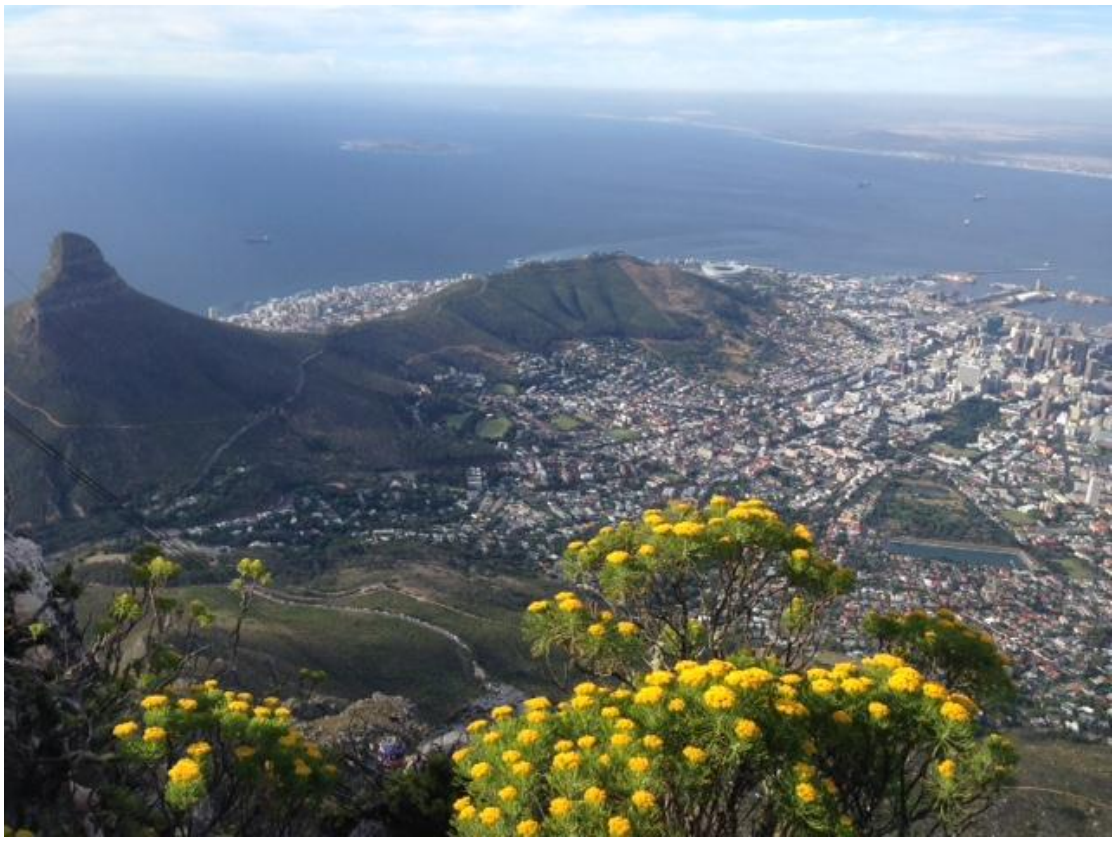
FOURTH MEETING OF THE CORE GROUP OF THE GLOBAL DRUG–RESISTANT TB INITIATIVE

1 DECEMBER 2015
CAPETOWN, SOUTH AFRICA



Global Drug-resistant TB Initiative
Accelerating the response

Contents

Background

This was the fourth meeting of the Global Drug Initiative's (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).

Meeting Objectives

- To follow up on recommendations made and action points agreed upon during 3rd GDI CG meeting in May 2015, and subsequent monthly teleconferences;
- To provide an update on progress in scale up of MDR−TB services and care, and updates on new policies;
- To provide an update on the Joint GDI and GLI Partners Forum, April 2015;
- To provide an update on the progress of the respective GDI Task Forces and from the Infection Control (IC) sub−group; and
- To discuss the GDI CG membership, the GDI "Costed Framework Plan, 2016−2017" and the GDI workplan for 2016.

