

SEVENTH MEETING OF THE CORE GROUP OF THE GLOBAL DRUG-RESISTANT TB INITIATIVE (GDI)

9 June 2017

Geneva, Switzerland



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Background

The Global Drug-resistant TB Initiative (GDI) has been constituted as a Working Group for drug-resistant TB related issues (DR-TB) replacing the previous MDR-TB Working Group and the global Green Light Committee (gGLC). The mission of the GDI is to serve as a multi-institutional, multi-disciplinary platform organizing and coordinating the efforts of stakeholders to assist countries build capacity for programmatic management of DR-TB (PMDT) in the public and private sectors. The ultimate aim is to ensure universal access to care and appropriate treatment for all DR-TB patients. The group mobilizes resources and undertakes activities to ensure a holistic, quality-assured, patient-centred approach for all DR-TB patients within existing TB care structures as well as through innovative new partnerships in priority countries.

The CG consists of 17 members, of which 6 seats are reserved for the chairs of the regional Green Light Committees (rGLCs), 4 observers and the secretariat. The rGLCs, aligned with the 6 WHO Regions, have been established to provide decentralised technical assistance to countries in scale-up of MDR-TB services, and hence will form an important link between the GDI's CG and countries,

providing an opportunity for experience sharing and apprising the GDI's CG members of ground realities and challenges.

This was the seventh meeting of the GDI Core Group (CG), coordinated by the GDI secretariat housed in the Laboratories, Diagnostics and Drug Resistance (LDR) unit of the WHO's Global TB Programme (GTB). The meeting took place in Geneva, Switzerland on 9 June 2017.

Meeting objectives

- ❖ To follow up on recommendations made and action points agreed upon during previous CG meetings and monthly teleconferences;
- ❖ To update the GDI on the upcoming global events and recent WHO policy or other technical developments;
- ❖ To discuss progress in scale up of MDR-TB services and care based on reports from regional initiatives and partner organizations;
- ❖ To review and discuss progress in the work of GDI Task Forces;
- ❖ To discuss GDI objectives and plan activities for the second half of 2017.



GDI core group meeting in Geneva, Switzerland on 9 June 2017

Session 1: Update from the Global TB Programme

Meeting started with a foreword by the chair of the working group and introduction of all participants. List of participants is annexed to the report (annex 2).

On behalf of the GDI Secretariat, Fuad Mirzayev provided an update of the progress since the last in-person meeting in October 2016 in Liverpool, UK. The GDI core group has had three webex-based online conference calls this year. The current face-to-face meeting is the group's first in 2017. Main developments were summarised:

- DR-TB STAT Task Force started implementing new work plan;
- GDI has received the funding tranche from the Stop TB partnership for year 2017;
- GDI core group discussed and agreed on the plans, activities and deliverables for the Task Forces;
- Contracts based on the core group deliberations have been developed and funding made available to the DR-TB STAT, and in process for TB, Human Rights and the Law (TBHRL) Task Force;

- The TBHRL TF launched the “TB, Human Right and the Law” case compendium on 9 March in a joint meeting co-organised by the Stop TB Partnership and KELIN (human rights NGO) in Geneva
- DR-TB STAT TF published an update on programmatic introduction of new TB drugs on the GDI website
- GDI Triage Task Force has updated the page on the GDI website
- Joint GDI-GLI workshop was submitted and accepted for the UNION conference in Mexico.

Three Task Forces are currently active: **DR-TB STAT Task Force, GDI Triage Task Force (former DR-TB Research Task Force) and TB Human Rights and the Law Task Force.**

An updated list of the core group was provided for information of all participants as well as a brief update of the current funding for activities. The funding stream for the GDI activities from the Global Fund via GLC MOU has been reoriented towards other activities by the decision of the donor.



Dr Ernesto Jaramillo presented the background, objectives and current progress towards the *First WHO Global Ministerial Conference “Ending TB in the Sustainable Development Era: A Multisectoral Response”*. This conference aims to secure political commitment towards accelerating implementation of the WHO End TB Strategy in order to reach the End TB targets set by the World Health Assembly and the United Nations (UN) Sustainable Development Goals (SDGs) through national and global commitments, deliverables and accountability. The Ministerial Conference will inform the UN General Assembly High-Level Meeting on TB in 2018. All 194 member states will be


invited to the conference that will take place in Moscow, Russian Federation on 16-17 November 2017. One of the eight thematic tracks of the conference is “Action on AMR, health Security and MDR-TB” featuring as part of the broader area of the Universal Coverage. Dr Jaramillo also presented priority actions countries will be asked for. The draft policy package on this thematic area and an early draft of the conference declaration were shared with meeting participants.

