

# Strengthening Laboratory Management Toward Accreditation, A Model Program for Pathology Laboratory Improvement

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## KEYWORDS

- SLMTA • SLIPTA • Laboratory • Training • Stepwise • Quality • Improvement
- History

## KEY POINTS

- Strengthening Laboratory Management Toward Accreditation (SLMTA) and Stepwise Laboratory Quality Improvement Process Toward Accreditation (SLIPTA) have proved to be effective tools to empower laboratorians and improve laboratory quality in developing settings.
- Participants progressed more quickly when the laboratory leaders attended training and involved the entire laboratory staff in the improvements and changes needed.
- Access to mentors as well as supervisory visits were key to success.
- SLMTA/SLIPTA can serve as a useful model for improving laboratory quality across pathology disciplines.

## BACKGROUND

Only 10 years ago, access to reliable diagnostic testing in sub-Saharan Africa was critically limited and misdiagnosis a common occurrence. Although reliable laboratory results can support clinical decision making and improve patient outcomes, unreliable

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laboratory results prolonged illness or resulted in unnecessary or ineffective treatment regimens. With the wrong treatment, time and financial resources were wasted.<sup>1</sup> If and when diagnostic testing was available, the results were suspect. It was common for clinicians to ignore test results and proceed with patient care using only the patient's symptoms and the physician's clinical impression. Reyburn and colleagues<sup>2</sup> found that, among 4670 patients admitted to hospitals in Tanzania and treated for malaria, less than 50% had malaria confirmed by a blood smear. In the absence of high-quality laboratory testing, disease surveillance and epidemiology programs also lag behind.

Shortly after the millennium, in response to the growing human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) epidemic, support for health systems strengthening in developing countries became a priority for many donors, including the World Bank; the United States (through the Global AIDS Program); and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Initially, funding was limited so efforts primarily focused on targeted technical assistance projects. With the introduction of the US President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, spending scaled up rapidly and monies were directed to procure medications and direct patient care supplies. In order to deliver care to the number of individuals supported by these programs, it was quickly realized that efficient and reliable health systems, including quality laboratory services, needed to be supported. Laboratory infrastructure and personnel in Africa were insufficient to fill their role in the accurate diagnosis and treatment of infectious and chronic diseases.<sup>3</sup>

The best way for laboratories to ensure the quality of their testing results is to implement a robust quality management system (QMS). The International Standards Organization (ISO) has adopted ISO 15189 as the standard for laboratory quality and competence and this is designed to provide laboratories and laboratory auditors with a common set of standards for assessing a laboratory QMS. At the outset of PEPFAR, however, achieving international accreditation seemed like a daunting task for many laboratories in developing settings. In response, the World Health Organization (WHO) Regional Office in Africa (WHO-AFRO) began developing a stepwise program toward accreditation that provided a framework for auditing and monitoring laboratory quality and that rewarded incremental progress. On completion of the WHO-AFRO process, laboratories were ready to go forward to potentially achieve accreditation through ISO 15189. This approach was ratified and gained consensus during 7 meetings that took place through 2008 to 2011.<sup>3</sup>

1. The Maputo Declaration (2008) included 33 countries with the WHO; the World Bank; and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. A declaration to strengthen laboratory systems was passed.
2. A meeting in Lyon, France, with WHO and the US Centers for Disease Control and Prevention (CDC) called for countries with limited resources to improve their quality systems by using a stepwise approach. It further recommended minimum standards be established.
3. At Yaoundé, Cameroon, in the 58th session of the Regional Committee (2008), a resolution was adopted emphasizing the urgency to strengthen laboratories with a request that WHO African Region support this effort to achieve improvement.
4. In Dakar, Senegal, at the fifth meeting of the Regional HIV/AIDS Network of Public Health Laboratories (2008), agreement was reached to support improvement for all laboratories without limitation to any specific disease.

5. In Kigali, Rwanda, in the presence of government health officials, WHO-AFRO in collaboration with CDC, The Clinton Health Access Initiative (CHAI), ASCP, and other partners launched the stepwise laboratory accreditation process (2009).
6. Later (2009) in Kigali, Rwanda, at the 59th session of the Regional Committee, among other infectious disease resolutions, a call for strengthening of public health laboratories was adopted.
7. In Nairobi in 2011, consensus of a key stakeholders meeting was achieved on the Stepwise Laboratory Quality Improvement Process Toward Accreditation (SLIPTA) Policy Guidance and Checklist.

