Summary report on the

Eleventh meeting of the regional Green Light Committee for the Eastern Mediterranean

WHO-EM/TUB/264/E

Karachi, Pakistan
20–22 November 2019

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1. Introduction

Tuberculosis (TB) is a highly contagious disease and the leading cause of death from a single infectious agent. Globally, TB affected 10 million people in 2018 and 1.5 million people lost their lives from the disease, including 250 000 people living with HIV. Drug-resistant TB (DR-TB) remains a public health crisis globally; about half a million people developed DR-TB in 2018, with only 1 in 3 having access to treatment.

The WHO Eastern Mediterranean Region represents 8% of the global TB burden, with an estimated 810 000 TB cases in 2018, although only 537 761 cases were notified, which corresponds to a treatment coverage rate (notified/estimated incidence) of 65%. In 2018, a total of 38 000 multidrug-resistant TB (MDR-TB) cases were estimated in the Region; out of these, only 12% (4566) started on treatment (out of total estimated MDR-TB cases). Within the Region, 95% of the DR-TB burden is in five countries (Pakistan 72.4%, Somalia 10.3%, Afghanistan 6.5%, Iraq 2.8% and Sudan 2.8%). The Region achieved a 91% treatment success rate among drug-susceptible TB patients in 2017 and a 65% rate among DR-TB treated patients in 2016, the highest among all WHO regions.

The regional Green Light Committee (rGLC) for the Eastern Mediterranean Region was established in 2012 in response to the need to scale up the programmatic management of DR-TB (PMDT). The rGLC functions as an advisory committee to Member States of the WHO Eastern Mediterranean Region, as well as partners, including donors. The Secretariat of the rGLC is hosted by the Regional Office. The rGLC aims to ensure compliance with WHO policies and guidelines, the quality of DR-TB activities and their scaling up through coordinated technical advice, with a focus on capacity-building and the revising and updating of technical support plans. Its support is extended to all countries receiving TB grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

The eleventh annual rGLC meeting was held on 20–22 November 2019 in Karachi, Pakistan. The meeting was attended by 17 participants, including eight of the 10 new rGLC members, WHO staff from headquarters, regional and country levels, and partners, including the Global Fund, International Organization for Migration (IOM), Stop TB Partnership, United States Agency for International Development (USAID), United Nations Development Programme (UNDP) and some nongovernmental organizations from Pakistan.

The current rGLC membership was renewed in 2019 through an open call for expressions of interest. The selection of members was done by an independent committee following standardized criteria. At present the rGLC is comprised of 10 permanent and two ad hoc members, covering the areas of DR-TB, laboratory and drug management. An additional member is included to lead on infection control. Members serve for a term of two years, renewable for a further consecutive term, based on criteria outlined in the rGLC's standard operating procedures.

The objectives of the meeting were to:

- review the overall DR-TB situation and progress on PMDT in the Region;
- assess progress made on the introduction of new DR-TB policies, treatment regimens and recommendations for universal PMDT coverage;
- review country-specific recommendations and actions proposed by rGLC missions conducted during 2019;
- agree on a rGLC work plan for 2020 and partner commitments for technical and financial support;
- assess and learn from the experience of public and non-public PMDT models in Karachi, Pakistan, and feedback given for PMDT improvement and universal access; and
- brief new rGLC members on their scope of work, roles and responsibilities.

Dr Palitha Mahipala, WHO Representative in Pakistan, in his opening remarks stressed the urgent need for action to combat the TB and DR-TB epidemics in the Region by addressing the significant challenges that remain. He noted that the meeting was happening at a critical juncture, when countries were expected to take significant action to meet their End TB and United Nations (UN) General Assembly Political Declaration on TB commitments, including concrete action to address the DR-TB crisis. Dr Mahipala praised the technical expertise of the rGLC committee, which would be instrumental in supporting countries to adopt the latest recommendations on DR-TB and providing technical support for implementation of the revised policies and new evidence-informed recommendations. Finally, he urged a concerted effort to support the transition towards the new WHO policies on DR-TB management for the greater benefit of patients and to end the DR-TB crisis.

