regarding challenges faced and expected support from rGLC and partners to overcome the challenges.

Some of the common challenges mentioned by participants were:
1. Insufficient laboratory capacity to screen all TB cases for drug resistance to first and second-line drugs. Designated laboratories with DST capacity are generally centralized and access to laboratory diagnostic services is hampered by a lack of efficient sputum transportation mechanisms
2. Rapidly expanding, and largely unregulated, private sector in several countries and limited engagement with the formal TB surveillance systems. Providers outside NTP are not well connected to the national notification system and do not necessarily follow national guidelines for the diagnosis of TB
3. Enrolling all diagnosed patients on appropriate treatment is not always seen due to stigma, centralised treatment in several countries and lack of treatment capacity
4. Insufficient community engagement and lack of efforts for community empowerment. Adherence and monitoring support for patients is insufficient and often not uniformly available
5. aDSM systems to monitor and manage potential adverse events need strengthening specifically capacity building of support staff in monitoring and reporting of adverse events.
6. Most domestic funding allocations are insufficient to meet the burden-driven demand for resources

Expectations of the NTP representatives from the rGLC:
1. Continued capacity building in laboratory and aDSM
2. Capacity building on other new technologies like genome sequencing
3. Support with adoption of new drugs and regimen, specifically discussions with technical expert committees in respective countries, and support for drug quantification and forecasting needed from the GDF
4. Support networking of laboratories and interconnection of laboratory with programmes to ensure complete reporting
5. Support in transition for procurement of new drugs and regimens / disposal of non-recommended drugs during the transition period
6. Sharing of innovation from other countries

Session 6: Community support in managing DR-TB

1. Patient group PETA and support in Indonesia: Ms Paransarimita Winarni, PETA, Indonesia
Ms Paran from PETA (Pejuang Tangguh), a civil society organisation of affected communities from Indonesia, presented their work that helped improve MDR-TB related services through a community-driven approach. The presentation consisted of vision of the organisation and how outreach activities to patients are being undertaken. Major activities include: increase community awareness about DR-TB/TB by disseminating information using social media, print and electronic IEC materials, in train stations, in hospitals for outpatients, etc; provide support to increase patients adherence by Hospital visit, Puskesmas (Primary Health Center) Visit, Home Visit, Focussed Group Discussions, informal gathering, WhatsApp group; increase case finding through contact investigation of DR TB patients; increasing capacity of cadre at Puskesmas by facilitating training and discussion; Advocacy to government, with other CSOs and social media campaign.

The possibility of replication of these activities depends on:

- Need and willingness for voluntary services
- Capacity building opportunities
- Support from hospital/health service and local government
- Support from NGOs and private sector facilities.

There is a need to establish a formal platform for networks of TB patient organizations in South-East Asia:

- Online platform/website to share knowledge, publish articles, put videos
- Learning module in English as well as local language(s) to increase Financial and Program Implementation capacities TB patient organization members
- To chat and update each other about potential sponsorships

2. Overview of tools for strengthening community capacity and way forward: Ms Blessi Kumar, GCTA, India

Ms Blessi Kumar started with magnitude of TB problem in the WHO South-East Asia Region and how this problem cannot be addressed without engagement of communities. Meaningful community engagement through empowerment of affected community and effective involvement can play a major role in significantly addressing challenges including:

- low case notification
- early diagnosis and initiation of treatment which in turn will make a difference in the treatment outcomes
- treatment adherence
- issues of high loss to follow up and high number of deaths
- Low treatment success