EIGHT THEMATIC TRACKS

Leading up to the United Nations General Assembly High-Level Meeting on TB in 2018. Ministerial commitment for:

MULTISECTORAL ACCOUNTABILITY

- +
1. UNIVERSAL COVERAGE OF TB CARE AND PREVENTION
- \$
2. SUSTAINABLE FINANCING FOR TB, UHC AND SOCIAL PROTECTION
- ⚖
3. RESPECT FOR EQUITY, ETHICS AND HUMAN RIGHTS
- 🔬
4. SCIENTIFIC RESEARCH AND INNOVATION
- 📈
5. MONITORING AND EVALUATION OF PROGRESS
- 👂
6. ACTION ON AMR, HEALTH SECURITY AND MDR-TB
- 👨🏻‍🦱
7. STEPPED-UP TB/HIV RESPONSE
- ⚙
8. SYNERGIES ACROSS THE RESPONSES TO TB AND NONCOMMUNICABLE DISEASES



World Health Organization

FIRST WHO GLOBAL MINISTERIAL CONFERENCE
ENDING TB IN THE SUSTAINABLE DEVELOPMENT ERA:
A MULTISECTORAL RESPONSE
16-17 NOVEMBER 2017, MOSCOW, RUSSIAN FEDERATION

MINISTRY OF HEALTH
OF THE RUSSIAN FEDERATION

Several suggestions were brought forward by the CG members. Subrat Mohanty proposed to prepare a list of topics on advocacy around MDR-TB that could be raised in potential meetings by civil society during or adjacent to the Ministerial Conference. Agnes Gebhard noted that technical partners may help countries to better prepare for the participation in the conference where there is a strong in-country presence.

The next presentation by Dennis Falzon and Chris Gilpin focused on the outcomes of the recent meeting on pharmacokinetics and pharmacodynamics of TB medicines and a meeting to review and update critical concentrations for DST to TB medicines. The detailed reports of both meetings will be placed on the WHO website in Q3 of 2017 with evidence reviewed, main findings and implications stemming from the discussions and decisions made during those meetings.

Session 2: New drugs and regimens for MDR-TB: regional and country updates

Updates from regional GLCs (rGLCs), presented by respective rGLC chairs provided highlights on the progress in regions since the last in-person meeting in Liverpool. Chair of rGLC AMRO could not participate in the meeting. Chairs of rGLC EMR, SEAR and WPR presented progress in rGLCs of their regions.

All rGLC chairs or their representatives reported on the progress in the regional PMDT activities. The presentations from EUR and AFR rGLC chairs reported progress with the rGLC work in the region but also provided an overview of the progress and achievements of South Africa and Russian Federation rolling out implementation of new TB drugs and regimens for treatment of MDR-TB. The two countries are in the lead with the number of patients started on second-line treatment regimen including bedaquiline, with 1,791 patients in Russian Federation and 6,320 patients in South Africa. Preliminary results from Russian Federation indicate cure rates around 70% in patients with XDR and pre-XDR-TB.

Fraser Wares from KNCV presented on the “Experiences of the Challenge TB Project in introduction of new drugs and regimens for DR-TB patients”. The presentation focused on the progress of the Challenge TB project, patient triage approach, DR-TB patient enrolment and outcomes and the lessons learnt.

The presentation by Gustavo V. Bastos from GDF reported on the procurement managed

by the GDF in a new MDR-TB policy environment, PSM challenges, technical assistance provided by the GDF and steps for expedited transition to new TB tools.

The discussion that followed presentations focused attention on the possible mechanisms for expanded collaboration and appropriate platforms for knowledge and experience sharing. The following were the salient points that came strongly during this discussion:

- the rGLC mechanism is not discriminating countries in need of technical support. However, the GF is the only donor to the mechanism and not all countries have a current grant from the GF.
- Some rGLCs are making efforts to identify additional resources to provide support to countries without GF grants;
- Low numbers of XDR patients in countries in Africa doesn't allow for significant in-country stocks and requires therefore some specific procurement solutions in collaboration with GDF and Regional Office.

Action points:

- The GDF and rGLC AFR to consider a follow up discussion on possible procurement solutions for new TB drugs and medicines constituting a shorter MDR-TB regimen in African region.

Session 3: GDI Task Forces.