2. Summary of discussions

Presentations were initially made on the TB situation in the Region, the UN General Assembly high-level meeting on TB and the resulting Political Declaration on TB, and WHO's multisectoral accountability framework. Participants were also updated on the progress made on the recommendations of the 10th annual rGLC meeting in 2018. The new rGLC members were briefed on the rGLC's scope of work, the roles and responsibilities of rGLC members and WHO's memorandum of understanding with the Global Fund. The rGLC mechanism plays a catalytic role in the uptake of the latest WHO diagnostic and treatment policies.

Review of rGLC missions in 2019 to countries of the Region

In 2019, the rGLC Secretariat coordinated rGLC missions to 11 countries of the Region to monitor progress on PMDT and provide technical support to accelerate introduction of new DR-TB treatment

regimens. The missions were conducted to countries with high burden of TB, experiencing complex emergencies and hosting large number of refugees and migrant populations, including Afghanistan, Djibouti, Iraq, Jordan, Lebanon, Morocco, Pakistan, Somalia, Sudan, Syrian Arab Republic and Yemen. Presentations were made on PMDT expansion progress and the transition towards the revised policies and treatment regimens in these countries (except for Somalia, as the mission was held at the same time as the rGLC meeting).

The rGLC mission to Afghanistan noticed significant progress in PMDT, despite continuous and overwhelming security challenges. Afghanistan's national TB programme (NTP) and its implementing partners have increased access to GeneXpert machines (44 in 2018) and DR-TB treatment, although access to DR-TB diagnosis and initiation of DR-TB treatment continues to remain a challenge, with only 13% of estimated MDR- or rifampicin resistant (RR)-TB cases initiated on treatment, comprising 319 MDR-TB and 8 extensively drug-resistant TB (XDR- TB) cases out of 2500. The latest treatment success rate was 62% for MDR/RR-TB for 2017 cohort. Laboratory network access and performance still present challenges, with a suboptimal specimen transport system, lack of access to be able to monitor and manage adverse events, limited patient support and routine long-term hospitalization. All these factors present challenges to DR-TB management and result in poor TB treatment outcomes. In 2019, a mid-term review recommended expanding laboratory capacities for DR-TB diagnosis and treatment, rapidly changing DR-TB policy to avoid routine hospitalization of patients and integrating service provision with provincial and district health services nearer to the community.

Djibouti has made progress in PMDT since DR-TB management was started in the country, with a functional TB national referral laboratory and dedicated central capacity for diagnosis and enrolling DR-TB

patients in treatment. The new all-oral treatment regimen for MDR-TB has been introduced and a functional active drug safety management system (aDSM) is in place. However, turnover of staff presents a key challenge for PMDT in the country. Other limitations include non-systematic culture for follow-up of MDR-TB patients, non-standardized forms for the recording and reporting system, limited treatment support and great difficulties in performing effective directly observed therapy for DR-TB patients. The mission's recommendations focused on improving laboratory DR-TB monitoring, aDSM and the recording and reporting system.

Iraq, despite its challenges, is working to ensure successful management of RR/MDR-TB, with a treatment success rate of 81% among MDR-TB cases who started treatment in 2016. However, only 75 MDR-TB cases out of an estimated 1100 were put on treatment in 2018. There has been progress on expansion of GeneXpert testing. Currently, the national reference laboratory has capacity for line probe assay and conventional drug susceptibility testing. All TB guidelines, including the national strategic plan, have been updated. One of the main challenges is an insufficient operational budget for the NTP for supply, supervision, training and operational research. Accordingly, the country should ensure the availability of resources and financial sustainability to secure continuous PMDT implementation.

