ASLM

Building laboratory capacity in Africa in a sustainable way

Tsehaynesh Messele, PhD
ASLM, Chief Executive Officer

Annual AMDS meeting
September 29-30, 2014
Geneva
1. **Workforce**: Less than 1 laboratory professional per 10,000 people.

2. **Quality**: Less than 500 laboratories accredited to international standards and 90% are in South Africa.

3. **Regulatory**: No countries with stringent IVD regulatory standards (as defined by the Global Harmonization Taskforce) and no diagnostic regulatory harmonization by economic zone.

4. **Lab Networks**: Few fully functional national public health reference laboratories and networks.
THE DEVELOPMENT AND CREATION OF THE AFRICAN SOCIETY FOR LABORATORY MEDICINE

2008 Maputo Declaration

- Called for integrated laboratory support for major diseases
- Called on governments to develop and implement national laboratory strategic plans

2008-2009 Yaoundé Resolutions

- Strengthen public health laboratories in the African region
- Establish laboratory centers of excellence

2009 Kigali Stepwise Accreditation

- Launch of WHO-AFRO Stepwise Laboratory Accreditation program

2010 Kampala Statement

- Called for creation of the African Society for Laboratory Medicine
ASLM MISSION

To advance professional laboratory medicine practice, science, systems and networks in Africa needed to support preventive medicine, quality care of patients and disease control through partnership with governments and relevant organizations.
## Goals for Laboratory Strengthening

<table>
<thead>
<tr>
<th>GOAL</th>
<th>2020 TARGETS</th>
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<tr>
<td>Workforce</td>
<td>✓ Train 30,000 laboratory professionals and clinicians</td>
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<tr>
<td>Accreditation</td>
<td>✓ 2500 SLIPTA enrolled&lt;br&gt;✓ 250 labs to achieve accreditation by international standards</td>
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<tr>
<td>Regulatory</td>
<td>✓ Raise regulatory standards for diagnostics products to international standards in 25 countries&lt;br&gt;✓ Establish harmonized regulation for new diagnostics across Africa’s 8 RECs</td>
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<tr>
<td>Lab networks</td>
<td>✓ Establish African Network of Public Health Reference Laboratories, with at least 30 member countries.</td>
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Laboratory workforce Development

• Establish national laboratory professional councils

• Improve regional standards for pre-service training, retention, and certification

• Facilitate cross-border certification
SLIPTA: A framework to encourage, support and recognize the implementation of QMS in medical laboratories in a stepwise manner

Star Levels

- **No Stars**
  - (0 – 142 pts)
  - < 55%

- **1 Star**
  - (143 – 165 pts)
  - 55 – 64%

- **2 Stars**
  - (166 – 191 pts)
  - 65 – 74%

- **3 Stars**
  - (192 – 217 pts)
  - 75 – 84%

- **4 Stars**
  - (218 – 243 pts)
  - 85 – 94%

- **5 Stars**
  - (244 – 258 pts)
  - ≥95%

**End Point**
Link to Accreditation Body

**Scores (%)**
- 0 Star
  - 55-64 %

- 1 Star
  - 65-74 %

- 2 Star
  - 75-84 %

- 3 Star
  - 85-94 %

- 4 Star
  - ≥ 95 %

- 5 Star
  - ≥95 %

**Stepwise Process**
SLIPTA Governance

- MoH SLIPTA Focal Point
- WHO AFRO SLIPTA Focal Point
- ASLM SLIPTA Secretariat
- ASLM SLIPTA-Certified Auditors
- SLIPTA Independent Advisory Group
- MoH Laboratory /Other
SLIPTA Auditor Training

- Developed a **Standardized Training Curriculum**
  - In collaboration with US-CDC, CLSI and Vijay Consulting

- Content includes, but not limited to:
  - SLMTA and SLIPTA
  - Introduction to accreditation and ISO 15189:2007 Standards
  - Audit techniques
  - WHO/AIRO SLIPTA Checklist
  - Identification of Nonconformities (Major/Minor)
  - Reporting
  - Professional Ethics

- Five days Program – 3 days for lectures & 2 days on lab audit practicum
- Post training practicum of 3-5 shadowed audits
Laboratory quality improvement towards accreditation

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

2020 Targets

- Enroll 2,500 labs in the WHO SLIPTA quality improvement program
- Enable 250 labs to achieve accreditation
Guidance for the WHO/AFRO SLIPTA Implementation

- Guidelines and Policy for implementation of WHO/AFRO SLIPTA was finalized and approved in July 2011 in Nairobi, Kenya.
- Has catalytic effect to enable countries develop their national laboratory strategic and operational plans.
- Established to bring laboratory quality improvement process in a stepwise manner.
- Country owned program.
WHO/AfRO SLIPTA Checklist


- Developed to monitor the progress and improvement of laboratory quality system

- Directly applicable to all laboratory settings and disciplines

- Based on 12 sections of Quality System Essentials (QSE)
The reach and spread of SLIPTA in Africa
Regulatory Strengthening

