Strengthening TB laboratory management toward accreditation (TB SLMTA) programme: customizing SLMTA for TB labs

Heidi Albert

SLMTA Workshop, ASLM 2014
29th November 2014
Three-pronged approach to diagnostics uptake

1. Ensure holistic solutions tailored to specific country needs are in place

2. Support development of country implementation plans for solutions

3. Strengthen country capabilities to implement and capture benefit of solutions

Country adoption

- Political commitment
- Strong lab / health systems
- Process & managerial efficiency
Accreditation of TB laboratories is a goal of Global Plan to Stop TB 2011 - 2015

GLI Stepwise Process Towards TB Laboratory Accreditation
- Online tool but no training and mentoring approach

TB laboratories have not been well represented and integrated into SLMTA programmes in many countries

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>DOTS/Laboratory strengthening</strong></td>
<td></td>
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<tr>
<td>Number of cases diagnosed, notified and treated according to the DOTS approach (per year)</td>
<td>5.8 million</td>
<td>6.9 million</td>
</tr>
<tr>
<td>Treatment success rate (in annual cohort)</td>
<td>86%</td>
<td>90%</td>
</tr>
<tr>
<td>Number of countries with ≥1 laboratory with sputum smear microscopy services per 100,000 population</td>
<td>≥75</td>
<td>149</td>
</tr>
<tr>
<td>Percentage of laboratories providing sputum smear microscopy services that are using LED microscopes for diagnosis of smear-positive TB</td>
<td>&lt;1%</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Drug-resistant TB/Laboratory strengthening</strong></td>
<td></td>
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</tr>
<tr>
<td>Percentage of previously treated TB patients tested for MDR-TB</td>
<td>7%</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of new TB patients tested for MDR-TB</td>
<td>7%</td>
<td>20%</td>
</tr>
<tr>
<td>Number of countries among the 22 HBCs and 27 high MDR-TB burden countries with ≥1 culture laboratory per 5 million population</td>
<td>18-21</td>
<td>36</td>
</tr>
<tr>
<td>Percentage of confirmed cases of MDR-TB enrolled on treatment according to international guidelines</td>
<td>36%</td>
<td>100%</td>
</tr>
<tr>
<td>Number of confirmed cases of MDR-TB enrolled on treatment according to international guidelines</td>
<td>11,000</td>
<td>≥270,000</td>
</tr>
<tr>
<td>Treatment success rate among confirmed cases of MDR-TB</td>
<td>60%</td>
<td>≥75%</td>
</tr>
<tr>
<td><strong>TB/HIV/Laboratory strengthening</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of acid-fast bacilli (AFB) smear-negative, newly notified TB cases screened using culture and/or molecular-based test</td>
<td>&lt;1%</td>
<td>≥50%</td>
</tr>
<tr>
<td>Percentage of TB patients tested for HIV</td>
<td>26%</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of HIV-positive TB patients treated with OPT</td>
<td>75%</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of HIV-positive TB patients treated with ART</td>
<td>37%</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of people living with HIV attending HIV care services who were screened for TB at their last visit</td>
<td>≥25%</td>
<td>100%</td>
</tr>
<tr>
<td>Percentage of people living with HIV attending HIV care services who were enrolled on IPT, among those eligible</td>
<td>&lt;1%</td>
<td>100%</td>
</tr>
<tr>
<td>Laboratory strengthening (additional to those above)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of national reference laboratories implementing a quality management system according to international standards</td>
<td>&lt;5%</td>
<td>≥50%</td>
</tr>
</tbody>
</table>
What is TB SLMTA?

- Harmonised checklist (SLIPTA + GLI)
- TB-specific modules and activities
- Master trainer support at least for 1st workshop
- Link to TB resources
- TB-specific site visit checklist
- Mentoring and improvement projects
# TB Laboratory Quality Management Towards Accreditation

## Harmonized Checklist

### GLI - TB

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are specimens packaged appropriately according to local and/or international regulations and transported to within acceptable timeframes?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does it also include the following:</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Is triple packing employed for sample transportation with forms separated from samples</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are samples transported to the laboratory by a secure process as soon after collection as practical?</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### SLIPTA

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the complete procedure manual available at the workstation or in the work area?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### GLI - TB

