DR-TB STAT - May 2017 call
18 May 2017

Attendees: Jennifer Furin (SWIFT); Fuad Mirzayev (GDI); Khairunisa Suleiman (South Africa); Sharonann Lynch (MSF); Brian Kaiser (GDF); Michael Rich (PIH); Erica Lessem (TAG); Mamel Quelapio (KNCV); Mercedes Becerra (HMS); Ramon Crespo (GDF); Heather Stone (FDA); Nataliya Morozova (PIH)

Agenda:
1. General update on DR-TB STAT activities (Jen Furin, 5 minutes)
2. Country presentation on access to new drugs: China (Jen Furin, 20 minutes)
3. Presentation on country level Global Fund transitions (Sharonann Lynch, 20 minutes)
4. Wrap up and date for June call (10 minutes)

Minutes: Nataliya Morozova

General Update

- DR-TB STAT to monitor data quarterly as opposed to monthly monitoring. The next data update will be sent in July; GDF may report on a quarterly basis as well.
- There are multiple groups that collect data on patients on Bdq/Dlm and a shortened regimen, including:
    - Triage Task Force, KNCV, GDF, WHO, DR-TB STAT. Many of groups would want to support the WHO survey since they have access to all countries;
    - KNCV and the endTB project are working to develop tools to help countries to forecast;
    - DR-TB STAT will update the groups on data collection
- DR-TB STAT submitted several sessions to the Union, including a post graduate workshop on implementing new drugs.; During the Union Conference DR-TB STAT will have a conference room in Hilton or Westin hotels for meetings and small events to meet with partner organizations.

Country presentation: China Jennifer Furin (SWIFT)

- Gates Foundation is supporting TB Program in China in introducing Bdq. Bdq is registered in China. The Clinical Chest Center at Beijing Chest Hospital will be implementing Bdq, where most of patients will have access to Bdq. Clinical guidelines are ready and they are doing training.
- It is a 3 year program at Beijing Chest Hospital, where 1,000 patients will start Bdq, but the plan may change;

- They reported that they had placed an order with GDF. Drugs to arrive later in 2017.
- Comments
  - Brian Kaiser (GDF) – Yes, we've received an order, we are in the process of validation to make sure it's in the regulatory department for importation.
- Questions:
  - Erica Lessem (TAG) – Why was that number of patients selected?
    - Answer (Jennifer Furin) - This is a pilot-like project. It is a preliminary start. Beijing Chest Hospital and other hospital are open to extend the project and add patients. There will be more patients who need the drug.

<u>Focus on other countries</u>:

- The next goal for DR-TB STAT will be to figure out what is going on in Brazil, to have a good handle of the BRICS countries, at least. With support from GDI, DR-TB STAT has focused on high-income countries, because they are not introducing new drugs or shortened regimens;
- We have been working closely with PAHO to figure out how to support countries in the region. It can be discussed on the July call.

<u>Presentation on country level Global Fund transitions - Sharonann Lynch (MSF Access Campaign)</u>

- The presentation focuses on Eastern Europe and Central Asia, and GF policies as they relate to procurement of SLD and management of DR-TB.
- Slide 2: EECA region has the fastest-growing HIV epidemic and highest prevalence of MDR-TB with 8 of the 16 MDR-TB high-burden countries;
  - There is an evolving GFATM Policy - The GFATM Sustainability, Transition and Co-financing (STC) policy – it will set guidelines for countries in the region;
  - In order to have countries pay for increasing percentage of drugs and diagnostics;
  - It has implications for management of DR-TB, having access to affordable drugs representing new classes to manage TB, as well as HIV and Hep C;
- As a result of a supply-driving demand, EECA region will suffer more;
  - The region has experienced 15% reduction in funding in 2014-2016 allocation period;
  - For the next allocation period – they will expect to lose 40%
- All countries, regardless of their schedule for transition are going to be impacted by co-financing policy;
- Slide 4- this is what countries are paying for commodities.
  - Example of ARVs: 2nd column – the lowest prices available mostly through generic manufacturers world-wide
  - The far right column shows how much some of the regions are paying.
    - For Dolutegravir Belarus is paying ~ $2,000 through the GFATM, as opposed to $44;
    - For Raltegravir (RAL) Armenia is paying $13,213 per patient per year, as opposed to $675