Community empowerment to ensure meaningful participation in the TB response is a cross cutting need. The challenges of the missing persons with TB symptoms, the huge numbers seeking care in the private sector, the self-diagnosis and seeking care with the un qualified traditional healers, a lack of ability to demand for the right care, all stem from a community that is not empowered with the right information and a lack of mechanisms put into place to follow the right pathway to care. Empowering communities needs to be part of the TB response which requires an informed community with the right training and tools. Investing in establishing an informed, committed, enthusiastic and empowered community will address many barriers to care. Affected communities and Community Based Organizations (CBOs) can play a crucial role in ensuring a person centred, rights-based approaches in management of DR TB in their countries, provided their capacity is built with appropriate training to understand the science and management of DR TB.
The modules titled “Capacity-building of affected communities for accelerated response to drug-resistant tuberculosis in the South-East Asia Region: Training modules” have been developed to build capacity and empower them to be valuable partners in the DR TB response. The module development process is cognizant of the fact that TB survivors and affected communities come from a range of economic and social backgrounds. The modules are intentionally kept generic to facilitate adaptation to suit different cultural and social mores. It is envisaged that the facilitators would be experienced trainers having in-depth understanding of working with communities to use the modules effectively. The rGLC members need to discuss and decide how these tools can be used,

Session 7: Key advances in drug monitoring, research and management of MDR-TB

1. Active drug safety monitoring and management (aDSM) experience from Myanmar & strengthening opportunities for other Countries: Dr Mohammed Asif, Challenge-TB project, Myanmar

Dr Asif shared country experiences in strengthening mechanisms for the monitoring and management of adverse events among patients on second-line drugs. It was stated that partners organizations’ support to NTPs is an important aspect for the appropriate implementation of aDSM and its scaling up. Bdq has been observed to be safer than expected from the clinical trial data, however it should be used with appropriate monitoring for AE i.e. under aDSM. Hypokalemia associated with second-line injectables (SLI) is frequent and severe, exacerbating QT interval prolongation in many patients in STR and requiring a switch to a LTR. SLI agents also cause significant nephrotoxicity, ototoxicity and major cause for switching from STR to LTR and availability of sufficient Bdq is essential to manage such toxicities. Lzd, though effective but much toxic, longer duration use may not be warranted, in diabetics with caution. Delays in reporting have been noticed because of extensive serious adverse events (SAEs) recording tools. Frequent and close monitoring of reported SAEs improves quality of reporting and care.

Challenges include:

- Human Resource (HR) being a major challenge along with staff turn-over in specialist hospitals
- Complex and lengthy SAE R&R tools which are time consuming and challenging to be filled out frequently by the doctors
- Incomplete data for SAE recording and reporting in some cases and challenge in SAE reporting timeline (due to limited HR and unstable internet)
- Challenges in Causality Assessment, centralized and difficult to expand
- Machines (Biochemistry machines, ECG, Audiometers) need proper infrastructure, maintenance and regular calibration
- As yet, limited implementation which requires further expansion of aDSM activities to peripheral sites, other states and regions
- Future funding and technical support by partners

Way forward

- Ensure future funding and regular technical support to the countries for sustainable aDSM mechanism
- Fill the gap of HR by having aDSM focal persons and trained data assistants as aDSM applicability across the board will require dedicated staff to manage
- SOPs for aDSM with clear R&R mechanism should be readily available in line with country context
• Better quality of data entry and completeness for better analysis, and improved causality assessment, need to be ensured,
• The R&R tools should be simplified and user-friendly with minimum variables as in future aDSM should be applicable across the board for all TB patients—best would be to have a user friendly digital tool
• FDAs/DRAs should be taken on board and properly involved in country’s MDR-TB PV/aDSM mechanisms
• Linkages should be developed and strengthened with WHO-PIDM (UMC)

2. Introduction to endTB projects: Dr K J Seung, Partners in Health, USA

Dr Seung presented an overview of the UNITAID supported endTB project undertaken by Partners in Health (PIH) and partners in 17 countries. The objectives of the projects are: to expand access to Bdq, Dlm and repurposed drugs; find better, shorter, less toxic regimens; and generate & disseminate evidence.

The endTB observational study is running in 17 countries with an enrollment target of 2,600 patients. This is largest multi-centric observational study on regimens containing bedaquiline and/or delamanid. The enrolled patients are receiving MDR-TB treatment regimens including bedaquiline and/or delamanid as per WHO recommendations. There is a standardized data collection at project sites with Electronic medical record (OpenMRS, Bahmni), pharmacovigilance database being used.

