Progress on adaptation and use of the SLMTA (Strengthening Laboratory Management Towards Accreditation) tool for TB laboratories

Heidi Albert
Overview of SLIPTA, SLMTA and GLI stepwise process
An auditing framework for improvement of laboratory quality system in developing countries to fulfill ISO 15189 standards in a stepwise process to achieve accreditation.

Guidelines and Policy for implementation approved in Nairobi, July 2011

Designed based on ISO 15189/17025/15190 standards and the 12 QSEs of CLSI (GP26:A4)
SLIPTA: A framework to encourage, support and recognize the implementation of QMS in medical laboratories in a stepwise manner
SLMTA: Strengthening Laboratory Management Towards Accreditation

Key areas of work = Training Module

Module Learning Objectives

Tasks

- 
- 
- 
- 

Module content

Hands-on Activities with Management Tools & Job Aides

Module Outcome

Checklist Items

- 
- 
- 
- 

Module content:

Activities

Management Tools
How is its effect evaluated?

Content + Implementation = Impact

Baseline Audit

Workshop #1
Improvement Projects (3 months)

Workshop #2
Improvement Projects (3 months)

Workshop #3
Improvement Projects (3 months)

Behavioral Changes & Laboratory Improvement

Exit Audit

Site Visits

Site Visits

Site Visits

Exit Score [AFTER] - Baseline Score [BEFORE] = SLMTA Effect
What is the difference between SLIPTA and [TB] SLMTA?

**SLIPTA**
- A framework of auditing to **measure and evaluate the progress** of laboratory quality system and award a certificate of recognition (five star levels).
- Can be used at baseline, during supervision, and for monitoring and evaluation of laboratory progress towards accreditation.
- SLIPTA audit report identified areas where improvement is needed and is used to generate lab specific implementable plans.

**[TB] SLMTA**
- A task-based training and mentoring programme delivered in multi-workshop implementation model.
- Participants work on structured projects to improve the quality management system of the laboratory.
- Measurement of progress using SLIPTA or TB Harmonized checklist.
Enrollment in SLIPTA programme

SLIPTA checklist can be used for self-assessment or external assessment. ASLM is implementer of the WHO-AFRO external SLIPTA programme.

Eligibility Criteria for enrolment of laboratory for SLIPTA Implementation:

- **Self-evaluation using SLIPTA Checklist**
  - Minimal score: 143 points (55%, 1 star)
- Participation in proficiency testing (PT) schemes or inter-laboratory comparisons for all tests that were reported back to clinicians for at least one PT cycle in past six months
- Routine quality controls for all test methods
- Evidence of internal audits conducted by laboratory
- Laboratory Quality Document/Manual
GLI Stepwise Process towards TB Laboratory Accreditation

http://www.gliquality.org
GLI activities

Activities Phase 2 - Equipment

- Write an SOP for Procurement and Reception of Equipment
- Label all equipment in accordance with the codes in the inventory list made in phase 1 under Equipment
- Determine which staff members are authorized and which are responsible for use of each piece of equipment
- Develop maintenance and Usage Log Sheets/Logbooks for each piece of equipment
- Collect all equipment documents and records and store these in the Equipment Archive
- Write an SOP explaining the system used for the identification and management of equipment
- Prepare Bench Aids for each piece of equipment including daily maintenance instructions
- Decide on the method of maintenance and calibration for each piece of equipment
- Establish a preventive maintenance program for equipment
- Define in an SOP the maintenance schedule for all listed equipment
- Ensure that defective equipment is taken out of service, clearly labeled and disinfected, and that proper validation is performed once equipment is repaired

Develop maintenance and Usage Log Sheets/Logbooks for each piece of equipment

Why
For several types of equipment the maintenance needs are depended on the hours of use. In addition, it is convenient to have an overview of when what maintenance was performed on each piece of equipment. Based on this overview new service appointments can be planned. It also provides an indication of the costs involved in using each piece of equipment. Therefore, maintenance and Usage Log Sheets need to be introduced on which this can be recorded. Based on that the Equipment Officer can decide when the next maintenance is needed.

What
Establish for each piece of equipment a Maintenance Log Sheet and, where applicable, a Usage Log Sheet. The Maintenance Log Sheet is used to record maintenance in one overview for each piece of equipment. The Usage Log Sheet only has to be made for equipment where this is needed. E.g. for a flow cabinet and for centrifuges must be recorded how many hours they have been used. This allows determination when maintenance is needed based on hours of use.

NOTE: Some laboratories distinguish between the terms “Servicing” and “Maintenance”, with “servicing” being the maintenance performed by an external maintenance company, and “maintenance” being the maintenance performed by the laboratory itself. In this tool we only use the term “Maintenance” which also includes servicing.