Session 1. Update from the GDI Secretariat

On behalf of the GDI Secretariat, Fraser Wares gave an update on the recommendations made and action points agreed upon during the 3rd GDI CG meeting in May 2015, and subsequent monthly teleconferences (TCs) of the GDI CG. The key actions taken are presented below:

1. GDI secretariat to follow up with MSF the next steps for establishing a new GDI Task Force as discussed and proposed.
   - *DR STAT Task Force established from July until December 2015 (see Session 4).*
2. GDI secretariat to coordinate selection of a new CG member
   - *Sirinapha Jittimanee selected as from May 2015*
3. GDI secretariat to hire a consultant to develop the final draft of the GDI "costed Framework" document.
   - *Open application for consultant was sent out in August 2015, with 7 applications received. Unfortunately, none were felt appropriate for the work. Dr Paul Nunn has been recontacted and has agreed to draft the document in January 2016*
4. GDI secretariat to finalize 2nd issue of the GDI newsletter
   - *Issue 2 of GDI newsletter published and widely disseminated in November 2015*
5. CG Chair or Vice Chair to request participation of 1 or 2 CG members in the Global Development Group (GDG) for the development of the WHO consolidated TB treatment guidelines
   - *CG Chair and Vice Chair participated in the GDG meeting on updating the WHO MDR−TB Treatment Guidelines, 9 to 11 November 2015*
6. Other actions
   - *Organised, in coordination with WHO AFRO, EMRO and EURO, workshops on "introduction of new DR TB drugs" for members of the respective rGLCs, partner organizations and WHO staff in Copenhagen (22−23 Sept 2015) and Nairobi (4 −5 Nov 2015) respectively. SEAR/WPR workshop planned for 24−25 Feb 2016 in Bangkok*
   - *Organised 6 x monthly GDI CG TCs held between June and Nov 2015*
   - *Maintained the GDI Listserv, which now has 340 members*
   - *Oversaw the administrative and contractual process for distribution of funding to the current 2 GDI Task Forces (DR−TB Research and DR STAT)*
   - *Drafted proposal for FY 2015 USAID funding of the GDI*

Discussions focused on the future role of the CG in the activities of the GDI and its relationship to the regional GLCs (rGLCs). It was agreed that there needs to be a regular update of the PMDT related work of the partners and large projects presented to the GDI CG. It is hoped that with the development of the GDI "Costed Framework" document, the work of the GDI and the role of the CG and partners within it, will be more clearly articulated.

It was agreed by all the two Task Forces (TFs) have done a good job, however the CG members felt that the DR STAT TF should widen its focus in future.

Session 2 Update on progress in scale up of MDR TB services and care, and updates on new policies

On behalf of WHO's GTB, Geneva, Dennis Falzon presented PMDT related updates from the WHO 2015 Annual Global TB Report. Detection and treatment gaps are especially serious among people with MDR-TB. Of the 480,000 cases estimated to have occurred in 2014, only about 25% (123,000) were detected and reported to national authorities. The 3 countries with the largest number of cases are China, India and the Russian Federation. Of further concern, globally, data show an average success rate of only 50% for treated MDR- TB patients.

Discussions focused on whether countries had adequate capacity to diagnose and treat even greater numbers of MDR−TB patients. There was recognition that for early diagnosis of TB and DR−TB, a rapid test and DST test were required. Currently this means molecular based diagnostics. However it was noted that despite a significant increase in the Xpert machines in countries that has occurred in recent years, this has not resulted in the anticipated increase in case detection of DR−TB. It was recognised that in some countries the machines are not being utilised optimally, and this may be partly due to the use of outdated diagnostic algorithms.

Ernesto Jaramillo then provided an update of WHO's policy making activities over the year. This included: Implementing TB diagnostics: A policy framework; Use of lateral flow urine lipoarabinomannan assay for the diagnosis and screening of active TB in people living with HIV; Companion Handbook on WHO policies for DR-TB, 2nd Edition; Introduction of bedaquiline for MDR-TB treatment at country level; Active TB drug safety management and monitoring (aDSM); Global Action Framework for TB research; ENGAGE-TB; Digital health for the End TB strategy; amended WHO Essential Medicines List (EML) with the addition of bedaquiline, delamanid,linezolid and terizidone; PPM for MDR-TB; and the updating of WHO Guidelines for DR-TB treatment and drug susceptible TB treatment, on Ethics of TB prevention, treatment and care, and on TB infection prevention and control.

