**DR-TB STAT - August 2017 call**

*31 August 2017*

Attendees: Vivian Cox (DR-TB STAT); Jennifer Furin (DR-TB STAT); Uzma Khan (IRD); Brian Kaiser (GDF); Fuad Mirsayev (WHO); Christian Lienhardt (WHO); Erica Lessem (TAG); Ramon Crespo (GDF); Grania Brigden (Union); Christophe Perrin (MSF); Sharonann Lynch (MSF); Isaac Chikwanha (MSF); Shelly Malhotra (TB Alliance); Dumebi Mordi (MSH); Blessi Kumar (GCTA); Mercedes Becerra (Harvard Medical School); Regina Osih (CHAI); Nataliya Morozova (PIH)

Agenda:

1. General Update – Vivian Cox (DR-TB STAT)
2. Access to new drugs in the private sector - Uzma Khan (IRD)

Minutes: Nataliya Morozova

General Update

- The latest global data on BDQ and DLM through June 2017 is posted on the DR-TB STAT website - http://drtb-stat.org/ , the data is public and can be used by anyone
- Quarterly data from Q3 (end of September) will likely not be available prior to the Union
- Sessions and workshops on the new drugs and shorter regimen at the Union Conference on 11th October 2017:
    - Implementing novel drugs and regimens for the treatment of MDR-TB: a skills-building workshop (coordinated by DR-TB STAT, USAID, MSF)
    - Accelerating the uptake of new diagnostics, medicines, and regimens to eliminate TB through improved guidance and coordination (chaired by GDI & GLI)
    - Programmatic implementation of BDQ and DLM: experiences in drug procurement, technical assistance, clinical management, and drug safety monitoring (chaired by USAID)
- The Union sessions on 12th October 2017
    - Overcoming challenges in the introduction and scale-up of newer drugs for the treatment of MDR-TB: Lessons from the field (speakers from different countries)
- The newest WHO guide on off-label use of BDQ and DLM was provided to DR-TB STAT via our email mailing list. It contains recommendations supporting the use of new drugs in certain situations where no formal recommendations can be made by the WHO due to lack of data in these populations – i.e. certain forms of extra-pulmonary TB, use of the new drugs in combination, extension of the new drugs beyond 24 weeks.This guidance supports individual clinicians to use the new drugs in ways not formally specified in

guidance and allows donors, regional WHO offices, and NTP managers to support clinicians in the use of the newer drugs in these circumstances.

Introduction - Jennifer Furin

- Dr. Uzma Khan, Director of Interactive Research and Development, a highly skilled physician in managing patients with MDR-TB. IRD is a member of the endTB project consortium.
- Dr. Khan and her team are working on introducing the new drugs for the treatment of MDR-TB in Pakistan, Bangladesh and Indonesia within a private sector. They encourage high quality private facilities to introduce BDQ and DLM.
- Background – Logistics - Uzma Khan (IRD)
    - 10 years with IRD working in public-private models – TB REACH project, TB programs treating patients for MDR-TB and active case finding
    - IRD is a Global Health NGO, we work in over 15 countries where we partner with other collaborators to provide care, we like to tailor and adapt approaches to meet the needs in different sites, e.g. Pakistan and Bangladesh. Within these countries, there are different strategies that can be applied to areas.
    - We learned from our experience that it is important to leverage on the existing systems.
    - Approaches – how we design different models of care
        - We build on existing network of private providers (e.g. TB REACH project)
        - 10 years ago, we started to work in Pakistan, in a private hospital providing care to everyone who need it.
        - We started providing treatment for TB, then drug-resistant TB; there was a big gap in providing care to everyone.
        - We have worked towards the existing private providers who do direct patient care and support
        - In Bangladesh, for a scale-up Gene-Xpert project, we worked with icddr,b
        - Work to ensure we are complementing activities, not duplicating efforts, drawing on existing resources and established systems in place
        - Linking diagnostic and screening systems in private sector: engage case finding network that already exists in private sector, then refer to public sector for testing and treatment
        - There was a gap in terms of how culture and DST would be referred to the centralized lab, mainly a public sector lab, who does cultures and DSTs.
        - We tried to develop public-private collaboration, since the public sector wasn't optimally engaging with the private sector.
        - Our teams are working in public sector hospitals, we have our own staff. Providing capacity-building activity, staff training, managing patients
        - We use technology and electronic tools (EMR, mhealth), since there are logistical challenges. We use it for patient's identification, enrollment and etc.
        - There is a sense of fear of treating MDR in a private sector because of suboptimal or poor care.
        - We make sure to provide comprehensive care, including mental health services and counseling
- endTB project – a Unitaid-funded project, a 4-year project.