    - It results from the ability of negotiation (prices are based on income) and access to generic drugs, with no partners available.
    - It is also linked to companies tiered pricing policies. Many countries in the region are in a triple bind:
        - I – countries get less funding
        - II – countries have to comply with WTO rule
        - III – because of tiered pricing policy countries have to pay more
- Slide 5 – EECA countries did not follow the GFATM guidance (2014-2017) for co-financing for commodities.
    - Low income countries had to pay 50-75% for SL TB drugs
- Slide 6 – there will be a new co-financing policy that will take disease burden into account
    - Market dynamic for SD TB drug should be taken into account
- Slide 8 – the GFATM is going to be smarter in terms of co-financing requirements
    - But countries have plans to increase their co-financing because they follow the previous investment guidance
    - Georgia - by 2019 75% of 2nd line drugs (DR-TB) will be procured using local budget – this information needs to be confirmed.
    - The goal is for government to cover 100% of SLDs by 2020.
    - Currently using GFs PPM and will onboard Wambo (a website for procurement of medical commodities)
- Slide 9 – What will be the implications when countries have to start procuring their own drugs? Impact of splitting market on GFATM/GDF negotiation for volume-based prices?
    - GDF is able to use its representation of volumes in order to negotiate with companies;
    - National procurement mechanisms lose the volume-based discounts that they might have gotten through GDF;
    - Now the GFTAM drugs receive a waiver for some countries where the drugs are not registered
    - Historical problems - Lack of transparency with national procurement processes; Quality issues; Forecasting and supply issues; Local production preference resulting in suboptimal options
- Slide 10 - Around the Union Conference 2016, MSF and other NGOs sent a letter to the GFATM Secretariat raising the issues:
    - What is country-specific roadmap for the GFATM supporting countries for optimal therapies and diagnostics?
    - Can waiver be provided for commodities given the fragile market dynamics?
        - The GFATM didn't get back to us
- Slide 11 – Risk assessment is needed; Freeze GFATM transition plan and co-financing requirements
- Slide 12 – Recommendations recently received from Implementer's Group for the GFATM Board Meeting.
    - Risk assessment needs to be done;
    - Co-financing recommendations have to be taken into account, etc.
- Slide 13 (final) – What's next

    - Will the GFATM Secretariat adopt the Implementer's Group recommendations?
    - Will the STC policy will be smarter?
    - Minsk Ministerial meeting from November 2016 (a document sent around). There will be a follow-up meeting.
- Comments
    - Jennifer Furin – In Mexico they have a law that says to procure nationally, which is a real problem. They are paying between 10-20 times to buy national commodities what they would pay through the GDF. The MoH would not sing off for procurement from GDF, due to political reasons. How can we bring this issue to the forefront?
        - Answer: Sharonann Lynch– It is important to involve some agencies (WHO, UNDP). It happens because of transparency issue. WHO TB Department didn't know about it, and now they are aware and concerned. We need to push the GFATM Secretariat.
    - Jennifer Furin – STAT will be happy to reach out to the GFATM but we need to make sure we advocate forcefully.
    - Sharonann Lynch - We can send the follow up information.
    - Jennifer Furin – Mexico is not going to use Bdq, they can't afford it, as well as Cs. We are trying to get Dlm for patients who qualify for new drugs and they can get it for compassionate use. Mexico is not Global Fund eligible.

<u>June 2017 call</u>

- Vivian Cox will be chairing the call;
- Dr. Alena Skrahina from Belarus will be talking about the problems in the country. They can't afford to get Linezolid or Clofazimine;
- Dr. Brian Citro will introduce the human rights-based approach.