Amongst the analysed 1,244 patients, the most common clinically relevant adverse events observed are hearing loss (17%) and electrolyte disturbances (26%). Peripheral neuropathy (9%) was the next most common, with linezolid being the most common cause. However other drugs can cause this, and 70% of patients received cycloserine (Cs). Also, this was all conducted in a population of patients with 11% having diabetes and/or HIV putting them at additional risk of AEs. Linezolid generally was initially used at 600 mg and then reduced to 300 mg per day. Clinically significant QT prolongation was not a major cause of adverse events (2.7%) – all patients in this cohort received bedaquiline or delamanid, with 70% receiving Cfz and 60% a FQ.

The endTB clinical trial (FQ-S) is ongoing in 7 countries with an enrolment target of 750 participants, and the endTB clinical trial (FQ-R) will have an enrolment target of 500 participants. These are randomized, controlled, open-label, non-inferiority, Phase III trial evaluating the efficacy and safety of shortened treatment regimens containing new and re-purposed drugs for MDR-TB. The primary endpoint is 73-week favorable outcome

3. Clinical Research in Multidrug Resistant Tuberculosis: Dr Padmapriya Chandrasekaran, NIRT, India

Dr Padampriya made a presentation on the ongoing global clinical research for new drugs and regimen. These include
• **Nix TB trial** using 6-9m BPaL
  • 109 Pulmonary XDR-TB in S.Africa enrolled
  • Timelines from March 2015 – Oct 2021
  • 40 / 72 initiated treatment completed a 6-month course of treatment with culture negativity by month 4
  • 31 completed 6-months post-treatment follow-up of whom 29 cleared XDR-TB
• **ZeNix trial**: 26w BPaL pulmonary XDR-TB, pre-XDR-TB
  • Russia, S.Africa, Georgia in 180 participants
Nov 2017 to April 2021
• **NCT03338621**: 26w BPaMZ daily adult DR-TB
  • Georgia in 450 pts
  • July 2018 to March 2020

July 2018 to March 2020
• **endTB**: five new, all-oral, shortened regimens for MDR-TB
  • BLMZ vs BLCLxZ vs BDLxZ vs DLCLxZ
  • S.Africa, Peru, Lesotho, Georgia, Kazakhstan (MSF) 750 participants
  • Dec 2017 – June 2020

Dec 2017 – June 2020
• **TB-PRACTECAL**: short treatment regimens containing bedaquiline and pretomanid in combination confirmed pulmonary MDR TB
  • BPL vs BPLM vs BPLC vs control
  • S. Africa, Belarus, Uzbekistan 630 participants
  • Jan 2017 to June 2020

Jan 2017 to June 2020
• **STREAM II** is also ongoing with further results expected on shorter treatment regimen

The presenter also quoted from a publication in the European Respiratory Journal regarding compassionate use of Delamanid with Bedaquiline for treatment of MDR-TB by Hafkin J et al in the Jan 2019 issue. Highlights of the study included:
  • Largest cohort of 84 pts receiving Bdq + Dlm
  • 67/84 – naive to both drugs at initiation
  • 62 XDR TB / 18 pre-XDR TB
  • Of 58 who completed Rx at 24 weeks
    • 51 (88%) culture negative
    • 4 (7%) culture positive & 3 result pending
  • No prior exposure to BDQ or Clofazimine - culture negativity 90% while prior exposure reduced it to 60%
  • QT prolongation: 5 (6%) pts, but only 1 had QTc > 500ms

**BEAT Study: India (expected to start within a couple of months)**
  • Effectiveness ans safety study of a non-injectable, all oral short course regimen
  • Prospective cohort at 6 sites in India
  • Adults with Pplmonary pre-XDR and XDR-TB to be included
  • 6-9 mon bedaquiline + delamanid +linezolid + clofazimine
  • 12 months post treatment follow-up

**Predictors of Resistance Emergence Evaluation in MDR-TB Patients on Treatment (PREEMPT)**

The objectives of this study are to determine whether low serum antimycobacterial drug concentrations are associated with the emergence of drug resistance in MDR-TB patients; determine whether HIV seropositivity is a risk factor for low serum drug levels; and determine the contribution of increased DNA mutation to clinical emergence of drug resistance in patients and if they can be detected early in Rx