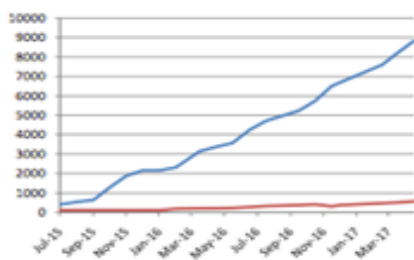
Vivian Cox, chair of the **DR-TB STAT Task Force**, shared a review of the core activities of

the task force, expansion of activities with increased focus on middle income countries

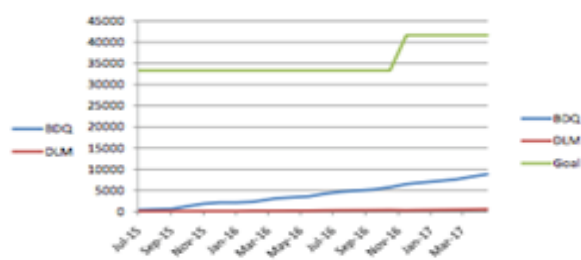
and a collaboration on data collection with the GDI Triage Task Force. The Task Force has been active providing global overview of the introduction of bedaquiline and delamanid under program conditions, also published on the Task Force webpage at GDI website <http://www.stoptb.org/wg/mdrtb/taskforces.asp?tf=4> , contributing to several scientific resources and continued monthly themed conference calls. The task force members have also been involved in technical assistance visits to a number of countries, either within the framework of rGLC activities

or separately. Coordination of technical assistance activities and linkage with partners to participate in the monthly calls or thematic webinars were noted and possible areas to strengthen integration with other activities in this area of work. The Task Force is planning several advocacy activities in collaboration with TAG and other civil society organizations. The DR-TB STAT also has in its plans support for completion and analysis of the WHO led survey on implementation of new anti-TB drugs, shorter MDR-TB regimen and the SL-LPA.

Monthly reports



*adjusted to exclude compassionate use of DLM in Nov 2015



*calculation of global estimated need for new drugs adjusted based on WHO Report 2015

After April 2017 report: DR-TB STAT to monitor data quarterly as opposed to monthly; next data update will be sent in July 2017



Mamel Quelapio, coordinator of the **GDI Triage Task Force**, presented preliminary results of data collection efforts to map enrolment of patients on shorter MDR-TB regimens and implementation of the second-line LPA testing. Most of the data collection was a collaboration with partners and a perspective of additional data is likely but details and extent are highly variable. The

sources of current and potentially future updates are as follows:

- DR-TB STAT: from countries it is collaborating with
- the UNION DR-TB working group: data collected via questionnaire from 12 francophone African countries
- GDF: procurement/orders data
- KNCV/USAID Challenge-TB project

- GDI Triage Task Force data collection from 7 countries
- WHO survey via rGLCs.

Final report of the Triage Task Force is expected to be ready in July 2017 and will be posted on the GDI website. It was noted that ideally all data sources might be compiled into one, web-based database accessible by different relevant partners.

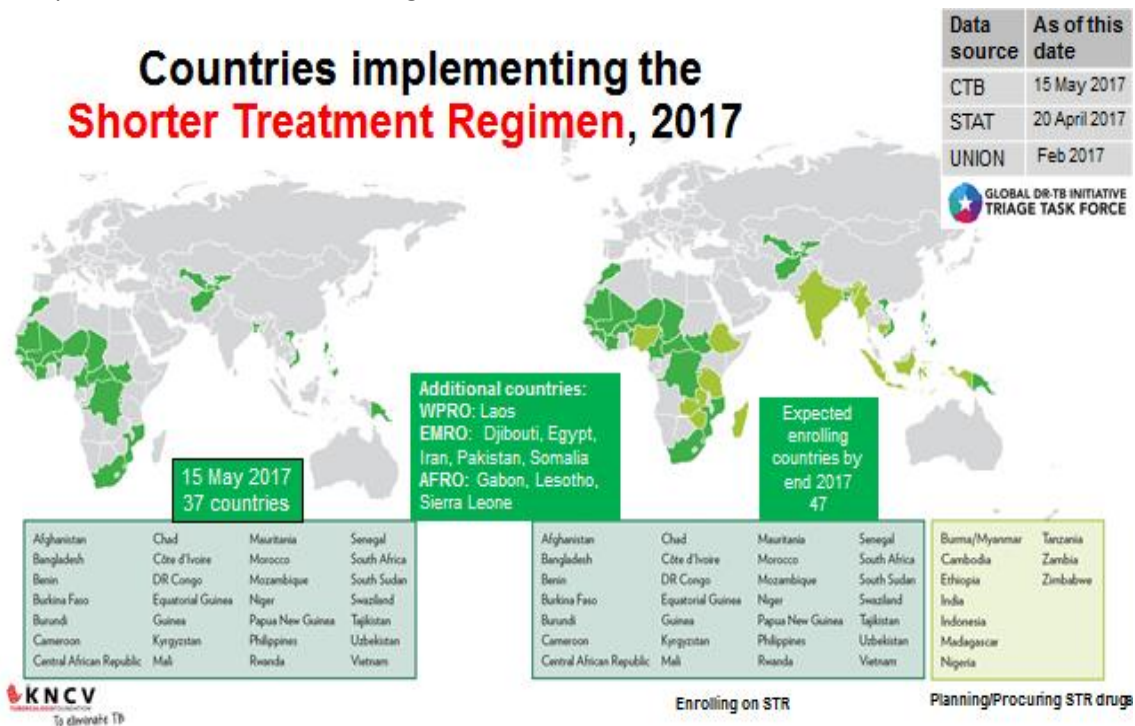
During discussion an emphasis was made by the GF representative that during the times of transition towards MDR-TB treatment using new TB drugs and new, shorter regimens, the GF is ready to accept some reasonable stock wastage of second line anti-TB medicines that can facilitate faster switch to the newly recommended MDR-TB treatment regimens.