Jordan and Lebanon have received rGLC support in recent years and both NTPs continue to deliver good results and have achieved a low TB incidence status. In Jordan, two DR-TB patients were put on treatment in 2018 out of an estimated 36 cases. Lebanon is performing well, including in management of DR-TB, management of contacts and contact tracing. Both countries are attending to many Syrian refugees with TB, with good outcomes.

Morocco has a well-organized NTP and national reference laboratory and a functional specimen transport system. It has implemented all-oral regimens as per WHO recommendations. The treatment success rate for the latest available cohort of DR-TB patients was 55% (2016). However, as the unavailability of line probe assay and second-line drugs remains a challenge, a long-term injectable regimen is used. The mission recommended adoption of the all-oral regimen, systematic bacteriological assessment, patient support (food and transport support) and decentralization of second-line drug kits to regional and local pharmacies.

Pakistan's PMDT expansion remains limited. Out of an estimated 28 000 DR-TB patients, only 14% (3919) were diagnosed and 11% put on treatment in 2018. PMDT services are available at 33 sites, with almost all managed by non-public sector partners. GeneXpert testing coverage has increased significantly and a limited sample transportation system is in place. Short MDR-TB treatment and all-oral drug regimens have been introduced. However, the treatment success rate declined to 62% for the cohort that started treatment in 2016, with 18% dying and 10% lost to follow-up. The joint programme review mission recommended: ensuring the availability of resources and financial sustainability; decentralizing DR-TB treatment in the public and private sectors to increase access, reduce delay in treatment enrolment and improve quality of services; implementing aDSM, patient support and linkage with basic management units; reducing the DR-TB detection gap; enhancing engagement of the private sector in DR-TB diagnosis and treatment; and enforcing regulations to restrict TB drug sales without prescription.

In Sudan, despite challenges, the NTP and its implementing partners have made considerable progress, with a steady increase in access to GeneXpert testing and provision of DR-TB treatment. The programme is quite centralized, with routine long-term hospitalization of DR-TB patients. Currently, PMDT services are available at 12 facilities. Sudan

has achieved one of the highest treatment success rates globally (84% for the 2016 cohort). Patient treatment and monitoring are provided free-of-cost and each patient receives financial support. However, the national reference laboratory is non-functional and there is limited drug susceptibility testing for second-line drugs. The referral system for specimen transport is ineffective or unavailable. Urgent assessment of the national reference laboratory was recommended to ensure access to quality testing for diagnosis and treatment monitoring, including second-line testing for RR-TB cases, along with decentralization of DR-TB care and limiting hospitalization to increase access to care, enhance local capacity to manage DR-TB and improve treatment outcomes.

The missions to the Syrian Arab Republic and Yemen were their first. Both countries are going to receive new drugs and regimens, but lack of training and other issues will make implementation of the new DR-TB guidelines challenging.

In discussion on the over-the-counter sale of TB medicines in the Region, particularly in Pakistan, the rGLC members noted the need to collaborate and coordinate with WHO departments working on antimicrobial resistance (AMR) for the successful enforcement of regulations restricting the sales of TB medicine without prescription.

There was discussion on the need for coordination between Médecins Sans Frontières (MSF), IOM and WHO on any implementation plan for the new WHO MDRRR-TB regimens in Iraq to avoid duplication in procurement of new second-line drugs, particularly bedaquiline.

In response to the mission reports to countries receiving grants from the Middle East Response (MER) initiative, rGLC members called for greater technical support to ensure rapid implementation of the new WHO MDR/RR-TB guidelines in these countries.

The rGLC members highlighted the urgent need to adopt aDSM to implement the latest recommended treatment regimens and introduce new DR-TB medicines. Recommendations were suggested for implementation of tools and indicators for aDSM. WHO headquarters agreed to conduct regional training to build capacity and ensure implementation of WHO tools on aDSM.