The WHO-AFRO SLIPTA checklist, derived from ISO 15189, not only became the tool to assess a laboratory's stepwise progress in improvement but it also provided guidelines as to quality expectations for implementation. It gave credit for partial achievement rather than the pass-fail nature of ISO 15189 accreditation assessment.<sup>3</sup>

### **DEVELOPMENT OF STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARD ACCREDITATION: STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION**

In addition to adopting the stepwise accreditation process for the 13 African countries during the first meeting in Kigali, Rwanda, a laboratory management improvement training called Strengthening Laboratory Management Toward Accreditation (SLMTA) was launched.<sup>4</sup> This program used 3 pillars, each essential in providing the necessary information for improvement in laboratory quality management.

#### ***Framework***

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The framework defined laboratory-specific management tasks that must be performed to accomplish quality outcomes in laboratory services. This list of tasks was created by ASCP, Clinton Health Access Initiative (CHAI), the Association of Public Health Laboratories (APHL), the American Society for Microbiology (ASM), the Clinical and Laboratory Standards Institutes (CLSI), and Becton Dickinson. The components of this framework were used to develop both the WHO-AFRO Laboratory Accreditation Checklist and the SLMTA training curriculum.

The framework organized laboratory quality management tasks into 4 levels (I–IV), which correlated to a typical tiered laboratory network. Level I tasks are those management tasks specific to national laboratories; level II for regional laboratories; level III for district laboratories; and level IV for community laboratories. Development partners decided to focus laboratory improvement at the regional and district levels, so the level II management tasks were used to guide the development of the SLMTA curriculum. Using the job task list as a guide, training was developed to detail: what to do, when to do it, and how to do it. An assessment checklist would then be used to observe the results.<sup>5</sup>

#### ***Strengthening Laboratory Management Toward Accreditation Curriculum***

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Based on the management tasks derived from the framework, training modules were developed to instruct laboratory managers (including managers of the laboratory, and quality and section heads) how to fulfill their duties in carrying out these tasks as expected. Rather than being descriptive or theoretic, SLMTA training was uniquely developed to be prescriptive and practical. Participants receive instructions for what to do and then perform the prescribed method either in the classroom or in their home laboratories. This hands-on approach provided assurance for both trainers

and participants that the processes were understood and could be performed as intended.

Within the curriculum, there are 10 key areas of work tasks fundamental to level II to IV laboratories, as described in the framework. These key areas are:

1. Productivity management
2. Work area management
3. Inventory management
4. Procurement management
5. Preventive maintenance and equipment
6. Quality assurance
7. Specimen collection and processing
8. Laboratory testing
9. Test result reporting
10. Documents and records management

Training for these key areas consists not only of the expectations for accreditation but also how to accomplish and perform the tasks. Learning with hands-on activities as well as job aids provides practical use for participants' home laboratories.<sup>5</sup>

#### ***World Health Organization Regional Office in Africa Stepwise Laboratory Quality Improvement Process Toward Accreditation Checklist***

The official accreditation tool to assess progress in laboratory improvement, the WHO-AFRO checklist, also functioned as a guide and an educational tool to instruct the exact expectations for quality and accreditation. The 12 sections of the WHO-AFRO checklist are based on the 12 CLSI quality system essentials (**Table 1**). By consensus of the 13 African countries, recognition for improvement in laboratory quality was to be awarded by a stepwise scheme of 1 to 5 stars, depending on the points accrued during a laboratory assessment using the WHO-AFRO checklist.

The checklist standards each have an assigned weighted value based on their complexity and/or importance. If fulfillment of a standard is incomplete but an

<b>Table 1</b>	
<b>Comparison of Clinical and Laboratory Standards Institutes 12 quality system essentials and Stepwise Laboratory Quality Improvement Process Toward Accreditation checklist sections</b>	
<b>WHO-AFRO SLIPTA checklist version 2:2015</b>	<b>CLSI 12 quality system essentials</b>
Documents and records	Documents and records
Management reviews	Personnel
Organization and personnel	Organization
Client management and customer service	Customer service
Equipment	Equipment
Evaluation and audits	Assessment
Purchasing and inventory	Purchasing and inventory
Process control	Process control
Information management	Information management
Identification of nonconformities, corrective and preventive actions	Process improvement
Occurrence management and process improvement	Occurrence management
Facilities	Facilities and safety

effort toward compliance is recognized, partial credit of 1 point is given. Laboratories are required to achieve at least 55% on the assessment to be awarded a 1-star recognition. When 95% or more is achieved, a laboratory is awarded a 5-star recognition and is deemed ready to apply for and receive ISO 15189 accreditation (Fig. 1).<sup>3,6</sup>

### STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION MODEL

SLMTA is a hands-on, activity-based curriculum developed to provide and empower laboratory personnel with the skills and tools needed to implement laboratory improvement toward best laboratory practices as defined by the 12 CLSI quality system essentials and the standards of ISO 15189. The implementation of SLMTA consists of an initial baseline evaluation using the WHO checklist performed by an experienced assessor. Following the assessment, 3 week-long training sessions are conducted by individuals specifically qualified for teaching the SLMTA methodology. Each key area of laboratory management is guided by both the tasks needed for successful implementation of best practices within that key area (derived from the laboratory management framework) and the WHO checklist items that are related to it and must be accomplished before recognition is granted. At the end of each workshop the participants have either practiced the skill or task within the classroom setting or have in their possession the information they need to implement the learned improvements when they return to their home laboratories. Supervisory visits to home laboratories ensure that the skills are implemented as intended.

Between each training workshop, participants are expected to use the skills and tools provided in the workshop by implementing improvement projects in their laboratories. These projects are assigned at the end of each workshop according to the material covered most recently in the workshop and the specific gaps found during the laboratory's baseline evaluation. Trained mentors are often assigned to focus on specific laboratories to act as an immediate resource and to coach the laboratory staff in carrying out the assigned improvements. Mentors also assist with staff behavior change during this period of intense hands-on practice. Several supportive site visits by an overseer supervisory team of laboratory experts ensures that improvement projects are understood and are on track.

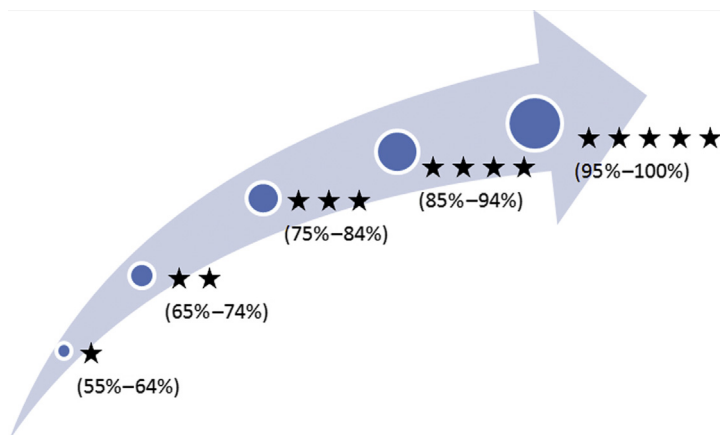


Fig. 1. SLIPTA tiers of recognition.

At the conclusion of 3 training sessions and 3 interim periods for implementation of improvements (typically 1 year), a second assessment of the laboratory using the WHO checklist is performed. From the second assessment, improvement is measured (Fig. 2).<sup>5,6</sup>

### STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION TRAINING OF TRAINERS

After an initial pilot introduction of the SLMTA curriculum taught by SLMTA-trained instructors, most countries train a team of in-country trainers. Participants chosen for this training may be stakeholders, mentors, and other laboratory experts, and often are SLMTA participants from the pilot program who have excelled in making improvements using the SLMTA methods they learned. By training in-country trainers, countries take ownership of the SLMTA program in order to perpetuate the improvements throughout their countries.

The Training of Trainers (TOT) is a 2-week session conducted by SLMTA master trainers. The curriculum follows the same SLMTA modules, albeit not necessarily in the same order. During the first week, master trainers reteach the more complex offerings with special attention given to methodology, how to prepare visual aids, and how to encourage participant input. In addition to the SLMTA material, subject matter relating to methods on how adults learn best is given.

The second week is performed, for the most part, by the participants who have been assigned several SLMTA topics they and their small group will teach back to the master trainers, as if the master trainers were SLMTA participants. After each group teaching, the master trainer gives immediate feedback to the aspiring trainers that focuses on the positive aspects of the instruction as well as where improvement could be made. Statements such as: "I liked the way you..." or "I wish you would have..." are meant to be instructive rather than critical. Clarification of any misunderstanding of subject matter is also addressed at this time. At the conclusion of the second week of training, SLMTA master trainers typically recommend trainers who are ready to teach.

