**Report of the GDI Triage Task Force**

October 2016-March 2017

**GDI Triage Task Force composition and objectives**

The Global Drug-resistant TB Initiative (GDI) Triage Task Force, previously named GDI Drug-resistant TB Research Task Force, consists of variable representations from implementing countries, the Global Drug Facility (GDF), the Union, KNCV TB Foundation, and other partners, and functions in close partnership with the DR-TB STAT Task Force, which is focused on collecting and sharing information on the introduction of new drugs for M-/XDR-TB. The GDI Triage Task Force (TF) is coordinated by KNCV (first by Agnes Gebhard, and, since November, by Mamel Quelapio).

The objectives of the Triage TF are as follows:

a) to facilitate and assist in the collection of information on the introduction of the shorter treatment regimen (STR) and second-line LPA (SL-LPA) to inform and guide the global PMDT support mechanisms;

b) to assist countries to contribute to the global body of evidence on the introduction of the patient triage approach; and

c) to facilitate problem-solving at the global level based on identified difficulties that countries face during STR and SL-LPA introduction.

**GDI Triage TF accomplishments**

1. *Collection of information on STR and SL-LPA*

The GDI Triage TF organized a meeting for information sharing on STR and SL-LPA during the Liverpool Union Conference on 29 October, attended by 7 countries (Bangladesh, India, Indonesia, Kyrgyzstan, Mozambique, Namibia and Ukraine). **Table 1** shows countries at different stages of planning and implementation of these novel tools. In October, Mozambique had enrolled 42 patients on STR; two countries had ordered STR drugs, and the remaining four were in the planning stage of STR introduction. SL-LPA was being implemented in Ukraine, being validated in India, and ready for routine performance in the 5 remaining countries. Among the challenges mentioned in STR introduction were lack of bed space for treatment initiation, difficult transition procedures from the conventional regimen to the new regimens, and the unavailability of companion drugs. More details can be found in the full meeting report **(Attachment 1)**.

**Table 1. Summary of the status of the introduction of STR and new drugs, and SL-LPA utilization in 7 countries (Liverpool Conference Meeting, 29 Oct 2016)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Country** | **Status of STR and new drugs** | | **SL-LPA** |
| **STR** | **New drugs** |
| **Bangladesh** | Drugs ordered (arriving 2017) | **√** Bdq: Enrolling (n=106 by end 2016) | NTRL starting soon (500 kits (endTB/IRD); 1500 kits (CTB) |
| **India** | Planned | **√** Bdq: Enrolling (n=86, Oct 2016) Dlm: Planned (Q1 2017) | Being validated in 5 sites, then rolled out in all 52 LPA labs. |
| **Indonesia** | Planned (Jul 2017) | **√** Bdq: Enrolling (44) | Two labs ready, awaiting kits; expand to 3-4 labs, need funds for LPA equipment |
| **Kyrgyzstan** | Drugs ordered (100 in 2016; 200 in 2017) | Bdq drugs ordered T: 100; & 200 in 2017  Dlm for request in Q1’17 | NTRL to perform in a programmatic approach |
| **Mozambique** | **√** Enrolling (n=42)  Target: 220 in 2017 | Bdq ordered (arriving June 2017) | Training in Dec in Maputo - start in Jan 2017, scale up Mar 2017 to regional lab |
| **Namibia** | Planned | **√** Enrolling (Bdq 11, & Dlm 1) | To start Jan 2017 |
| **Ukraine** | Planned | Planned:  Target Bdq: 600 | Three Hain laboratories (NRL and 2 regional sites) |

At the same time, the Triage TF coordinated with the Union to align with the new IUATLD DR-TB Working Group (WG), led by Bob Horsburgh, Arnaud Trebucq and Chen-Yuan Chiang, which attracted numerous people from different countries, expressing their interest in the introduction of the STR.

To enhance systematic information gathering on the implementation and scale-up of the STR and SL-LPA, the Triage TF initiated harmonization of efforts by different partners. On 18 Nov 2016, the Triage TF organized a teleconference (TC) attended by WHO, KNCV, and GDF. Other invited partners, the Stop TB Partnership, the Union, and DR-TB STAT could not attend the meeting. An inventory of partners collecting information on the STR and SL-LPA includes the following:

* GDF together with WHO (following on from initial work done by WHO-AFRO and others) was developing a questionnaire with 19 questions: one question on the number of patients expected to be enrolled on the different regimens over the coming 2 years; and the remaining questions mostly on the progress of implementation steps.
* KCNV with the Challenge TB project (CTB), collects information from its 22 supported countries using a template, primarily on patient enrolment on the new drugs and the STR, and laboratory capacity;
* Regional GLCs (rGLCs) use questionnaires partially based on the CTB Generic Guide for the introduction of new drugs and regimens
* The Union was preparing a questionnairre on the STR for the Francophone-supported countries

This meeting agreed on action points, namely, 1) for GDF/WHO to finalize its questionnaire and share with partners, and send to countries cc to the main PMDT TA partners of these countries, to enable them to assist NTPs complete the questionnaire, as relevant, and to prevent double data collection efforts; 2) KNCV to explore which role the CTB project can play in making relevant information available to global partners to facilitate drug and laboratory supplies forecasting and TA planning; 3) TF Co-chairs to reach out to the Union WG to share the discussion in this TF meeting; 4) WHO to share with TF Co-chair a mailing list for recipients of the meeting notes; 5) GDF to share a mailing list of GDF regional staff to share the meeting notes; 6) GDI Triage TF to coordinate with DR-TB STAT for the TF to join the next meeting as a combined DR-STAT/Triage TF call, add a checklist of elements to ensure sufficient information on STR and SL-LPA, inform and invite countries to share their experience of the STR and SL-LPA. The meeting notes are in **Attachment 2**.