Questions were asked about WHO's policy on isoniazid (H) resistance and future changes to the WHO's EML. The issue of H resistance was discussed at the Nov 2015 GDG meeting for updating WHO's DR−TB Treatment Guidelines, and will be re−examined in March 2016. The WHO's EML is updated every 2 years. Once the update of the WHO's DR−TB Treatment Guidelines has been finalized, a further submission will be made to update the WHO EML in early 2017.

This was then followed by updates from the rGLC Chairs on the implementation of regional plans, and activities and progress of the respective 6 rGLCs. AFR rGLC has overseen 42 missions in 2015, and have been trying to include a laboratory expert and "new" PMDT consultants in the missions. A major issue facing AMR rGLC is that of funding in 2016 as currently only 2 countries will have GF grants with MDR−TB components included in them. Mechanisms of combining rGLC missions with NTP review missions, and finding other funding sources have been explored. In the EMR, a large number of countries have complex emergencies and refugee issues. Missions to a number of countries have been impossible due to security issues in the respective countries. For the EUR rGLC, a big challenge has been the implementation of pharmacovigilance systems in countries that are introducing either new or re−purposed drugs for the treatment of DR−TB. There is much resistance both from the health systems and staff to the introduction of said systems. In SEAR, the major issues start with the challenge of maintaining the basic TB services which requires wider strengthening of the health systems, and poor regulation of case notification and drugs. For WPR, PMDT related activities feature prominently in the "Regional Framework for Action on Implementation of the End TB Strategy in the Western Pacific (2016–2020)", which was approved by the

Regional Committee in October 2015. Recently however attention has been focused on the MDR−TB "outbreak" in the Western Province of Papua New Guinea.

Session 3. Joint update from the GDI and Global Laboratory Initiative (GLI) CGs
The subsequent session was a joint session of the GDI and GLI Core Groups. Due to financial limitations, no joint GDI/GLI activities have been taken forward since the last joint meeting of the respective Core Groups in May 2015. However the issue of linkages of diagnostic and treatment services for DR−TB cases remains crucial.

The focus of the discussions was on the concept of the diagnostic / clinical cascade, and the development of a harmonized assessment tool to assess this area of work at the country level. During the discussions, it became clear that many groups have been working on, or plan to work on, different parts of the cascade. However none have addressed the complete cascade and no harmonized assessment tool currently exists. It was agreed that it would be important that the one harmonized assessment tool be developed by the inputs of the different groups. This could then be piloted in various country settings and the results brought back to the GDI/GLI Core Groups for their review and planning of next steps.

Session 4. Updates from the respective GDI Task Forces and from the TB Infection Control (IC) sub−group
Updates on the progress and activities of the DR−TB Research and DR STAT TFs were presented by Agnes Gebhard and Jennifer Furin respectively. The CG unanimously agreed that both TFs had fully achieved the goals that they had set out with and that bot TFs should continue with their activities in 2016. It was suggested that the DR STAT TF should widen its remit to look at issues relating to the access and availability of the companion drugs that are required along with bedaquiline and delamanid.

An update from the TB Infection Control sub−group was presented by Carrie Tudor. Along with providing an update on the 2015 activities of the sub−group, including finalization of their strategic plan and plans for 2016, was the announcement that the sub−group is now called the "End TB Transmission (IPC) Initiative".

Session 5. To discuss the CG membership, the GDI "Costed Framework Plan, 2016−2017", GDI funding and workplan for 2016
All current CG members, bar Dalene von Delft, have expressed their wish to continue on the CG for a second 2−year term. The Secretariat was requested to proceed with filling the vacant CG position resulting from Dalene's leaving the CG.