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are smear preparation procedures available and followed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Before making the smear, the slide is cleaned with alcohol and clearly labeled with the laboratory number</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Is a swab-stick (or loop) used to collect from the specimen sediment (pellet) a representative portion of the sample for smearing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) Is there only one smear per sample?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>d) Is the smear approx. 2cm x 1cm and in the center of the slide?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e) After drying, is fixation done by gentle heating?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) Does the fixed smear have the appearance of a milky white film on the slide?</td>
<td></td>
<td></td>
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<tr>
<td>g) Is the objective lens wiped clean after use on a positive smear?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>h) Are smears prepared on clean, unused glass slides?</td>
<td></td>
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<td></td>
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</tbody>
</table>

### Culture

<table>
<thead>
<tr>
<th>Question</th>
<th>Y</th>
<th>P</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the correct culture techniques and procedures followed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) The volume of the specimen is checked and equal volume of digestion-decontamination reagent is added and thoroughly mixed</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Training of trainers workshops

Lesotho, Nov 2013
Vietnam, Feb 2014
South Africa, Oct 2014
2 Master Trainers
62 participants trained from 19 countries in TOT
51 trainers graduated
21 TB SLMTA laboratories enrolled in country implementation, 14+ starting by end 2014
TB SLMTA: implementation models

Workshop vs. Facility-based?
Integration of workshops with SLMTA?
Integration of mentoring with SLMTA?

No. qualified trainers and mentors

• Set targets with MOH
• Include QMS in NSP

No. and location of TB laboratories

Extent of SLMTA implementation
Baseline audit data - Ethiopia

Documents and records
Facilities & safety
Occurrence Mgmt
Corrective Action
Process control/IQC/EQA
Information Mgmt
Internal Audits
Purchasing & Inventory
Organization & Personnel
Client Management
Magnt reviews

- Adama
- EPHI
- Bahir Dar
- Harar
- Hawassa
- Mekele
- St. Peters
- Jimma

Ethiopia
Ethiopia: impact of TB SLMTA

EPHI, NTRL- baseline and follow up audit

- Follow up visits by trainers
- Additional mentor rotates around labs for mentoring, approx 1 week per visit after each workshop
Cameroon

Bamenda lab, Cameroon - baseline and interim audit

Facility-based approach
1 regional lab
10 participants
2 trainers
Interim visit by TB SLMTA MT

8%
Dominican Republic

TB SLMTA DR – 9 labs; baseline audit data

Documents & records
Facilities and safety
Occurrence/incident management
Corrective action
Information management
Procurement & inventory
Equipment
Management reviews
Organization & personnel
Client management &...
Lesotho, NTRL & 2 regional labs - baseline audit

- Documents
- Management
- Organization
- Customer
- Equipment
- Internal Audit
- Inventory
- Facilities & Safety
- Process Improvement
- Corrective Action
- IQC & EQA

NTRL
Motebang
Mafeteng

0 stars

Improvement projects
- Creating and updating personnel files
- Monitoring Equipment maintenance
- Acid alcohol usage
- Establishing TAT at NTRL
- Monitoring TAT at Motebang Laboratory
- Reducing Gene Xpert error rates
- Completing requisition forms
### TB SLMTA M&E

#### FIND
Because diagnosis matters

#### Summary

**Country:**

**Author:**

**Instructions:**

Phases have been determined as follows:
- **Phase 1:** Baseline Audit, Workshop 1, IP1, the first two mentorship visits
- **Phase 2:** Baseline audit, Workshop 2, IP2, the next two mentorship visits
- **Phase 3:** Baseline audit, Workshop 3, IP3, the last two mentorship visits
- **Phase 4:** Exit Audit

Please enter the right number into the grey boxes. If necessary, please explain in the narrative why the target has not been met.

