Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA)

Advanced Course on Diagnostics
Annecy, France | November, 2013
ASLM and SLIPTA background
ASLM’s work centers around four primary goals:

1. Laboratory workforce development
2. Laboratory accreditation
3. African national and regional regulatory capacity
4. African network of National Public Health Reference Laboratories (NPHRLs)
Key mechanisms behind goal 2: laboratory accreditation

- ASLM is an implementing partner in the WHO AFRO SLIPTA (Stepwise Laboratory Quality Improvement Toward Accreditation) Programme

**Auditor training** → **Auditing** → **Certification**

2020 Targets

- Enroll 2,500 labs in the WHO SLIPTA quality improvement program
- Enable 250 labs to achieve accreditation
Objective of audits

- Evaluate and recognize the progress of laboratory quality management systems (QMS)

- Provide feedback and guidance to address the requirements of QMS based on ISO15189:2012 standards

- Mentoring of SLIPTA trainee auditors
The SLIPTA checklist assesses laboratory performance in 12 different categories.

Laboratories are awarded a score of 0-5 stars based on their performance.

<table>
<thead>
<tr>
<th>Audit Sections</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1: Documents and Records</td>
<td>25</td>
</tr>
<tr>
<td>Section 2: Management Reviews</td>
<td>17</td>
</tr>
<tr>
<td>Section 3: Organization &amp; Personnel</td>
<td>20</td>
</tr>
<tr>
<td>Section 4: Client Management &amp; Customer Service</td>
<td>8</td>
</tr>
<tr>
<td>Section 5: Equipment</td>
<td>30</td>
</tr>
<tr>
<td>Section 6: Internal Audit</td>
<td>10</td>
</tr>
<tr>
<td>Section 7: Purchasing &amp; Inventory</td>
<td>30</td>
</tr>
<tr>
<td>Section 8: Process Control and Internal &amp; External Quality Assessment</td>
<td>33</td>
</tr>
<tr>
<td>Section 9: Information Management</td>
<td>18</td>
</tr>
<tr>
<td>Section 10: Corrective Action</td>
<td>12</td>
</tr>
<tr>
<td>Section 11: Occurrence Management &amp; Process Improvement</td>
<td>12</td>
</tr>
<tr>
<td>Section 12: Facilities and Safety</td>
<td>43</td>
</tr>
<tr>
<td><strong>TOTAL SCORE</strong></td>
<td><strong>258</strong></td>
</tr>
</tbody>
</table>
Audit process

Audit methods
- Document and record review
- On-site observations
- Personnel and management interviews

Debrief
- Laboratory level
- Hospital level

Reporting
- Submitted to IAC
WHO-AFRO SLIPTA programme provides a stepwise framework to encourage, support, and recognize the implementation of quality management systems in medical laboratories.
Auditor training

- Trainees should hold a B.Sc. Degree or advanced diploma in medical laboratory sciences or a related field, and have 5-10 years experience working in medical laboratories

- First, ASLM SLIPTA auditors complete a 5 day didactic training course

- Those trainees that score ≥ 70% on the final examination are invited to participate in three post-training audit practica under the guidance of a lead auditor

- Trainees that successfully complete three post-training audit practica become certified as ASLM SLIPTA auditors

- Each certified auditor must conduct three audits per year to remain certified
SLIPTA achievements to date
ASLM auditor pool

- ASLM has provided initial SLIPTA training to 138 trainees to date.
- 25 of these trainees have become certified as ASLM SLIPTA auditors.

<table>
<thead>
<tr>
<th>Country or organization</th>
<th>Number of certified auditors</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASLM</td>
<td>3</td>
</tr>
<tr>
<td>Botswana</td>
<td>1</td>
</tr>
<tr>
<td>Cameroon</td>
<td>4</td>
</tr>
<tr>
<td>Lesotho</td>
<td>1</td>
</tr>
<tr>
<td>Mozambique</td>
<td>3</td>
</tr>
<tr>
<td>Nigeria</td>
<td>1</td>
</tr>
<tr>
<td>South Africa</td>
<td>2</td>
</tr>
<tr>
<td>Tanzania</td>
<td>8</td>
</tr>
<tr>
<td>Zambia</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>25</strong></td>
</tr>
</tbody>
</table>
Audits conducted by ASLM

ASLM has conducted SLIPTA audits in 11 African countries

- 0 stars: 2 laboratories
- 1 stars: 14 laboratories
- 2 stars: 15 laboratories
- 3 stars: 11 laboratories
- 4 stars: 2 laboratories
- 5 stars: 0 laboratories

Total: 44 laboratories
Audited laboratories: strengths

- Support from laboratory management
- High commitment and teamwork of laboratory staff
- Evidence of QMS implementation in documents and records reviewed
- Implementation of biosafety programs
Audited laboratories: weaknesses

- Inadequate reagents and consumable supplies
- Insufficient servicing, repair and calibration of equipment
- Deficient verification of methods and equipment
SLIPTA: the way forward
Reaching 2020 accreditation goal: building partnerships

- ASLM’s strategy of auditing 2,500 laboratories and helping 250 laboratories reach international accreditation is ambitious, yet achievable

- ASLM has recently established a formal partnership framework in order to collaborate with other institutions in order to expand the SLIPTA programme. These include:
  - African accreditation bodies (KENAS, SANAS, SADCAS)
  - African laboratory councils
  - African regulatory bodies (BOBS)
  - African regional economic communities (CEN-SAD, COMESA, EAC, ECOWAS, IGAD, SADC)
  - African regional health bodies (ECSA, WAHO)
  - Local indigenous NGOs
  - Research foundations (AMREF)
  - Universities
Reaching 2020 accreditation goal: strategic plan

- ASLM expects to start 2014 with the same pool of 25 laboratory auditors.

- If each auditor conducts his three required audits in 2014 and is accompanied by one trainee, 75 laboratories will be audited in 2014, and there will be 50 new auditors by 2015.

<table>
<thead>
<tr>
<th>Year</th>
<th>Auditor pool</th>
<th>Audits conducted</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>25 auditors</td>
<td>75 audits</td>
</tr>
<tr>
<td>2015</td>
<td>50 auditors</td>
<td></td>
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</table>
Continuing with the conservative assumption that each auditor conducts only three audits per year and that each auditor certifies each one new auditor per year, it is clear that ASLM will be able to conduct well over 2,500 laboratory audits by 2020.

Total audits = 9,525
Thank you.