Daniela Cirillo discussed possible integration of activities of GDI and GLI working groups and possible areas for this integration, for

example testing algorithms for triage of patients to shorter or other MDR-TB regimens, use of results from molecular DST or sequencing to guide regimen design and training of clinicians on interpretation of laboratory DST results.

Action points:

- The rGLC and DR-TB STAT to engage in closer interaction and sharing of activity plans and schedule of conference calls and webinars
- GDI Triage Task Force and DR-TB STAT to continue efforts to collect and compile all available data to map enrolment of patients on shorter MDR-TB regimens and implementation of the second-line LPA testing.



Session 4: Planning session.

The discussion highlighted several prominent topics for the GDI core group and Task Force activities during 2017:

- Development of detailed operational guides on use of new drugs and new regimens for treatment of DR-TB to bridge the space between the current policy guidance, higher level implementation guidance in the Companion handbook and daily practice by clinicians, nurses and community health-care workers.
- More specific and detailed advice on use of delamanid since its uptake in countries appears to be seriously limited to date.
- Additional efforts to harmonize data collection on the use of new and repurposed anti-TB drugs and regimens for treatment of MDR-TB.
- To develop core indicators on progress with implementation of current

approached to PMDT that can be collected during country visits (by rGLCs) to monitor progress in countries.

In addition to this discussion, it was brought to the attention of the GDI core group that rotation of members is due to start by the end of 2017. In order to ensure gradual change and continuity, the effort will be made to spread this rotation over the period of time rather than initiating on the same date for a number of CG members.

Action points:

- GDI core group members and leaders of the Task Forces to review topics proposed during the planning session and express interest to develop one or several priority products listed.

Summary of action points

- The GDF and rGLC AFR to consider a follow up discussion on possible procurement solutions for new TB drugs and medicines constituting a shorter MDR-TB regimen in African region.
- DR-TB STAT TF to document the successful and less successful models of new TB drugs' introduction and present it to the CG with eventual plan of making this summary available to countries and their partners.
- The rGLC and DR-TB STAT to engage in closer interaction and sharing of activity plans and schedule of conference calls and webinars
- GDI Triage Task Force and DR-TB STAT to continue efforts to collect and compile all available data to map enrolment of patients on shorter MDR-TB regimens and implementation of the second-line LPA testing.
- GDI core group members and leaders of the Task Forces to review topics proposed during the planning session and express interest to develop one or several priority products listed.

Annex 1. Agenda

AGENDA

WHO/UNAIDS D Building (4th floor; HTM65) Geneva, Switzerland, 9 June 2017

Implementation of new drugs and regimens for MDR-TB in countries.

