



## **DR-TB STAT - June 2017 call**

*15 June 2017*

Attendees: Vivian Cox (DR-TB STAT); Jennifer Furin (SWIFT); Brian Citro (University of Chicago Law School); Ramon Crespo (GDF); Erica Lessem (TAG); Grania Brigden (Union); Khairunisa Suleiman (South Africa); Brian Kaiser (GDF); Blessina Kumar (Global Coalition of TB Activists); Dumebi Mordi (MSH); Jay Achar (MSF); Mercedes Becerra (HMS); Marcia Moepi; Fraser Wares (KNCV); Charles Horsburgh; Regina Osih (CHAI); Tiziana Masini (MPP); Nataliya Morozova (PIH)

### Agenda:

1. Update and discussion on new drug access in middle income countries
2. Presentation and discussion on TB and human rights (Brian Citro)
3. MSH – New e-course: Use of new drugs and shorter regimens

Minutes: Nataliya Morozova

### General Update – Vivian Cox (DR-TB STAT)

- Quarterly reports of the data will be sent out starting July 2017

### Update on the use of bedaquiline and delamanid in the PAHO Region - Jennifer Furin (SWIFT)

- Caveats – DR-TB STAT does not get numbers from the countries from the PAHO region on a regular basis. Some activities and information may be missing.
- This update is based on the 2016 Global TB report and DR-TB STAT monthly reports to provide cumulative numbers of patients started on new TB drugs. We look at GDF reports for orders placed. Feedback and input are welcomed.
- According to the 2016 Global TB report:
  - Estimated 11,000 MDR-TB in 2015 in the PAHO region
  - 3,477 MDR-TB patients were started on treatment in 2015
  - 55% - overall treatment success rate in 2013 cohort
  - Conservative estimate - 1 out of 3 MDR-TB patients on treatment need access to new TB drugs
- For patients who were started on treatment in 2015:
  - ~1,100 patients need access to a new TB drug (estimate based on patients started on DR-TB treatment)
  - ~3,700 patients each year who would need access to new drugs (based on the estimated 11,000 MDR-TB patients in 2015 in the PAHO region)
- According to DR-TB STAT reports between April 1, 2015 – April 1, 2017:

- 103 patients were started on bedaquiline under program conditions:
  - 4 – in Dominican Republic
  - 15 – in Haiti
  - 84 - in Peru
- 3 patients were started on delamanid in Dominican Republic
- Estimated number of patients who needed a new drug from April 1, 2015 – April 1, 2017: between 2,318 (estimate based on patients started on treatment) to 7,334 (based on WHO Report estimates)
  - Only 4.6% who were started on MDR-TB treatment received a new drug
  - Only 1.4% of estimated number of MDR-TB cases in the PAHO region received a new drug
- According to GDF orders:
  - 4 countries are using BDQ under program conditions
  - 1 country is using DLM under program conditions
  - No formal report from Brazil
  - Janssen opened a compassionate use program in Brazil in 2017; they have 20 requests for BDQ use. They are planning to register the drug in the country later this year
- Issues:
  - Most countries in the PAHO region are middle- or high-income countries, (e.g. Mexico), they are not able to access GDF pricing or USAID donation due to their income level
  - Mexico TB program is poorly funded, they are not able to procure basic commodities for diagnosis and treatment
  - Technical support materials are in English not in Spanish
  - Low burden of MDR-TB in PAHO compared to other regions of the world – not enough global attention or resources are dedicated to the problem
  - There is a perception that new drugs are only for XDR
  - There are concerning trends with DLM, since only Dominican Republic is considering using it
- Comments:
  - Erica Lessem (TAG) - BDQ has been available in Peru for a few years, but there are a lot of challenges to get DLM available:
    - Low move to register on the company site, although Otsuka are preparing a dossier. It takes time to translate documents into Spanish. By the end of July – August we should expect the dossier to be filed for DLM access
    - Country side challenges – it can take several years for a new drug application approval. Peru has not been open to use DLM for a compassionate use or under research conditions. The endTB project from Partners in Health, MSF and IRD, funded by UNITAID have been doing clinical research with BDQ and DLM in several countries
    - Other issues in Peru – humanitarian crisis, dengue fever outbreak
    - There are several patients in Peru who need DLM urgently

- Jennifer Furin – Otsuka keeps saying about delays in several countries, and there is no follow-up on that
  - We need to be careful when Otsuka tells us that they cannot manage registering a new drug
  - Because it is hard to get access to DLM, and now people have a lot of experience using BDQ, many countries are not considering using DLM
- Vivian Cox – It was brought up at the annual GDI meeting in Geneva last week why DLM has been slow and what can be done about it
  - Dr. Norbert Ndjeka from South Africa said that DLM had been very slow in the country. Clinicians are experienced in using BDQ, and less experienced with DLM
  - Suggestions are welcome on what we can do to work on access to DLM and highlight issues in the PAHO region
- Jennifer Furin - this issue is beyond the PAHO region. It is very typical in low burden higher-income countries
  - South Africa and Russia are interesting cases, they buy BDQ on the market, but they are high-burden countries
  - Question - What do we do as community to support high-income low-burden countries?
- Erica Lessem – The pediatric FDC update has been very slow in the PAHO region. NTP managers are interested in it but they do not have a lot of resources to update their guidelines or do trainings. A call for donors for the region to adopt new tools would be helpful
- Vivian Cox – At the UNION conference this October in Mexico, we should brainstorm ways to highlight the issues there

Presentation and discussion on TB and human rights - Brian Citro (International Human Rights Clinic, University of Chicago Law School)