    - IRD is a part of consortium, which includes PIH and MSF
    - The objective is to increase uptake of new TB drugs in 16 countries
    - One of the key outputs – Output 1 - to enroll 2600 patients as part of the observational study to generate evidence of safety of regimens with the new drugs.
    - IRD has enrolled 330 patients on BDQ or DLM
    - Our sites – Bangladesh, Pakistan, Indonesia; 1 site in Jakarta; we recently started to work in Durban South Africa, which is a part of the endTB Initiative to strengthen a community-based system.
    - Vietnam to be another IRD endTB site; it will only include DLM patients. They have BDQ but DLM was not accessible. Hopefully, it will be accessible by the end of the year.
- Private – Public Model (PPM) – focus on Bangladesh, Pakistan, and Indonesia
    - All Sites have health care facilities, either public or private
    - There are different logistical challenges that need to be adapted to the situation
    - In Bangladesh, we enroll patients at the National Institute of Lung Diseases, a big referral site, where we enroll patients for new drugs.
    - In Pakistan we have 3 sites, 1 - public sector site, 1 – private sector site, and 1 – semi-private site (they receive funding from 2 sources – the government and donations)
    - In Pakistan, we are going to include 2 or 3 more sites. We have an approval to roll out national access to the new drugs.
    - NTP has enrolled patients in public sector site on BDQ. In Pakistan we are using DLM as well. NTP is planning to get DLM into the country.
    - We have 2 waivers from the drug regulatory authorities for new drugs.
    - Treatment sites differ:
        - Indonesia (Jakarta) is a private sector site, they have access to BDQ, DLM is in the process of being imported and will be available later this year.
        - An example of a patient who sought treatment our facility:
            - A patient diagnosed with susceptible TB was enrolled in 2001 in a private facility, then in 2004 she received category 1 treatment in a private facility, then in 2010 she started to receive 2$^{nd}$ line TB drugs with only Amikacin, Ofloxacin and Pyrazinamide. In 2011, treatment was discontinued due to pregnancy. In 2013 she started MDR-TB treatment at the MDR-TB treatment site. In May 2015 she was declared as treatment competed. In 2016 she relapsed and DST result showed XDR-TB, the same month she was enrolled into endTB treatment, now she is culture negative on new drugs
- Public-private sector referrals:
    - In public sector we find referrals from primary health care centers and tertiary hospitals
    - In private sector we find referrals from primary health care facilities, private clinics, and walk-ins
    - Contacts with active disease
- Numbers:
    - 331 patients enrolled across out sites, Bdq – 64%, Dlm – 31%, patients on BDQ extension - about 15%; BDQ/DLM combination - 17 patients. Most of the

patients who require treatment with new drugs didn't receive optimal treatment at first place. Optimal care should be provided as the first resort, not the last one.

- Preliminary data shows, about 56% patients enrolled on BDQ or DLM treatment are coming from the private sector:
  - In Bangladesh we treat patients in the public sector in a referral hospital, we don't know all the information where the patients have been treated before; for those that we know these are at least 43% private sector referrals
  - In Pakistan – 63%;
- A lot of patients found in a private sector, at least 53%, are younger than 30 years old. People choose to go to the private clinic at the early stage of disease. The more sick they get, then they go to the tertiary clinic.
- Again some preliminary data from Pakistan shows, out of those who are enrolled at the private sector treatment site:
  - 10% were contacts of index cases
  - 45% - coming from primary health care facility
  - 26% - walk-ins
  - 15% - from private clinic

- Suggestions for successful PPM:
  - M&E: data should be used for the benefit of the program, including monitoring and reducing diagnostic gap
  - Build or engage strong community teams to also help reduce the diagnostic gap
  - Pull together existing partners (e.g. BRAC)
  - Engagement of private sector is essential, as patients are already going back and forth between public and private sector, and a lot of expertise can be found in private sector
- Symposium at the Union conference:
  - 12 October – endTB data will be presented

<u>Questions:</u>

Vivian Cox – How do you keep track of patients? It can get difficult especially when patients visit both public and private facilities.

- Answer (Uzma Khan) – there are vigorous systems we have developed as part of endTB project – customized electronic medical record – for patients' monitoring. IRD is testing a mobile health tool, it is a platform for field workers for monitoring checks and visits. It can integrate into the EMR for regimen changes, send out SMS or alerts.
- We have hot line systems, SMS system for DR-TB patients to ask and answer questions on treatment and adverse events.

Vivian Cox - How do your encourage uniformity in guidelines and regimens in public and private sector?

- Answer - We do training every quarter. We need to make sure the field staff is available. Develop a team of trainers.
- We make sure to have a good management mechanism, develop a level of trust and give them enough ownership at different levels. Capacity building is lacking at all levels, it is wrong to say that private sector is not supervised or

regulated. There is a huge opportunity in understanding where we can learn from the gaps that exist in public and private sector.

Next DR-TB STAT call: **after the Union conference, 26 October 2017, Thursday,** at 11:00am EDT, agenda to follow