As a result, the GDI Triage TF contributed to the finalization of the GDF questionnaire ensuring that the essential points pertaining to STR and SL-LPA are included. Till February, however, decision-making on the use of this questionnaire at GDF has been taking time, while the different partners continued their own data collection:

* The rGLCs, using an earlier version of the GDF questionnaire
* The Union distributed a questionnaire to the African Francophone countries in February 2017, with seven questions related to the current situation and challenges in the programmatic implementation of the STR and new drugs. From the results shared to the TF, among the 15 supported countries, 11 have considered the STR a national strategy, with pending data in the others **(Annex 1)**. Six countries are utilizing SL-LPA, while the rest are planning to utilize the test starting this year and in 2018.
* CTB continues to collect patient triage information for project monitoring.
* The Triage TF added some questions pertaining to the introduction and scale-up of STR and SL-LPA to the STAT questionnairre **(Annex 2)** to facilitate the monthly discussions with countries on the patient triage approach.

After initial agreement on collaboration between the STAT and the Triage TF in November 2016, the first joint monthly call took place in February 2017.

1. *Assisting countries to contribute to the global body of evidence*.

The Triage TF, using the WHO and GDF mailing lists, has circulated the TF’s meeting notes to inform countries and partners of the TF’s aim to support data collection on the STR and SL-LPA. With most countries still in early stages of implementation of the patient triage approach, evidence for scale-up is still limited. In February 2017, the Triage TF facilitated the participation of Kyrgyzstan in presenting the patient triage approach and its experience in the introduction of STR and SL-LPA plan in the joint STAT/Triage TC **(Attachment 3).** More countries will be facilitated to share their experience in subsequent STAT/Triage TC’s.

1. *Facilitating problem-solving at the global level based on identified difficulties that countries face*

The Triage TF takes note of technical assistance needs and challenges encountered by countries and strives to help resolve these issues.

In October 2016, an important barrier to the introduction of the STR was the unavailability of SL Hain tests. This was discussed and partially solved by GDF, making the test available in its catalogue for a very reasonable price; Hain Life Sciences is working with local partners on product registration in countries. In other countries, importation of tests procured from GDF is possible without registration. The TF is following up on the progress towards patient access to the SL-LPA test in countries.

Another identified barrier was the perceived cost of switching from the conventional regimen to the STR (or the patient triage approach) and the hesitation at the side of funders to facilitate the transition, as discussed during the Union Conference at the GDI meeting on 23 October 2016, and a “Friends of Indonesia” meeting on 26 October in Liverpool. These meetings led to a discussion in the Global TB “Situation Room” meeting on 9 November attended by the Stop TB Partnership, WHO, GDF, Global Fund (GF), USAID and many partner organizations, including members of the GDI Triage TF. The meeting agreed that the rapid introduction of the STR is beneficial to large groups of MDR-TB patients with different approaches needed in different countries. The meeting recognized that there are differences in the approach to countries by the different GF Portfolio Managers (PFM) and that there are costs to the transition to the STR, which have to be covered in the framework of the current and future GF grants. This is a topic on which countries as well as GF PFMs and GDF advisors need guidance. Therefore, the meeting agreed for the secretariat to send a document to the GF prior to the board meeting end of November, outlining the importance of GF support to facilitate rapid and well-planned transition of countries to using the STR, as appropriate to their respective situation. Also, the partners at the meeting agreed to coordinate the monitoring of drug stocks and required procurements, and the implementation of the STR and related diagnostics in the countries. This Global TB “Situation Room” meeting has strategically catalyzed partners in supporting countries in the transition.

**Next steps for the Triage TF**

With more and more countries implementing the STR and SL-LPA, the Triage TF strives to intensify information sharing, using collaborative approaches among countries and partners, thereby optimizing and integrating efforts, and avoiding duplication in information gathering. The Triage TF together, with the DR-TB STAT TF, will continue to work jointly on monthly calls to facilitate data sharing on the patient triage approach, focusing on the use of STR and SL-LPA. The Triage TF will, likewise, link with countries that are developing GF Funding Requests, in order to be informed on plans for STR and SL-LPA implementation in 2018-2020. Information gathered will be presented in a special session in an international meeting in Geneva in June 2017. The presentations and minutes of this meeting will be compiled in a progress report.