**Summary**
  • Despite Shorter regimens & new drugs – Treatment success in DR-TB remains low
  • Injectables being replaced by Bedaquiline under research mode
  • Fully oral short course regimen need to be explored by NTPs, based on their expertise & comfort level with new drugs as OR
  • adSM – Training for Nurses & peripheral level HCW
  • Challenges include:
4. Strategic Information support using modelling for planning and prioritization of interventions on MDR-TB – Dr Nimalan Arinaminpathy, Imperial College, UK

Dr Nim Pathy presented his perspective on the use of modelling for generating strategic information. For MDR-TB, modelling can be used as guidance for establishing priorities for DR-TB control and to answer questions like to whom we should offer rapid DST, preference for new or previously treated cases or everyone diagnosed with TB or at the time of presenting with symptoms. Modelling can also inform incremental value of each of the policies and hence enable prioritization. These questions can benefit from a population perspective and get direction towards not just improvement of outcomes, but also how much incidence reduction can be achieved. The End TB goals are about incidence reductions as well as mortality.

The presenter then gave the example of the MDR-TB modelling exercise being undertaken with SEARO and the pathway established for modelling. The modelling compared three interventions against the baseline, incremental benefit as well as cost-benefit analysis.

The three scenarios modelled include:

- Diagnosis of TB among new symptomatics with smear and rapid molecular test only in those considered at risk
- Diagnosis of TB among new symptomatics with smear and rapid molecular test only in those considered at risk as well as those starting on TB treatment (i.e. new smear positive and new smear negative/clinically diagnosed cases)
- Offering upfront rapid molecular test to all symptomatics

This is still work in progress and hence conclusions cannot be drawn from it as yet. Limitations of the modelling include:

- Not a ‘crystal ball’
- Model outcomes can depend sensitively on the assumptions
- Always important to know why a model suggests certain conclusions
- Better to think of a model as bringing together our best understanding of an epidemic (biology, epidemiology, existing TB care, etc), and
- Projecting their implications under given future scenarios
- ‘Project’ rather than ‘predict’

The rGLC, using the results of the modelling exercise with SEARO, could take an enhanced strategic role in assisting countries to identify the critical DR-TB priorities that should be implemented.

Session 8: Planning for 2019

The session was a plenary discussion moderated by the Chair and Vice-Chair of the rGLC with support from the rGLC secretariat. The main issues discussed were:

I. TA and mission plan for 2019 – activities to strengthen laboratory capacity and capacity building for new PMDT guidelines;
II. Improving partner coordination and collaboration in the Region – enhanced pool of consultants for the Region;
III. Enhancing relevance of rGLC for member States; and
IV. Use of community capacity building tools.

The session was opened by the Chair and he mentioned that this was is not a summary session rather it was intended to be a brain-storming session to hear ideas from the new rGLC members on how to move forwards in 2019. One of the key questions to be answered is - What as a committee or as a group or as a collective body can be done to move forward the agenda of expanding DR-TB services in the Region?

The secretariat explained that initially it was mandatory to conduct a review mission every year to each eligible country. But since 2017, the scope of the rGLC role has expanded. TA are now being planned based on country demand, especially from the high burden countries. Though the countries raised a demand for continued use of the same consultant on consecutive missions as said consultant will have a better knowledge about the visited country. Effort has been made to change the consultants after two consecutive visits to the same country. The missions were usually short for one-week duration.

There are a few essential conditions to be followed after the mission:

- Report needs to be submitted to the rGLC secretariat submitted not more than 4 weeks after the mission, for review by rGLC members followed by a response to queries by the author.
- The final report is to be submitted within two months to the Global Fund as per the MoU.

To answer to additional tasks for capacity building, the secretariat could pool GF and other resources to conduct three important activities in 2018. These include:

- Lab capacity strengthening
- aDSM capacity strengthening
- Civil society engagement

Regarding the meeting conclusions, three sets of recommendations are generally provided by the committee members

- One for Member States
- One for the secretariat and
- One for the committee itself for its functioning over the coming year

The members subsequently deliberated on possible recommendations and action points as follows.