- Tuberculosis, Human Rights and the Law Case Compendium is a continuation of similar work done in HIV. UNDP Global Commission on HIV and the Law made a report, and as part of follow-up and implementation of the report they helped two judicial dialogues in Nairobi and Bangkok in 2014. Two recourses for the meetings were developed by Brian Citro. They were a collection of legal cases, involving HIV that have been identified, summarized and categorized
- The idea was that lawyers knew there were cases involving healthcare issues, which might be good for opinions in other countries of the world, but they didn't have access to them. As a result, this resource was developed
- Purpose – lawyers benefit from knowing what is happening in other jurisdictions
- This compendium is a result of work of difference groups
  - International Human Rights Clinic, University of Chicago Law School
  - Team of LLM, Cambridge
  - Researchers hired through funding from GDI
- Research and Case Summary Methodology

- Cases from different countries (20 jurisdictions represented in the compendium, it's 18 countries, and 2 regional courts)
- The case law of TB is underdeveloped compared to HIV. TB patients are not going to court
- Cases are identified and summarized based on:
  - how prominent TB was in the case,
  - what jurisdiction is/what country it is from,
  - focused on countries with high TB incidence and countries of influential case law,
  - diversity of issues and level of the court
- We didn't summarize every single case. Many cases were very similar. We tried to find representative cases
- Table of Case Summaries – The categories are not of the same kind, they are descriptive. We did the research, identified the cases, and started to see trends in the case law. They represent the common issues and common things in a case law.
- Highlights of interesting cases
  - Issues in prisons - claims of torture or cruel, inhuman or degrading treatment or punishment. Many of the cases from the European court involving torture, it's prisoners who are not receiving appropriate care or might have died in prison or contracted TB in prison.
  - Case 1 - From Inter-American Court of Human Rights. It is a large case against Brazil, that looked at variety of problems in the Penitentiary Complex of Curado.
    - This case comes from the regional court
    - The court is very clear in its decision that the countries in the American system have an obligation to ensure that people with TB are given treatment and that the conditions in prison do not increase the risk of contracting TB
  - All summaries are presented in tables
    - Facts and Law - the most important part describing what happened to the people involved and what the law of the issue is
    - Issues and Holdings – the quickest way to find what happened, what the court decided in this case
    - Decisions and Reasoning – the explanation of the actual decision of the court
  - Page 6 - A representative case from the European Court of Human Rights. A person in a jail in Russia experienced delay in TB testing and inconsistent treatment of TB. The court decided that that constituted inhuman or degrading treatment or punishment under European Convention
  - Page 24 – A case from the US. It involves a claim on the Constitution of the US. The prison had no protocol of TB treatment and experienced an outbreak. The court decided it was a deliberate indifference to serious medical need that violated the Constitution
  - Page 36 – A case from Kenya. The Nairobi High Court ruled that putting people who start their TB treatment in jail violates the Constitution of Kenya, it violates

their rights to liberty and freedom of movement. It calls on the Ministry of Health to come up with a better system, to stop imprisoning people who stopped taking their treatment. A medical facility needs to be used

Questions – Erica Lessem:

- It is helpful to see different avenues for leverage to make sure TB patients are treated according to human rights. Many of us are excited about BDQ victory in India, is there a potential to do similar legal work in other countries for the access of new drugs? Does it require having a strong local partner?
- Blessi Kumar (Global Coalition of TB Activists) – We are still struggling for access, because of reluctance or lack of resources. How can we use this resource for others, what is the direction we should be looking at?

Answer - Brian Citro:

- Some cases could not be included into the Compendium. In the BDQ case and the other recent Indian case, involving daily dosage, the court does not explain the decision it is making. There is no legal reasoning at all, nothing to summarize. The High Court of Delhi wanted to avoid making difficult and broad-ranging decision about access to TB medicine. It does not create any precedent.
- How to use quasi-victories and the Compendium to move this work forward? I am interested in doing lawyers' training in India and other places to start get lawyers interested. In Geneva, they did a training of lawyers from South Africa. If we can create a network of people and start sharing this information in other countries, then people will become more likely to start bringing cases in the court.

New e-course: Use of new drugs and shorter regimens – Information provided by Dumebi Mordi (MSH SIAPS)

The USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is excited to announce the launch of the Using New TB Medicines and Regimens eCourse—a free, self-paced course for health professionals on new TB medicines, such as bedaquiline and delamanid, and new regimens, such as the nine-month regimen. The course also covers responsible use of these medicines and regimens for the treatment of multi-drug-resistant TB (MDR-TB).

This course is intended for use by physicians, nurses, pharmacists, and all health care workers who are currently engaged in the management of MDR-TB patients. Workers in national TB control programs, ministries of health, and nongovernmental organizations who are looking to introduce new TB medicines and regimens in their countries will also greatly benefit from this course.

The eCourse is available on Leadernet.org. The information in this course has been developed based on publicly available resources from the World Health Organization and elsewhere. It has

been taught via in-person workshops to hundreds of health care workers in five countries. Now this information is available to you at no cost.

The course includes eight modules with interactive case studies. You can choose to review all the modules in this course or simply pick the ones that are most relevant to your practice setting. Whether you are new to the topics and want to view the entire course in sequential order, or if you need a refresher or want to view a specific topic or resource, you can do so. You do not have to complete all the modules at once; you can go at your own pace and learn in your free time as desired. A certificate will be provided for those who complete the full course.

For more information or to register for this free course, please visit <https://leadernet.org/groups/courses/using-new-tb-medicines-and-regimens/>

Next DR-TB STAT call: 20 July 2017 at 11:00am EDT, agenda to follow