#### TB SLMTA

<table>
<thead>
<tr>
<th>Group A</th>
<th>Number of laboratories involved in this Group: 0</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of participants involved in this Group: 0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Start date</th>
<th>Expected</th>
<th>Actual</th>
<th>Start date</th>
<th>Expected</th>
<th>Actual</th>
<th>Start date</th>
<th>Expected</th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>Aug 14</td>
<td></td>
<td></td>
<td>Aug 14</td>
<td></td>
<td></td>
<td>Aug 14</td>
<td></td>
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<tr>
<td>Phase 2</td>
<td>Aug 28</td>
<td></td>
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<td>Dec 14</td>
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<td></td>
<td>Dec 14</td>
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<tr>
<td>Phase 3</td>
<td>Aug 28</td>
<td></td>
<td></td>
<td>Dec 14</td>
<td></td>
<td></td>
<td>Dec 14</td>
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<tr>
<td>Phase 4</td>
<td>Aug 28</td>
<td></td>
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<td>Apr 15</td>
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<td>Apr 15</td>
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<tr>
<td>Completion date</td>
<td>Aug 14</td>
<td></td>
<td></td>
<td>Dec 14</td>
<td></td>
<td></td>
<td>Dec 14</td>
<td></td>
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<tr>
<td>Number of IPs completed</td>
<td>22</td>
<td></td>
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<td>22</td>
<td></td>
<td></td>
<td>22</td>
<td></td>
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<tr>
<td>Number of workshops conducted</td>
<td>1</td>
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<td>1</td>
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<td></td>
<td>1</td>
<td></td>
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<tr>
<td>Number of participants who successfully passed all workshops</td>
<td>22</td>
<td></td>
<td></td>
<td>22</td>
<td></td>
<td></td>
<td>22</td>
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<tr>
<td>Number of baseline assessments conducted</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
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<tr>
<td>Number of mentorship visits conducted</td>
<td>16</td>
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<td>16</td>
<td></td>
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<td>16</td>
<td></td>
<td></td>
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<tr>
<td>Number of exit assessments conducted</td>
<td>-</td>
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<td>-</td>
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<tr>
<td>Average of the participant satisfaction</td>
<td>#VALUE!</td>
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<td>#VALUE!</td>
<td></td>
<td>#VALUE!</td>
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</tbody>
</table>

#### Narrative

- If the target of baseline audit has been met, explanation.
- If the target of IP has been met, explanation.
- If the target of workshops has been met, explanation.
- If the target of mentorship visits has been met, explanation.
- If the target of exit audits has been met, explanation.

**General challenges and their solutions:**
- Concerning the challenges noted.
- Harmonized checklist used during the training was not the finalized version.
- Trainers showed lack of preparation during the first day of the workshop. However, there was improvement from D2 to D5.
- Not all participants managed to attend.
- One trainer did not work in a team with his colleagues and did not attend assistance from his colleagues.
- Recommendations were relevant to train the trainer on mentorship to help them to assist their colleagues more effectively.

**Narrative feedback from participants:**
- Concerning the feedback from the participants of the first workshop:
  - Modules were not aligned.
  - Short training duration and congested.
  - Training evaluation should be done daily.
  - Inadequate time was provided for questions and discussions.
  - Some key documents should have been provided in hard copy or USB.
Data management - audit database

- Offline and online use
- SLIPTA, TB harmonised and follow up visit checklists
- Other checklists can be added
- Automated reporting
- Use on tablets
- Initial pilot in Dominican Republic
Challenges and opportunities

- Strengthen mentoring and country level support
- Enlarge pool of master trainers
- Publish and share experiences
- Prioritise GLI phase 1 activities in initial IPs

- Expand in Latin America, Africa and Asia
- Focus on high MDR-TB countries/regions, e.g. E Europe/Central Asia
- Link with other related trainings for holistic solution, e.g. lab leadership
- Strengthen partnerships:
  - GLI/SNRLs
  - ASLM
  - Other partners, especially for mentoring
STRENGTHENING TB LABORATORY MANAGEMENT TOWARDS ACCREDITATION

FIND:
Jessica Bennett
Donatelle Erni
Diana Gomez
Rosa Hazim
Kekeletso Kao
Aleida Landestoy
Mathabo Lebina
Erika Lencses
Blessing Marondera
Pamela Nabeta
Vidya Nidhi Gumma
Yen Nguyen Thi Huang
Andre Trollip
Jesse Wambugu

Kim Lewis
Talkmore Maruta

TB SLMTA trainers and participants

Brad Cunningham, Lucerae

CDC: Heather Alexander, Katy Yao