Recommendations and actions to be taken

**Recommendations for Member States**

- All SEAR Member States to ensure universal DST for all TB patients starting treatment for first line TB drugs and if found resistant, to second line TB drugs. Algorithms should be extended to include indirect DST of Bdq and Lzd in the MGIT assay. Based on the new WHO Consolidated DR-TB Treatment Guidelines, all H mono-resistant cases should also be tested for further second line treatment drug resistance.
- Engage communities and civil society organisations actively in DR-TB management planning, treatment delivery and monitoring through capacity building. CSOs may also
be engaged in post-treatment monitoring and rehabilitation process for patients after treatment

- Member States are encouraged to start with OR on all oral shorter regimen based on good initial experience so far in other countries where such trials are underway
- Access to new drugs and regimen as per the new WHO guidelines for treatment of RR/MDR-TB needs to be improved in all countries. Member States need to develop a transition plan to assist the move to the new WHO DR-TB Treatment Guidelines. NTPs must take a leadership role in coordination and encouraging partners to collaborate in the activities required for the transition.
- Strengthen capacity for monitoring, management and reporting of adverse events to second-line drugs. Ensure reporting of serious adverse events to global aDSM database

**Action points for rGLC members**

- Develop/ adopt an OR protocol for standardised data collection on studies being conducted for all-oral shorter regimen in SEA Member States
- Develop checklists to support rGLC consultants in carrying out evaluations of areas possibly beyond their example, for example laboratory diagnostics.
- Review mission reports as and when available. Any two members would volunteer by rotation for an in-depth review and share their inputs with other members for further discussions. Special attention should be taken of previous recommendations and reasons for lack of implementation. Common reasons for low detection and treatment outcomes across different member states, need to be discussed by the rGLC and evidence/data-based actions proposed. Progress in community engagement needs to be included in all mission reports. rGLC consultants should make a short executive summary with their recommendations, available the week following the end of the mission
- Review and provide inputs, if any, into MDR-TB modules being developed. Promote the use of modules, once finalised, for training and capacity building of community members
- Develop a set of indicators to measure extent of community involvement and impact.
- Coordination among partners for streamlining country support missions.
- Develop advocacy message to be shared with all member states for the introduction of new drugs and regimens, including transition to the 2019 WHO Guidelines on DR-TB treatment
- Devise mechanisms for follow-up of recommendations from the rGLC missions as well as other relevant reviews
- Consider ‘data for action’ workshop to help countries use the available data in establishing strategic priorities
- Suggest topics for Webinars to the secretariat