Changes in WHO DR-TB treatment guidelines and their implications for country implementation and partner support

Participants were briefed on changes to WHO guidelines on DR-TB treatment and their implications for country implementation were discussed. Significant changes were outlined in: MDR-TB drug classification; treatment composition, regimen and duration; monitoring patient response to MDR-TB treatment; and patient care and support. A presentation was given on the support available for implementation of the new MDR-TB guidelines through the rGLC network mechanism.

The participants were updated on the progress made on the recommendations of the last regional consultation meeting on DR-TB transition planning in which countries were urged to prepare a transition plan towards introduction of new DR-TB policies, updating of guidelines, laboratory expansion and patient support. Countries were urged to implement the new DR-TB treatment as soon as possible. It was suggested that countries make funding estimates for the implementation of the new policy and guidelines, and PMDT expansion, and identify any technical support needed.

A presentation was made on Global Fund support to country DR-TB programmes, detailing the Fund's financial investment in TB, which reached US$ 1.85 billion for 2017–2019. Participants were briefed about the Fund's technical support for DR-TB through the rGLC

mechanism and suggestions were made to countries to incorporate funding for adoption of new recommendations in grant applications in 2020. The MER initiative is a multi-country project funded by the Global Fund and implemented by IOM. It mainly supports NTPs with diagnostics, medicine and technical capacity development. The TB-related budget for the initiative's second phase is US$ 10.675 million.

It was noted that USAID technical assistance is available for Morocco, Pakistan and Somalia through a specific mechanism, and these countries are eligible for support missions to ensure optimal implementation of the new WHO RR/MDR-TB guidelines.

Presentations were also made by civil society organizations on community perspectives on advocacy, expansion of PMDT and the introduction of new policies and treatment regimens with strong local ownership in high-burden settings.

A presentation was given on the drug management situation and procurement of new DR-TB drugs in the Region. The role of the Global Drug Facility (GDF) and effective implementation of DR-TB management and procurement supply chain management were discussed. The GDF has successfully facilitated the introduction of a new tool at country and global levels. Pooled procurement via GDF was highlighted as a solution. Along with this, countries should update national guidelines, ensure timely registration of TB products and take all necessary action to avoid medicine and commodities supply gaps, including through provision of sufficient domestic or alternative financing during the transition period and beyond.

Updates were presented on AMR status in the Region and an overview was provided of the strategic objectives of the global action plan on AMR, including improving awareness, strengthening knowledge through

surveillance and research, reduction of incidence of infection, optimization of the use of antimicrobial agents, and sustainability of AMR investment. Possible areas of TB and AMR collaboration were discussed.

Field visits were organized to public and private sector PMDT centres in Karachi, including the Ojha Institute of Chest Diseases, Jinnah Postgraduate Medical Centre and Indus Hospital. Common problems in all three PMDT sites visited included a loss to follow up, inadequate sample transport systems, lack of infection control mechanisms and non-optimal access to first- and second-line TB drug tests. The rGLC members recommended urgently decentralizing DR-TB services to the peripheral level, ensuring infection control and strengthening coordination among all public and private sector partners.

3. Conclusion

By the end of the meeting, rGLC members had reviewed the progress made in PMDT and the introduction of new DR-TB policies and treatment regimens in countries of the Region, and had produced recommendations to address the challenge of DR-TB diagnosis and treatment.

The key recommendations included: 1) enhancing laboratory diagnosis capacities through expanding the availability of a quality assured laboratory system, defining and implementing clear screening and diagnostic TB algorithms, and strengthening communication between the laboratory network and PMDT sites; 2) ensuring access through PMDT decentralization, patient-centred care and approaches for treatment adherence and follow-up, and scaling up use of recommended all-oral regimens; 3) ensuring uninterrupted access to quality TB and DR-TB medicines; 4) improving data quality and recording and reporting for DR-TB; and 5) promoting operational research to produce country evidence on successful approaches to improving DR-TB services.

The rGLC also recommended that WHO continue to provide technical support for the DR-TB component of TB programmes.