Chair: Charles Daley **Secretariat:** Fuad Mirzayev

09:00 Meeting objectives and declaration of interests **Charles Daley**

09:15 Follow up on action points from 6th GDI CG meeting and monthly teleconferences **Fuad Mirzayev**

Session 1: Updates from Global TB Programme

09:30

- Information session on the Moscow Ministerial Conference focusing on the “AMR, Health Security and MDR-TB” thematic area
- Outcomes of the PK/PD and critical concentrations meeting

Ernesto Jaramillo (on behalf of Karin Weyer)

Discussion **Dennis Falzon**

Chris Gilpin

10:30 Coffee break

Session 2: New drugs and regimens for MDR-TB: regional and country updates

11:00

- Presentations from rGLC chairs on regional implementation of new drugs and regimens for DR-TB. (EMR; SEAR; WPR)
- Presentations from rGLC chairs on implementation of new drugs in AFR and EUR, detailed report on progress in South Africa and Russian Federation.

rGLC chairpersons

Discussion **Norbert Ndjeka**

Andrey Maryandyshev

12:30 Lunch

13:30

- Challenge TB project overview and progress **Fraser Wares**
- GDF, procurement in a new MDR-TB policy environment **Gustavo Do Valle Bastos**

Discussion

Session 3: GDI Task Forces

14:30

- DR-TB STAT Task Force: update on 2017 activities for new DR-TB drugs introduction in countries **Vivian Cox**
- GDI Triage Task Force – shorter MDR-TB regimen implementation in countries, update **Mamel Quelapio**
- GDI-GLI Task Force – progress and updated plan of activities

Discussion **Daniela Cirillo**

16:00 Coffee break

Session 4: Planning session

16:30 • Plan of activities and deliverables 2017: discussion **Charles Daley**

17:30 Wrap up and next steps

Annex 2. List of Participants

7th Meeting of the Core Group of the Global Drug-resistant TB Initiative 9 June 2017 UNAIDS D Building (4th floor; HTM65) Geneva, Switzerland

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- 25. Dr Medea Gegia, TSC/GTB
- 26. Ms Licé Gonzalez-Angulo, RTE/GTB
- 27. Dr Charlie Nathanson, TSC/GTB
- 28. Dr Linh Nhat Nguyen, TSC/GTB
- 29. Dr Kefas Samson, TSC/GTB
- 30. Dr Karin Weyer, Coordinator LDR

Annex 3. Summary of Declaration of Interests

All core group members who participated in the meeting completed Declaration of Interests (DoI) form. No significant conflicts of interest were declared. Three CG members made the following disclosures that were considered insignificant in relation to the subjects discussed during the meeting: Charles Daley have served in an advisor capacity in scientific committees convened by Otsuka and Novartis, Daniela Cirillo declared that the Supranational TB reference laboratory in Milan , where she works, is involved, along with other SRLs and FIND, in evaluation of new diagnostic tools for TB detection.

Annex 4. GDI Core Group (as of April 2017)

Name	Surname	Status	Affiliation	Constituency
Charles	Daley	member	National Jewish Health, USA	GDI chair
Agnes	Gebhard	member	KNCV, Netherlands	GDI vice-chair
Subrat	Mohanty	member	The UNION, India	Civil society, patients and affected communities
Amy	Bloom	member	USAID	Donor/ funding agencies
Sirinapha Wungmanee	Jitimane	member	National TB Programme, Thailand	National TB programmes of high DR-TB burden countries
Kuldeep Singh	Sachdeva	member	National TB Programme, India	National TB programmes of high DR-TB burden countries
Carrie	Tudor	member	International Council of Nurses, South Africa	National/international/ scientific/professional medical associations and nursing associations
Saira	Khowaja	member	IRD, Pakistan	Private for profit sector
Chen-Yuan	Chiang	member	The UNION, France	Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
Daniela	Cirillo	member	Fondazione Centro San Raffaele, Italy	Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
Kwonjune Justin	Seung	member	Partners in Health, USA	Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
Norbert	Ndjeka	member	National TB Program, South Africa	AFRO rGLC chair
Rafael Laniado	Laborin	member	National TB Programme, Mexico	AMRO rGLC chair
Asma	EISony	member	Epi-Lab, Khartoum, Sudan	EMRO rGLC chair
Andrey	Maryandysh ev	member	Northern State Medical University, Russian Federation	EURO rGLC chair
Sarabjit	Chadha	member	The UNION, India	SEARO rGLC chair
Jacques	van den Broek	member	KNCV, Netherlands	WPRO rGLC chair
Heather	Alexander	observer	CDC, USA	GLI chair
Mamel	Quelapio	observer	KNCV, Netherlands	Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
Andre	Zagorski	observer	GDF, Switzerland	Technical agencies and implementation partners assisting NTPs of high burden DR-TB countries
Vivian	Cox	observer	MSF	Non-governmental sector partners
Brian	Citro	observer	Director, International Human Rights Clinic, Chicago University Law School	Non-governmental sector partners
Mohammed	Yassin	observer	Global Fund	Donor/ funding agencies
Fuad	Mirzayev	secretariat	WHO Headquarters	WHO secretariat