**Action points for rGLC secretariat**
• Develop inventory of partners engaged in PMDT work in the SEA Member States
• Based on comments of the rGLC, develop a summary of common areas of concern across
  the different Member States and proposed actions, and disseminate to all Member States
• Organise a Webinar for all members once every two months
• Undertake a laboratory capacity assessment for Member States and share with rGLC
  members
• Share available information on aDSM status in countries, based on the workshop
  conducted last year. Organise a follow-up workshop to last year’s workshop to share
  experiences and develop/amend framework plans for the implementation of aDSM in
  member states.
• Facilitate development of the OR protocol and its dissemination to all Member States.
  Organise a regional meeting of interested countries to further develop and adopt
  standardised OR protocol for the mSTR to be implemented across members States.
• Finalisation and dissemination of modules for community engagement in RR/MDR-TB.
  Explore how the training modules can be converted into e-training format.
• Discuss conduct of rGLC country support missions to Member States and get inputs from
  rGLC members. Co-ordinate with countries and other organizations to have either joint
  missions e.g. with GLI or GDF, or have the rGLC mission as part of nation Joint Monitoring
  Missions, whenever possible.
• Link up the member country with an appropriate partner (wherever needed) for
  implementation of suggested recommendations following a mission
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenters</th>
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<tr>
<td>08:30 – 09:00</td>
<td>Registration</td>
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<tr>
<td>09:00 – 10:00</td>
<td><strong>Welcome Session</strong></td>
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<td>Welcome remarks</td>
<td>WR, Bangladesh</td>
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<td>Inaugural remarks</td>
<td>Director, CDS, WHO SEARO</td>
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<td>Opening address</td>
<td>Secretary Health, Bangladesh</td>
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<td>Vote of thanks</td>
<td>Director, MBDC, Bangladesh</td>
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<td>10:00 – 10:30</td>
<td><strong>Tea/Coffee break</strong></td>
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<td>10:30 – 11:00</td>
<td>Security briefing and administrative announcements</td>
<td>WCO Bangladesh</td>
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<tr>
<td>11.00 – 12.00</td>
<td><strong>1. Background and introduction</strong></td>
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<td>1a. Introduction of members and election of Chair</td>
<td>Plenary</td>
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<td>and vice-Chair of the rGLC for one year</td>
<td>Rohit Sarin</td>
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<td>1b. rGLC MoU and conduct of activities over past</td>
<td>Medea Gegia</td>
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<td>years</td>
<td>rGLC Secretariat</td>
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<td>1c. rGLC – global perspective</td>
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<td>1d. Regional progress report</td>
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<td>12.00 – 12.15</td>
<td><strong>Discussions</strong></td>
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<td>12.15 – 13.15</td>
<td><strong>2. Partner support in the Region</strong></td>
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<td>2a. Technical support to DR-TB programmes in the</td>
<td>Fraser Wares</td>
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<td>Region – KNCV experience</td>
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<td>2b. Support to Bangladesh and other countries –</td>
<td>Aung Kya Jai Maug</td>
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<td>2c. Laboratory strengthening needs in the Region</td>
<td>Sanjay Sarin</td>
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<td>2d. XPERT EQA: make sure your program is doing</td>
<td>Christine Ho</td>
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<td>what you want it to</td>
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<td>13.15 – 13.30</td>
<td><strong>Discussions</strong></td>
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<td>13.30 – 14.30</td>
<td><strong>Lunch</strong></td>
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<td>14.30 – 15:30</td>
<td><strong>3. Planning transition to newer drugs and regimen</strong></td>
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<td>3a. Supporting quantification and forecasting for</td>
<td>Alessio Mola</td>
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<td>transition to new regimen</td>
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<td>3b. Private sector engagement for transitioning to</td>
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<td>new WHO guidelines for MDR-TB’</td>
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<td></td>
<td>3c. Challenges in implementing new MDR-TB</td>
<td>Wipa Reechaipichitkul</td>
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<td>15.30 – 15.45</td>
<td><strong>Discussions</strong></td>
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<td>15:45 – 16:15</td>
<td>Tea/Coffee break</td>
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<td>16.15 - 16.45</td>
<td><strong>4. Donor support for transitioning in the Region</strong></td>
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<td>4a. Global Fund perspective on PMDT expansion in light of the new WHO recommendations</td>
<td>Mohammed Yassin</td>
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<td>4b. Donor perspective and support available for transition to new regimen</td>
<td>Viktoria Livchits</td>
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<tr>
<td>16.45 - 17.00</td>
<td>Discussions</td>
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<td>17.00 - 17.15</td>
<td>Wrap-up of day 1</td>
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<td><strong>Day 2: Tuesday, 26 February 2019</strong></td>
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<td>08:30 – 11:00</td>
<td>5. Plenary discussions on challenges faced in achieving universal DST, transition to new drugs and regimen, and expectations from SEA rGLC</td>
<td>All NTP nominees for 10 minutes each followed by discussions</td>
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<td>11:00 – 11:30</td>
<td>Tea/Coffee break</td>
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<td>11:30 – 12:00</td>
<td><strong>6. Community support for ending MDR-TB</strong></td>
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<td>6a. Examples of community led initiatives on support for MDR-TB patients – challenges and possible replication</td>
<td>Paran Sarimita</td>
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<td>6b. Overview of tools for strengthening community capacity and planned way forward</td>
<td>Blessi Kumar</td>
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<td>12.00 - 12.15</td>
<td>Discussions</td>
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<td>12.15 - 13.15</td>
<td>7a. aDSM experience and strengthening opportunities for other countries</td>
<td>Asif Muhammad</td>
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<td>7b. Clinical Research in MDR-TB</td>
<td>Padmapriyadarsini</td>
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<td>7c. Interim results of End TB project and likely implications</td>
<td>K J Seung</td>
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<td>7d. Strategic Information support using modelling for planning and prioritization of interventions on MDR-TB</td>
<td>Nimalan Arinaminpathy</td>
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<td>13.15 - 13.30</td>
<td>Discussions</td>
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<td><strong>13.30 – 14.30</strong></td>
<td><strong>Lunch</strong></td>
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<td>14.30 - 16.00</td>
<td>8. Planning for 2019</td>
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<td></td>
<td>i. TA and mission plan for 2019 – activities to strengthen lab capacity and capacity building for new PMDT guidelines</td>
<td>Plenary moderated by Chair and Vice-Chair of rGLC</td>
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<td>ii. Improving partner coordination and collaboration in the Region – enhanced pool of consultants for the Region</td>
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<td>iii. Enhancing relevance of rGLC for member States</td>
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<td>iv. Use of community capacity building tools</td>
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<td>v. Use of real-time data, specifically for transition in SEA Member States</td>
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<td>16.00 - 16.30</td>
<td>Coffee break</td>
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<tr>
<td>16:00 – 17:00</td>
<td>Wrap-up, steps forward and recommendations</td>
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</table>
Annexure 2: List of Participants