The CG discussed the scope of what should be included in the GDI "Costed Framework Plan, 2016−2017" document. It was noted that the draft documents from the small group meeting in Jan 2015 dealt mainly with Task Force activities. This was however felt not to be the aim of the framework document. Rather it needs to be strategic in nature and address global issues relating to the scale up of PMDT. The document should outline a wide focus of work, which needs to be aligned with the WHO's End TB Strategy, and also clearly lay out the role and relationship of the GDI CG vis a vis the rGLCs. Whilst laying out the opportunities brought by new diagnostics and drugs, it will need to also lay out what needs to be done to reach the PMDT related targets, and the role that GDI can play in achieving these targets. A query was raised whether an assessment of the GDI and its structures should be done along with drafting of the framework document. Questions were also raised about the sustainability of the structure of the GDI CG and rGLCs as they are heavily dependent on the funding stream via the current GLC−related Memorandum of Understanding (MoU) between the Global Fund and the WHO, which comes to an end after December 2016. The framework document needs not only to cost out the wider costings of PMDT scale up, but also to advocate for funding to the GDI and rGLC network. This latter issue was highlighted by the presentation made by the GDI Secretariat on the GDI funding, which currently shows that there are funds available in

2016 for holding future CG meetings but no funding available for GDI activities. It was noted by the Chair that as the GDI is a Working Group of the Stop TB Partnership (TBP), the costed framework document will be placed before the TBP for funding support. It was agreed that the framework, whilst needing to also align with the TBP's Global Plan to Stop TB 2016 to 2020, should be made for the 3−year period of 2016 to 2018.

In August 2015, an open application for a consultant to draft the GDI "Costed Framework Plan, 2016−2017" document was posted widely. Unfortunately, no applicant was found appropriate for the work. However Dr Paul Nunn has been recontacted and has agreed to draft the document in January 2016. The draft document should be available for the CG members to review in early February 2016.

Action Points

- GDI Secretariat to time future CG TCs to suit the respective rGLC Chair who will present their update.
- Partners to provide regular updates of PMDT related activities to the GDI CG meetings and TCs.
- rGLC Chairs to provide regular updates on funding situation of the respective rGLCs to the GDI CG.
- rGLCs and respective Secretariats, GDI Secretariat, and GF Secretariat to document activities of the rGLCs, related both to the GF−WHO GLC related MoU and wider mandate of the respective rGLC.
- Establish a Joint Task Force with the GLI CG on developing a harmonised diagnostic and clinical cascade assessment tool.
- The Task Forces on DR−TB Research and Access to new DR−TB drugs ("DR STAT") should continue their activities in 2016. Respective TF Leaders to draft new TORs and workplan for submission to the GDI Secretariat at the earliest.
- GDI Secretariat to proceed with the process for replacing Dalene von Delft on the GDI CG.
- GDI Secretariat to proceed with hiring of Dr Paul Nunn for the drafting of the "GDI costed framework, 2016 to 2018", and circulate the draft document to the CG members as soon as it is available. Subsequent to this, a wider discussion needs to be held to finalise the document and to discuss future support beyond December 2016 when the current GLC−related MoU between the Global Fund and WHO ends.

Annex 1. Agenda

Chair: Charles Daley

08.30 – 08.45	Welcome Meeting objectives and declaration of interests	GDI Secretariat (FW)
Session 1 08.45 – 09.15	Objective: To follow up on recommendations made and action points agreed upon during 3rd GDI CG meeting in May 2015, and subsequent monthly teleconferences • Report from the GDI Secretariat • Discussions	GDI Secretariat (FW) ALL
Session 2 09.15 – 10.30	Objective: To provide an update on progress in scale up of MDR–TB services and care, and updates on new policies • Updates from WHO 2015 Annual Global TB and on new WHO policies and guidance • Updates on implementation of regional plans, and activities and progress of the rGLCs	GTB/LDR (DF / EJ) Chairs of the 6 rGLCs
10.30 – 11.00 Coffee		
Session 2 ctd 11.00 – 11.45	• Updates on implementation of regional plans, and activities and progress of the rGLCs ctd • Discussions	Chairs of the 6 rGLCs ALL
Session 3 11.45 – 13.00	Objective: To provide an update on the Joint GDI and GLI Partners Forum, April 2015 • Updates from GDI and GLI perspectives • Joint activities to align diagnostics and treatment • Discussions	GDI (CD) / GLI (TS) GDI (CD) / GLI (TS) ALL
13.00 - 14.00 Lunch		
Session 4 14.00 – 15.00	Objective: To provide an update on the progress of the respective GDI Task Forces and from the Infection Control (IC) sub–group • Progress of the respective GDI Task Forces (Research and DR STAT) • Update from the IC sub–group • Discussions	Task Force Leaders Co–Chair, IC sub–group ALL
Session 5 15.00 – 15.30	Objective: To discuss the CG membership, the GDI "Costed Framework Plan, 2016 – 2017", GDI funding and workplan for 2016 • Membership of the GDI Core Group in 2016 onwards	Chair (CD)
15.30 – 16.00 Coffee		
Session 5 ctd 16.00 – 17.00	• Update on development of the GDI "Costed Framework Plan, 2016 – 2017" • GDI funding and workplan for 2016 • Discussions	Chair (CD) / GDI Secretariat (FW) GDI Secretariat (FW) / ALL ALL
17.00 – 17.30	Wrap up and next steps Other business	Chair (CD)