A preliminary plan for the rGLC for 2020 was discussed, including proposed missions to all eligible countries, capacity-building, consultant training and support for countries to develop transition plans for the introduction and expansion of the new DR-TB policy and guidelines to address latent TB infection.

There was a proposal to hold the next rGLC meeting in Kish Island, Islamic Republic of Iran, during the third quarter of 2020.

4. Recommendations

To Member States

1. Ensure the availability of resources to accelerate detection of TB and DR-TB to reduce the gap in missing cases and that all diagnosed cases are initiated in a timely manner on treatment that is free-of-charge, and that there is a multisectoral accountability framework, in coordination with HIV and other country-specific prevalent disease programmes (such as diabetes, hepatitis C, and so on) to maximize access to diagnosis in community programmes.
2. Ensure timely diagnosis and treatment initiation by:
    - expanding availability of a quality-assured laboratory system in each country for WHO approved diagnostics, including GeneXpert testing, culture, drug susceptibility testing and line probe assay (for first and second line medicines, and rifampicin and fluoroquinolone at a minimum);
    - optimizing utilization and expansion of GeneXpert testing, while maintaining microscopy and culture (for follow-up, infection control and back-up diagnosis, as applicable);

- defining and implementing clear screening and diagnostic TB algorithms with optimal use of microscopy, GeneXpert testing and chest x-ray, followed by culture, drug susceptibility testing and line probe assay;
- establishing a specimen transport mechanism to enhance access to diagnostics;
- considering active case finding for identified high risk groups, including prisoners, internally displaced people, diabetics, drugs users, people with mental health disorders, people living with HIV and other vulnerable groups; and
- strengthening communication links between GeneXpert testing laboratories, PMDT sites and basic management units for the routine notification, reporting and monitoring of test coverage and timely initiation of second line treatment.

3. Improve access to appropriate DR-TB treatment by:
   - decentralizing PMDT services to enhance access and ensuring conditions that support ambulatory care;
   - ensuring early detection and management of serious adverse events by implementing an active TB drug-safety monitoring and management core package with protocols and training, especially for patients on linezolid;
   - ensuring patient-centred care and approaches for treatment adherence and follow-up, including access to free-of-cost monitoring tests for all DR-TB patients, sufficient financial support for patients and their families for follow-up visits and treatment adherence, and mobilizing community leaders and advocates to decrease stigma and increase awareness;
   - scaling up use of all-oral (injectable-free) treatment regimens; and
   - preparing transition plans to adopt the latest WHO recommendations.

4. Ensure uninterrupted access to and adequate use of TB and DR-TB medicines by:
   - including new anti-TB medicines in national essential medicine lists to facilitate registration, importation and implementation; and
   - implementing an effective early warning system (QuanTB) to avoid wastage and stock-out of expensive medicines.
5. Ensure access to quality TB diagnosis, treatment and care for migrants, refugees and internally displaced people in host countries (including Jordan and Lebanon);
6. Expand effective engagement of the private sector in PMDT across the DR-TB cascade of care, including drug regulation under the stewardship of NTPs and according to country context and policy.
7. Enforce laws and/or regulations banning over-the-counter sale of anti-TB medicines without prescription.
8. Ensure quality routine recording and reporting for DR-TB, and strengthen data use for management, ensuring supervision and taking advantage of new technologies.
9. Promote operational research across the cascade of care to produce country-level evidence on successful approaches for the detection and treatment of TB and the improvement of DR-TB services, such as the use of all-oral shorter regimens and decentralization, that can be adopted at scale.

To WHO

10. Build capacity and prepare a pool of consultants to support PMDT and provide the technical support needed by Member States. This should be done in coordination with all country-level TB stakeholders, such as nongovernmental organizations, civil society organizations and the public and private sectors, as applicable to country context, to ensure long-term engagement and benefits to all DR-TB implementers.

11. Provide technical support for countries to develop quantification and forecasting plans (gap analysis) for the new funding cycle (for WHO and partners).

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