rGLC Members

1. Dr Aung Kya Jai Maung
   Country Director
   Damien Foundation
   Dhaka, Bangladesh
   Email: aung@damienfoundation-bd.com

2. Dr Nimalan Arinaminpathy
   Reader (Associate Professor)
   Imperial College
   London, UK
   Email: nim.pathy@imperial.ac.uk

3. Dr Padmapriyadarsini Chandrasekaran
   Scientist
   National Institute for Research in Tuberculosis
   Chennai, India
   Email: pcorchids@gmail.com

4. Dr Christine Sandra Ho
   TB Advisor
   Centers for Disease Control and Prevention
   Atlanta
   Email: gtb9@cdc.gov

5. Dr Asif Muhammad
   Technical Advisor
   National TB Control Program
   Myanmar
   Email: masifawan75@gmail.com

6. Dr Wipa Reechaipichitkul
   Professor
   Khon Kaen University
   Thailand
   Email: wipree@yahoo.com

7. Dr Sanjay Sarin
   Head
   FIND India
   Email: sanjay.sarin@finddx.org

8. Dr Kwonjune Justin Seung
   Instructor in Medicine
   Harvard Medical School
   Boston, MA, USA
   Email: kseung@pih.org;
   kseung@partners.org

9. Prof Ye Tun
   Professor/Head
   Thingankyun General Hospital
   Myanmar
   Email: dryetunjp@gmail.com;
   dryetun@yahoo.com

10. Dr Douglas Fraser Wares
    Senior Consultant
    KNCV Tuberculosis Foundation,
    The Hague, Netherlands
    Email: fraser.wares@kncvtbc.org;
    waresf@virginmedia.com

11. Ms Paran Sarimita Winarni
    Monitoring and Evaluation staff
    SSR POP TB
    Jakarta, Republic of Indonesia
    Email: paransarimitawinarni@gmail.com;
    psarimitawinarni@gmail.com

12. Dr Rohit Sarin (Ex rGLC Chair)
    Director
    National Institute of Tuberculosis and Respiratory Diseases
    New Delhi, India
    Email: drsarin@yahoo.com

Government Nominations

Bangladesh

13. Mr Md. Motaher Hossain
    Deputy Secretary,
    MOHFW
    Bangladesh
    Email: motaher6679@icould.com
14. Mr Khandokar Zakir Hossain  
Deputy Secretary,  
MOHFW  
Bangladesh  
Email: zakir77hossain@gmail.com

