**Updates on the Shorter Regimen and SL-LPA**

Liverpool Union Conference, 29 Oct 2016

**Meeting notes:**

A GDI DR-TB Research Task Force project aims to establish a venue for sharing updates regarding the introduction and use of the Shorter Treatment Regimen (STR) and SL-LPA in countries, challenges encountered, lessons learned and technical assistance needed. KNCV Agnes Gebhard leads the Task Force and will be collaborating with other technical partners such as the UNION, and DR-TB STAT which regularly holds a conference call regarding the use of the new drugs in countries. Updates on STR will be included in the existing DR-STAT calls on new drugs. Below are country updates on STR, (the new drugs), and SL-LPA.

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| **Country** | **Shorter treatment regimen (STR), new drugs**  | **SL-LPA** |
| **Bangladesh** | **STR** drugs have been ordered and will arrive next year **Bdq**: 106 enrolled by year end (40 started in June 2016)Challenge: bed space in NIDCH  | NTRL can perform **SL-LPA**. 500 SL-LPA test kits are already in country (procured by endTB project/IRD); and expecting to start SL-LPA soon. CTB has plan and budget (in APA3) for 1500 SL-LPA test kits**.** |
| **India**  | **STR:** The Expert Committee recommended its implementation and was approved by the high level ‘TB Diagnostics & Treatment Committee’. Detailed plans are being worked out in the coming months. India already has Bdq CAP in six sites across the country and these could be the sites for introducing STR.  **Bdq:** 86 patients enrolled as of Sept 2016

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|  | Targets for Bdq |
| Year 1 (end 2016) |   150 |
| Year 2 (end 2017) | 1450 |
| Year 3 (end 2018) | 2000 |
| Year 4 ( end 2019) | 4000 |
| 2020 | 3000 |

6 sites implementing (increased to 20 in APA3) Expert committee has revised eligibility: include cases with any FQ resistance and mixed pattern resistance (any FLD/SLI/FQ, Lzd), in contrast to earlier criterion of resistance to all FQ. **Dlm**: guidelines ready by Q1 2017, discussions with Otsuka held.  | Has strong network of culture and DST but **SL-LPA** is a bottleneck. Currently, **SL-LPA** is being validated in 5 sites, following which it will be rolled out in all 52 LPA labs.Diagnostic algorithm for Bdq: FL/SL DST is to be done in a single step on liquid culture. At the labs linked to BDQ sites, DST would be offered for 7 drugs.  |
| **Indonesia** | **STR**: The government has agreed to introduce the STR with plan to start July 2017. Challenge is that SLDs for 24-month regimen are on the procurement process, and NTP needs to find the possible best scenario for transition, considering STR will minimize the lost-to-follow-up cases. Target for STR is not set yet **Bdq** started last year (2015l, with 44 enrolled as of Oct 2016. Implemented in 3 hospitals (plan for 1 additional site this year) and 1 control site for CEM (also for std MDR/Pre-/XDR treatment, not just Bdq) First 100 patients are monitored via CEM; thereafter, it will be aDSM (core package).  | 4 labs with capacity to do **FL-LPA**. Assessment already conducted; 2 labs (BBLK Surabaya and Persahabatan Hospital) are ready to start **SL-LPA,** awaiting SL-LPA kits assisted by KNCV under APA 3). Two options for the future:1. Utilize the 2 ready labs as both are still able to cover the need. This needs support on specimen transport system.
2. Expand SL-LPA to other 3-4 potential labs (existing biomolecular labs); needs procurement of LPA equipment, but currently no funding
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| **Kyrgystan**  | Drugs for both **STR** and **Bdq** have been ordered through UNDP- GF. While MSF provides project TA in only 1 region, KNCV is assisting a more programmatic approach starting with the National Center and 1 TB Center. Targets: 100 **(STR)** and 200 in the next year; and 100 in 2 years (**Bdq)**. **Dlm** is planned to be requested in the 1st quarter of 2017.  | The NTRL will perform **SL-LPA** in a programmatic approach.  |
| **Mozambique**  | 1. CTB supports in the development of **STR** implementation plan. Its introduction has been approved informally at the national level by the MOH, but formal approval is still pending. However, MSF in close coordination with NTP is piloting the use of STR in six selected sites, in Maputo city.
2. Phased introduction of STR:

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|  | Sites | Patients | Total |
| Maputo city | 6 | 2 | 12 |
| Maputo Province | 2 | 6 | 12 |
| Gaza Province | 2 | 6 | 12 |
| Nampula Prov | 2 | 10 | 20 |
| Sofala Province | 2 | 10 | 20 |

Total : 54 (?) 76As of Sept 2016 = 42 enrolled on **STR** by MSF among eligibles; target next year= 220Selected 14 sites to monitor; SLDs are available in country; **new drugs** are expected to be available in country by June 2017; drug quantification already done and the procurement ongoing. | **SL-LPA**: Training will be done in Dec for Maputo, and in Mar 2017 for Nampula, then the lab will start to operate.Very weak peripheral laboratory network3 labs can perform DST1 lab can do SL-LPA (starting Jan 2017)Scale up in 2017 to regional labs (Nampula Regional lab: **SL-LPA**, and Sofala Regional lab: **FL-LPA**)  |
| **Namibia** |  NTP sensitized, and **STR** incorporated in the strategic plan and new PMDT guidelines, both under development. Will be issued in Dec 2016. National roll-out envisaged in Jan 2017 onwards. The gov’t pharmaceutical services have prepared a forecast for the coming year and procurement will occur in due course (all drugs procured through the government).Challenge: companion drugs are by competitive bidding, and we may not have control over when adequate quantities will be available**Bdq and Dlm** are already in Essential Drugs list and are in use. So far 11 patients treated with Bdq (via GDF from USAID donation programme), and 1 with Dlm (Compassionate use, Otsuka)  | The lab network just completed validation of **SL LPA** and will start using in Jan 2017.No universal DST yet, but new algorithm incorporates Xpert for all presumptive cases, followed by SL-LPA for the RR cases to be implemented from Jan 2017. Challenge: CTB in Namibia does not provide direct support to the lab network but does advocate for the new algorithm & guidelines.  |
| **Ukraine** | **STR:** plan to replace Clofazimine (Clz) with Bdq. Clz is not registered (although included in the essential medicines list). But Bdq is also not registered and is being considered because of the following. 1 – BDQ is available through donation program 2 – Clz was not properly used lately so CTB team was sure that BDQ will have better results  3 – According to the NTP information received this summer Clz, will not be available for procurement by 2018 In Ukraine; there is a law to sell only registered drugs. Year 3 – Triage protocol was divided into two separate documents- one for NDR implementation that CTB currently pushing to be endorsed. This document will create legal framework for Bdq implementation in country. In parallel, CTB will pilot Bdq in pilot sites. STR – CTB will work with NTP to implement STR and NDRs through the revision of the national TB guidelines.**Bdq** -  600 patients target in **1-2 sites** planned (Q2-Q3). This information could be updated in early 2018. | There are 3 **HIAN**s in country:One in NRL and two in regions. |

**Meeting participants**

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