How & who

Equipment Officer:
1. Make a Maintenance Log Sheet. A template of such a form is provided in the right-hand column. Note that this is just an example. If another format works better for you, use that format. Make sure that the unique code and name of each piece of equipment is clearly shown on each sheet.
2. Take a new folder and name this “Equipment Archive”. Insert a tab for each piece of equipment.
3. Each time maintenance is done on a piece of equipment a Maintenance Log Sheet needs to be filled out and dated by the responsible. Store filled

## Checklist Phase 1

<table>
<thead>
<tr>
<th>Question</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have the staff adequately been instructed on the symptoms of infection with <em>Mycobacterium tuberculosis</em>, the HIV virus and other pathogens worked with in the laboratory?</td>
<td></td>
</tr>
<tr>
<td>Is there a written procedure on how to act in case of a suspected laboratory associated infection/laboratory accident whereby a staff-member has potentially become infected?</td>
<td></td>
</tr>
<tr>
<td>Is there an action plan to upgrade the facilities and safety to comply with the essential TB laboratory safety requirements of the WHO TB Laboratory Biosafety Manual?</td>
<td></td>
</tr>
<tr>
<td>Has the Risk Group for each laboratory room been determined?</td>
<td></td>
</tr>
<tr>
<td>Is there an action plan to upgrade the facilities and safety to get each laboratory room into compliance with the risk group defined for that room (based on the WHO TB Laboratory Biosafety Manual)?</td>
<td></td>
</tr>
<tr>
<td>Does the laboratory have a procedure for processing and disposal of the different types of waste produced?</td>
<td></td>
</tr>
<tr>
<td>Does the laboratory demonstrably adhere to procedures for processing and disposal of different types of waste produced?</td>
<td></td>
</tr>
</tbody>
</table>
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Heidi Albert
Strengthening lab systems: a critical element for TB control

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
Why TB SLMTA?

- Quality-assured diagnostic services are essential to meeting goals of TB control
- Accreditation of TB laboratories: 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
- SLMTA does not comprehensively cover some sections critical in TB labs e.g. biosafety, QA
- TB laboratories have not been well represented and integrated into SLMTA programmes in many countries
What is TB SLMTA?

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

TB Laboratory Quality Management Systems Towards Accreditation
Harmonized Checklist
(Incorporating SLIPTA and GLI Stepwise Process towards TB Laboratory Accreditation)
Training of trainers workshops

Lesotho, Nov 2013
Vietnam, Feb 2014
South Africa, Oct 2014
31 laboratories, 6 countries
2 Master Trainers
62 participants trained from 19 countries in TOT; 51 trainers graduated
Ethiopia: TB SLMTA baseline audit

- 8 labs enrolled in TB SLMTA and 5 showing significant QMS improvement
- Follow up visits by trainers and mentor to 7 regional labs
- Resident mentor NTRL
EPHI, Ethiopia

- 1 Star
- 2 Star
- 3 Star
- 4 Star
- 5 Star

0 Star

Mar 14 (baseline)

200 Aug 14 (ASLM SLIPTA)

233 Mar 15 (GLI)

Jun 15 (exit)

2015

2016

55-64 %

65-74 %

75-84 %

85-94 %

> 95 %

National accreditation ENAU

INTL accreditation
Lesotho

- 3 Labs enrolled in TB SLMTA
- 5 zero star audits at NTRL prior to TB SLMTA
- Staff at NTRL committed to implementing TB SLMTA
- Mentor based at the NTRL
- 1 regional lab remained at 0 stars
- 1 regional lab moved from 0 to 1 star
- Ongoing efforts in quality improvement
Baseline TB SLMTA audit scores

- Cameroon – 1 lab
- Vietnam – 6 labs
TB SLMTA new developments

- Revisions being made to TB SLMTA based on experience to date
  - Stronger link of improvement projects to the major non-conformities found in the baseline assessment
  - More guidance with selection of improvement projects
  - Define clearly the path to accreditation beyond TB SLMTA and develop/implement approaches
  - Improve linkages with GLI tool activities
  - Provide guidance for coordination of SLIPTA and {TB}SLMTA and GLI tool to avoid confusion at country level

- Update of TB Harmonized checklist once SLIPTA updated to ISO 15189:2012
Reaching accreditation: which route to take?
Substantial quality improvement of TB labs is possible in relatively short time frame from low baseline

- Factors contributing to success – motivated staff, management support, structured approach, project management, mentoring

With sufficient and well-targeted investment, accreditation of TB labs is an achievable goal

- More investment needed to expand this approach to other countries and sustain progress all the way to accreditation
  - Comprehensive costing analysis underway
  - Linking lab quality impact to patient impact
- Strengthen and better coordinate mentoring and country level support
- Link with other related trainings for holistic solution, e.g. lab leadership, technical trainings

Lessons learned and next steps
STRENGTHENING TB LABORATORY MANAGEMENT TOWARDS ACCREDITATION

FIND:
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CDC:
Katy Yao, Heather Alexander
CDC Lesotho, Dominican Republic, Tanzania, Vietnam

Country trainers and mentors

EPHI and regional TB labs, Ethiopia
NTP/NTRL, Vietnam
NTP/CTRL, Tanzania
NTP/NTRL, Lesotho
MOH, Dominican Republic