FW	Fraser Wares	DF	Dennis Falzon
EJ	Ernesto Jaramillo	TS	Tom Shinnick
CD	Charles Daley		

Annex 2. List of participants

GDI Core Group

1. **Raimond Armengol**
   Chair, AMR rGLC
   The UNION, SPAIN
   Email: rarmengol@theunion.org

2. **Amy Bloom**
   US Agency for International Development, UNITED STATES of AMERICA
   Email: abloom@usaid.gov

3. **Chen-Yuan Chiang**
   The UNION, FRANCE
   Email: cychiang@theunion.org

4. **Daniela Maria Cirillo**
   SRL, Fondazione Centre San Raffaele, ITALY
   Email: cirillo.daniela@hsr.it

5. **Charles Daley**
   Chair, GDI
   National Jewish Health, UNITED STATES of AMERICA
   Email: DaleyC@njhealth.org

6. **Dalene von Delft**
   TB Proof, SOUTH AFRICA
   Email: daleneduples@gmail.com

7. **Agnes Gebhard**
   Vice−Chair, GDI
   KNCV Tuberculosis Foundation, The NETHERLANDS
   Email: agnes.gebhard@kncvtbc.org

8. **Rumina Hasan,** Acting Chair, EMR rGLC
   Agha Khan University, PAKISTAN
   Email: rumina.hasan@aku.edu

9. **Sirinapha Wungmanee Jittmanee**
   Ministry of Public Health, THAILAND
   Email: sxj2014@yahoo.com

10. **Saira Khowaja**
    IRD, PAKISTAN
    Email: saira.khowaja@irdresearch.org

11. **Andrey Olegorich Maryandyshev**
    Chair, rGLC Europe
    Northern State Medical University, The RUSSIAN FEDERATION
    Email: maryandyshev@mail.ru

12. **Lee B. Reichman**
    Chair, WPR rGLC
    New Jersey Medical School Global, UNITED STATES of AMERICA
    Email: reichmlb@njms.rutgers.edu

13. **Rohit Sarin**
    Chair, SEAR rGLC
    LRS Institute of TB and Respiratory Diseases, INDIA
    Email: drsarin@yahoo.com

14. **Hind Satti**
    Chair, AFR rGLC
    Partners In Health, UNITED STATES of AMERICA
    Email: hsatti@pih.org

15. **Kwonjune Justin Seung**
    Partners In Health, UNITED STATES of AMERICA
    Email: Kjseung@pih.org

16. **Carrie Tudor,** Co−Chair IC sub−group
    ICN, SOUTH AFRICA
    Email: carrie_tudor@hotmail.com

Observer

17. **Jennifer Furin,** GDI Access to New DR−TB Drugs Task Force. Email: jenniferfurin@gmail.com
18. **Alex Golubkov,** USAID. Email: agolubkov@usaid.gov
19. **Michael Rich,** GDI Access to New DR−TB Drugs Task Force. Email: mrich@pih.org
20. **Tom Shinnick,** Chair, GLI. Email: tms1@cdc.gov
21. **Mohammed Yassin,** Global Fund. Email: Mohammed.Yassin@theglobalfund.org
22. **Andre Zagorski,** Manager, GDF. Email: andrez@stoptb.org

WHO Geneva

23. **Dennis Falzon,** GTB/LDR
24. **Ernesto Jaramillo,** GTB/LDR
25. **Lynne Mrah−Harrop,** GTB/LDR
26. **Fraser Wares,** GDI Secretariat, GTB/LDR