WHO Pre-qualification

Strengthening National Regulation of Diagnostics
Product Registration and Post-Market Surveillance

Report of
The 2nd African Regulatory Forum on Medical Diagnostics
Cape Town, South Africa
21-24th January 2014
Establishing functional laboratory Networks

- Regional Network of National Public Health Reference Laboratories
- Improved south-south collaboration, research and training
- Improved surveillance and early disease detection
- High quality data to inform policy and technology selection/deployment
STRENGTHENING THE CULTURE OF LABORATORY COMMUNICATION

Development of quarterly newsletter

• Inform stakeholders and the public health laboratory network of ASLM activities, accomplishments, partnerships, opportunities

• Inform members of new and innovative ventures in the field of laboratory medicine

• Promote Laboratory Medicines success stories and best practices
Systematic reviews of diagnostic test accuracy for evidence-based diagnostic practice in Africa

In 2009, a debate started about whether there was enough evidence to change current guidelines, from presumptive malarial treatment of children under 5 years who present with fever, to testing these children before treating them. A major argument against this policy change was the lack of evidence on the accuracy of diagnostic tests for malaria in this population.

Review and comparison of quality standards, guidelines and regulations for laboratories

Background: The variety and number of laboratory quality standards, guidelines and regulations (hereafter: quality documents) makes it difficult to choose the most suitable for establishing and maintaining a laboratory quality management system.

Immunohaematological reference values for HIV-negative healthy adults in Botswana

Background: Clinical laboratories in Botswana have relied entirely on the reference intervals for normal immunohaematological values provided by manufacturers’ kits and textbooks.

Identifying HIV infection in women: How does a fourth generation HIV rapid test perform?

Background: HIV rapid tests (RT) play an important role in tackling the HIV pandemic in South Africa. Third generation RTs that detect HIV antibodies are currently used to diagnose HIV infection at the point of care. Determine Combo (DC) is the first fourth generation RT that
Accurate Laboratory Diagnostics –
A Pillar of Quality Healthcare

Cape Town International Convention Centre, South Africa
December 1–7, 2012

Knowledge, networking and partnerships for advancing best laboratory practices

We invite you to join an expected 1500 healthcare professionals, program managers, policy makers, students and industry leaders for the First International Conference of the African Society for Laboratory Medicine!

Why attend ASLM2012?
- Network with global leaders and professionals of laboratory medicine and public health
- Receive CLE credit
- Attend interactive satellite sessions and virtual exhibition booths
- Hear presentations from keynote and plenary speakers, including Dr. Asha Stone Migiro, the UN Secretary-General’s Special Envoy for AIDS in Africa, and US Ambassador Eric Goosby, Global AIDS Coordinator for the United States

ASLM2012 Keynote Speaker
Dr. Asha Stone Migiro has dedicated her career to AIDS response as well as to women’s rights. Dr. Migiro served as Deputy Secretary-General of the United Nations from 2007–2013. While in office, she brought a great spirit of partnership to the UN, urging public-private partnerships and collaboration to make progress towards global health targets.

ASLM2012 Highlights
- Diverse satellite meetings and workshops including technical working group meetings, equipment demonstrations, and training sessions.
- Plenary sessions, oral and poster presentations, and symposia
- Keynote addresses and plenary speeches from leaders in the fields of laboratory medicine and public health.

What is ASLM?
The African Society for Laboratory Medicine (www.aslm.org) is an African professional body with a mission to advance professional laboratory medicine practice, science, systems, and networks in Africa needed to support preventive medicine, quality care of patients and disease control through partnerships with governments and relevant organizations.

• Seven Ministers of Health
• Over 1000 attendees
• Over 60 countries
• Over 500 high quality scientific presentation
• 85% of which were from 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-7th, 2012 under the theme ‘Accurate Laboratory Diagnostics – A Pillar of Quality Health Care’”
ASLM Convening Power: Meetings are targeted and cross-cutting

- POC Meeting, Addis Ababa, Ethiopia, May 2012
- ASLM2012 Conference, Cape Town, South Africa, December 2012
- Viral Load Meeting, Cape Town, South Africa, April 2013
- HIV Drug Resistance Meetings, Cape Town and Addis Ababa, June and July 2013
- HIV and Microbial drug resistance Meeting, October 2013, Cote d’Ivoire
- Improving Access and Increasing Quality of HIV Testing in Africa
  Dar es Salaam, June 2014
UNAIDS in partnership with ASLM, WHO, PEPFAR, UNICEF, CDC and CHAI launched the Diagnostic Access Initiative in July 2014 at the international IAS meeting in Melbourne, Australia.
Partnership

- Consolidate fragmented efforts
- Scale up by pooling limited resources
- Promote result oriented collaborative efforts
- Engage partners outside the lab health sector