**Annexes**

*Annex 1 - Status of STR, new drugs, SL-LPA and challenges in Francophone countries, Feb 2017*

*Annex 2 - Checklist for presentation of STR and SL-LPA during the DR-TB STAT calls*

**Attachments**

*Attachment 1 – Meeting notes, Updates on the STR and SL-LPA, Liverpool UNION Conference (29 Oct 2016)*

*Attachment 2 – Meeting notes, DGI Triage TF conference call (18 Nov 2016)*

*Attachment 3 – Country (Kyrgyzstan) presentation of experience in STR and SL-LPA planning and implementation (16 Feb 2017)*

**ANNEXES**

**ANNEX 1. Status of STR, new drugs, SL-LPA and challenges in Francophone countries:, Feb 2017**

*Source: The UNION*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Country** | **STR** | **New drugs** | **SL-LPA** | **Challenge(s)** |
| Benin | Already national strategy | 2 patients pre-XDR with Bdq | Plan to implement in 2017 in the LNR: training and equipment OK but still some technical issues. | Only 1 MDR treatment center : a second center is planned |
| Burkina Faso | Already national strategy | Not available | Plan to implement in March-April 2017 in the LNR. | Post treatment follow-up  Training of MDR TB staff  Supervision of MDR TB activities in the BMUs  Operationalization of SL-LPA |
| Burundi | Already national strategy | 1 pre-XDR patient. Died before the arrival of the drugs. | Plan to introduce it in the next concept note 2018 – 2020 | Strengthen the screening of MDR-TB among presume patient  Training of MDR TB staff  Monitoring and management of potential pre/XDR patients |
| Cameroun | Already national strategy | BDQ: 3 patients  Dlm: 1.000 pills | Performed in the 2 national reference lab | Finish the National RR-TB Guide |
| Côte d'Ivoire | Already national strategy | Bdq: 4 patients.  Dlm: 1 patient | Performed in only 1 of the 2 national culture labs for failures of STR (not on initial specimen). | Improve capacity for culture/DST. Improve management of side effects  Finish the National RR-TB Guide. |
| Guinea Conakry | Already national strategy | BDQ: 1 patient | Planned for Q1 2017 in the NRLM of Conakry | Update MDR-TB Guide  Follow up MDR-TB cases outside Conakry |
| Guinea Equatorial | Already national strategy | Bdq is ordered  Dlm not ordered | Sputum are sent to Bamenda (Cameroon) | Develop TB control |
| Madagascar | Not yet implemented | Will be included in the next Guidelines revision (Q1 -2017).  Not yet ordered | Performed at national TB MR reference laboratory (“Pasteur Institute of Antananarivo”) | Transition plan to start the STR in September 2017 |
| Mali | Already national strategy but Cfz not yet available | Bdq and Dmd requested to GFATM (waiting for WHO approval of regimens proposed) | Starting in Q1 2017 in CICM and SEREFO labs in Bamako | Finish the National RR-TB Guide  Cfz supply  aDSM to develop  2 XDR cases with high level resistance to all SLI and FQ declared |
| Mauritania |  |  |  |  |
| Niger | Already national strategy | Bdq: 10 patients enrolled since 2012 (1 XDR and 9 pre XDR-FQ). 7 cured, 1 died and 2 under treatment. | Performed in the NRL | Finish the National RR-TB Guide |
| RCA | Already national strategy | 1 pre-XDR patient. But she died before the arrival of the drugs. | Plan to implement in the next MDR management plan which has not yet been funded. | Only 1 MDR treatment centre; others are planned. |
| RDC | Already national strategy. Drug order for 2017 uses the following ratio : 80% STR and 20% in order to finish those under LTR and treat those who do not meet criteria for STR. | 11 patients pre-XDR with Bdq and 11 patients waiting for their treatment | SL-LPA is performed in private laboratory. It is planned to implement in 2017 in the LNR a SL-LPA. | Screening of all presume patients  Reduce delay of screening and starting treatment  Management of pre-XDR / XDR patient |
| Rwanda |  |  |  |  |
| Senegal |  |  |  |  |

**ANNEX 2. Checklist to guide the presentation of STR and SL-LPA during DR-TB STAT calls**

1. **Shorter Treatment Regimen (STR):**

* Funding source
* Date of start of enrolment
* Target number to be enrolled for the year (2016, 2017, 2018, etc.)
* Current number enrolled
  + Total
  + Children <15 y/0
  + HIV +
* Regimen used if other than the WHO-recommended regimen
* Drug dosages if other than WHO-recommended dosages for STR
* Main challenges
* Facilitating factors
* Plans and technical assistance needs

1. **SL-LPA:**

* Funding source (If not yet implementing, state planned funding, if applicable)
* Number of labs planned to have SL-LPA testing in place
  + Date of start of SL-LPA testing (If not implementing, state timeline, if applicable)
* Target number to be tested for the year (2016, 2017, 2018, etc.) and by lab
* Current number tested (N/A if not implementing)
* Turn-around time in practice (from specimen collection till feedback to clinician, and start of treatment)
* Percentage of readable/interpretable results
* Main challenges
* Facilitating factors
* Plans and technical assistance needs