Progress Made in the Implementation of the Stepwise Laboratory Quality Improvement Process Towards Accreditation

Talkmore Maruta

ASLM2014, Cape Town
Background
ASLM is a pan-African professional body launched in 2011

Receives support from African Union, World Health Organization (WHO), United States (US) Centers for Disease Control and Prevention (CDC), Clinton Health Access Initiative (CHAI), US President's Emergency Plan for AIDS Relief (PEPFAR), Several African ministries of health and other international partners
ASLM 2020 Vision
Vision2020: Its Motivation

- Strengthening Public Health Labs in Africa
- Strengthening of Laboratory Systems

WHO Resolution AFR/RC58R2

2008 Maputo Declaration
### ASLM’s Work Centers around its 4 Strategic Goals

<table>
<thead>
<tr>
<th>GOAL</th>
<th>2020 TARGETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workforce</td>
<td>✓ Curriculum review, establish professional/regulatory bodies</td>
</tr>
<tr>
<td></td>
<td>✓ Train 30,000 professionals</td>
</tr>
<tr>
<td>Accreditation</td>
<td>✓ 2500 Labs to be enrolled into SLIPTA</td>
</tr>
<tr>
<td></td>
<td>✓ 250 labs to achieve accreditation by international standards</td>
</tr>
<tr>
<td>Regulatory</td>
<td>✓ Raise regulatory standards for diagnostics products to international standards in 25 countries</td>
</tr>
<tr>
<td></td>
<td>✓ Establish harmonized regulation for new diagnostics across Africa’s 8 RECs</td>
</tr>
<tr>
<td>Lab networks</td>
<td>✓ Establish African Network of Public Health Reference Laboratories, with at least 30 member countries.</td>
</tr>
</tbody>
</table>
Goal 2 Laboratory Accreditation: Key Mechanisms

ASLM is Implementing Partner for SLIPTA.

2020 Targets

- Enroll 2,500 labs in the WHO SLIPTA quality improvement program
- Enable 250 labs to achieve accreditation
## Audit Process

<table>
<thead>
<tr>
<th>Tools</th>
<th>WHO AFRO SLIPTA Checklist</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ISO 15189:2012</td>
</tr>
</tbody>
</table>

### Audit methods
- Review of documents and records
- Observations
- Interviews

### De-brief
- Lab Level
- Centrally

### Report
Submission to IAC
SLIPTA Progress

16 Countries visited
122 labs Audited
Audited Laboratories: Star Distribution (n=122)

- Zero: 12
- One Star: 23
- Two Stars: 46
- Three Stars: 31
- Four Stars: 8
- Five Stars: 2

Nigeria S Africa
Performance of the 122 Laboratories
Progress Towards 250 Laboratories Accredited

7 Laboratories being prepared for International Accreditation

42 (34%) Labs recommended to Prepare for International Accreditation

4 Pre SANAS Audits scheduled for Dec 2014 (2) and March 2015 (2)

NTRL Audited by PAC. Expect accreditation Q1 2015
Building capacity to conduct Laboratory audits

Portuguese = 3; French = 9; English = 59
Capacity To Audit: Impact on Vision 2020 Goal

Impact of Increased Auditor Base
Framework for Engaging Other Institutions for SLIPTA Implementation

Purpose
1. In line with ASLM2020: Strategies and Vision to Strengthen Public Health Laboratory Medicine in Africa through working collaboratively with governments, national, regional and international organizations, implementing partners, the private sector and other agencies, this document establishes a structural role for potential partners and formalizes the modalities of their participation in supporting and implementing the WHO AFRO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).
High Level Advocacy to build support for Laboratory System Strengthening in Africa

- Support to visit accredited labs
- Support to apply for ISO accreditation
- Commitment to support Labs for accreditation
- MOH level Implementation plans to resolve systemic issues
MINISTERIAL CALL FOR ACTION
- STRENGTHENING LABORATORY SERVICES IN AFRICA -

We, the undersigned Ministers of Health from African countries, attending and meeting at the 1st International Conference of the African Society for Laboratory Medicine (ASLM), Cape Town, South Africa, December 1st th, 2012 under the theme “Accurate Laboratory Diagnostics – A Pillar of Quality Health Care”
Looking Ahead

ADVANCING THE LABORATORY PROFESSION AND NETWORKS IN AFRICA
Status of QMS in Africa: Where Are We and Why are We there and How can we move
Average performance of the 122 Laboratories in Africa
i. Review Current Training on Internal Auditing
   Most programs train but do not check for competency
ii. Corrective Action and Root Cause Analysis
    Most training theoretical
Barriers to Implementation of QMS Towards Accreditation

- Zero Stars: 12
- One Star: 23
- Two Stars: 41
- Three Stars: 29
- Four Stars: 8
- Five Stars: 2
Barriers to Implementation of QMS Towards Accreditation

Infrastructure
• Most Significant barrier ($P=0001$)
  o Size: Scope of testing
  o Design

Make Available Standard Lab Plans for different risk Levels
E.g. WHO, ASLM websites
Barriers to Implementation of QMS Towards Accreditation

Availability of a QMS Expert (OR: 20; p = 0.011)

- Lab mentor
- Consultant

Training of more Lab mentors
Establish Structured Mentorship Programs
Develop local and regional Expertise
Barriers to Implementation of QMS Towards Accreditation

Staff commitment
(OR = 8.4; p = 0.013)

- **Workload to staff ratio not significant! In other words, having more staff does not necessarily predict that a lab will get >= 3 stars**

Well defined career paths
Staff Retention Strategies
Increase Staff motivation and morale
Barriers to Implementation of QMS Towards Accreditation

Availability of adequate financial resources:
(OR = 7.0; p = 0.036)

Include Accreditation in Strategic Plans
Increase allocations for Labs
Increase involvement of the Lab in the Budgeting Process
ASLM’s Work Centers around its 4 Strategic Goals

<table>
<thead>
<tr>
<th>GOAL</th>
<th>2020 TARGETS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workforce</td>
<td></td>
</tr>
<tr>
<td>Accreditation</td>
<td></td>
</tr>
<tr>
<td>Regulatory</td>
<td></td>
</tr>
<tr>
<td>Lab networks</td>
<td></td>
</tr>
</tbody>
</table>
Acknowledgements

- ASLM
- WHO
- CDC
- Audited countries MOH and Laboratories
- SLIPTA Auditors
- Partners Supporting Laboratories