15. Dr Nazis Arefin Saki  
Medical Officer  
MBDC, DGHS  
MOHFW, Bangladesh  
Email: nazis.arefin@yahoo.com

Indonesia
16. Dr Endang Lukitosari  
Focal Point TB Resistant  
Directorate of Communicable Diseases Prevention and Control  
Ministry of Health, Indonesia  
Email: endanglukitosari@yahoo.com

Myanmar
17. Dr Cho Cho San (Ms)  
Deputy Director (TB)  
Department of Public Health  
Naypyitaw, Myanmar  
Email: drchochosanmph@gmail.com

Thailand
18. Dr Visit Permdharmasin  
Medical Officer, Senior Professional Level  
Bureau of Tuberculosis  
Department of Disease Control  
Thailand  
Email: visit2512@outlook.co.th

Partner Agencies
19. Dr Mohammed Yassin  
TB Adviser  
The Global Fund  
Chemin Blandonnet 8  
1214 Vernier-Geneva, Switzerland  
Email: Mohammed.Yassin@theglobalfund.org

20. Dr Alessio Mola  
Country Supply Officer for South-East Asia  
Stop TB Partnership  
Geneva, Switzerland  
Email: alessiom@stoptb.org

21. Ms Viktoria Livchits  
USAID Contractor & TB Research Advisor  
Tuberculosis Division  
Bureau for Global Health  
Email: vlivchits@usaid.gov

22. Dr Samina Pushpita  
Clinical Services Lead  
USAID  
Bangladesh  
Email ID: psamina@usaid.gov

23. Dr Sreenivas Nair  
Technical Advisor  
Stop TB Partnership  
Geneva, Switzerland  
Email: sreenivasn@stoptb.org

Facilitators
24. Ms Blessina Kumar  
CEO, Global Coalition of TB Activists  
New Delhi, India  
Email: blessi.k@gmail.com

25. Ms Anandi Yuvaraj  
Consultant  
ICW Global  
Chennai, India  
Email: anandiy@hotmail.com

WHO/HQ
26. Ms Medea Gegia  
Technical Officer  
HQ/CDS/GTB/TSC  
Email: gegiam@who.int

Country Offices
27. Dr Mya Sapal Ngon  
Medical Officer - CDS  
WCO-Bangladesh  
Email: ngonm@who.int

28. Dr Sabera Sultana  
National Professional Officer  
WCO-Bangladesh  
Email: sultanas@who.int

29. Mohammad Mahabubul Islam  
Team Assistant, Tuberculosis
30. Dr Md. Kamar Rezwan  
Project Manager-TB Division  
WCO-DPR Korea  
Email: rezwank@who.int

31. Dr Parmar Malik  
National Professional Officer  
WHO Country Office  
India  
Email: parmarm@who.int

32. Dr Aung Thu  
National Professional Officer (TB)  
WCO-Myanmar  
Email: thua@who.int

33. Dr Lungten Wangchuk  
Scientist  
WCO-Nepal  
Email: wangchukl@who.int

34. Dr Manjula Danansuriya  
National Professional Officer  
WCO-Sri Lanka  
Email: danansuriyam@who.int

Observers

35. Dr Pronob Kumar Modak  
Deputy Programme Manager (Training)  
and Focal Person – Laboratory  
National Tuberculosis Control Programme (NTP), Bangladesh  
Email: pronab.modak@yahoo.com

36. Dr Rupali Sisir Banu  
National Program Co-ordinator  
National Tuberculosis Control Programme (NTP), Bangladesh  
Email: npcntpban@gmail.com

37. Dr Shahid Anwar  
Divisional TB Expert  
Sylhet, Bangladesh  
Email: sanwar_rumi@yahoo.com

38. Dr Kamrunnahar  
Microbiologist  
NTR, Bangladesh  
Email: kamrun7731@gmail.com

WHO/SEARO

39. Dr Tjandra Yoga Aditama  
Ag. Director, CDS  
Email: aditamat@who.int

40. Dr Vineet Bhatia  
Medical Officer – MDR-TB  
TBC/CDS  
Email: bhatiav@who.int

41. Ms Reena John  
Team Assistant  
TBC/CDS  
Email: johnr@who.int