### ESTABLISHMENT OF AFRICAN SOCIETY FOR LABORATORY MEDICINE AND ADOPTION OF THE WORLD HEALTH ORGANIZATION STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARD ACCREDITATION CHECKLIST

The African Society for Laboratory Medicine (ASLM) is a professional organization, partnered with the CDC, advocating for the important role and needs of laboratory medicine throughout Africa. The ASLM was established as a response to WHO Resolution AFR/RC58/R2 for strengthening public health laboratories and the Maputo Declaration on strengthening laboratory systems by working collaboratively with

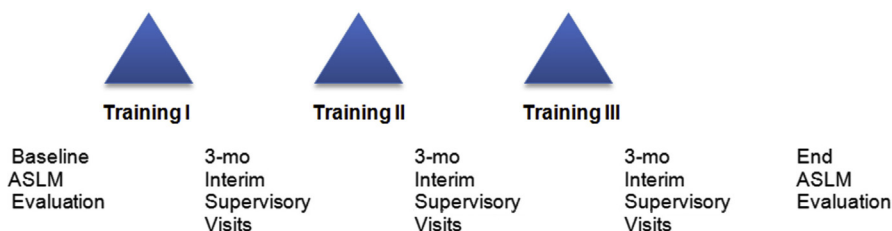


Fig. 2. SLMTA program model. ASLM, African Society for Laboratory Medicine.

governments, local and international organizations, implementing partners, and private sectors to achieve the following goals by 2020:

- Strengthening laboratory workforces by training and certifying laboratory professionals and clinicians through standardized frameworks
- Transforming laboratory testing quality by enrolling laboratories in quality improvement programs to achieve accreditation by international standards
- Developing strong, harmonized regulatory systems for diagnostic products as defined by the Global Harmonization Taskforce
- Building a network of national public health reference laboratories to improve early disease detection and collaborative research

In 2011, the ASLM began its role in certifying laboratories with the use of the WHO-AFRO checklist derived from ISO 15189 standards and the CLSI 12 quality system essentials. This checklist was implemented by ASLM and, along with the assessment process, became known as SLIPTA.

During a standardized process of application and assessment, SLIPTA measures and evaluates the progress that laboratories make toward international accreditation (ISO 15189). SLIPTA enables laboratories to develop their QMSs to improve and produce timely and accurate laboratory results in a stepwise manner. A certificate of recognition is awarded (0–5 star ratings) for the progress made at the time of the assessment. When 5-star recognition is awarded, laboratories are considered ready for international ISO 15189 accreditation.<sup>7</sup>

#### **PARTICIPATING COUNTRIES AND PROGRESS**

As of December 2016, 1103 laboratories in 47 countries have implemented the SLMTA program. In total, 63 master trainers have been trained, capable of rolling out SLMTA TOT workshops and supporting the dissemination of the curriculum.<sup>8</sup> Of participating laboratories, 38 (3.4%) have gone on to achieve ISO 15189 accreditation.<sup>9</sup>

Over the past 4 years, the ASLM has established its role as the lead auditor for the SLIPTA program. By the end of 2016, 242 laboratories in 19 countries had been audited by ASLM teams. ASLM has identified several common weaknesses across countries, regions, and laboratory tiers.<sup>10</sup> Of all laboratories audited by ASLM, 11.7% received 0 stars, 23.5% received 1 star, 33.2% received 2 stars, 23.5% received 3 stars, 7% received 4 stars, and 1% received 5 stars.<sup>11</sup> The topics of management reviews, internal audits, and corrective action are consistently identified as areas of weakness in the assessed laboratories. The ASLM has set ambitious goals for 2020: enrolling 2500 laboratories and supporting the accreditation of 250 laboratories to international standards. To accomplish this, they propose to scale-up training programs and further expand their team of qualified laboratory quality auditors.<sup>10</sup>

#### **THE CONTRIBUTION OF THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY AND ITS MEMBERS TO THE STRENGTHENING LABORATORY MANAGEMENT TOWARD ACCREDITATION MOVEMENT**

The American Society for Clinical Pathology (ASCP) has supported the SLMTA program since its inception in 2009. To date, ASCP has directly supported the training of 829 SLMTA participants in 22 training cohorts. In order to institutionalize SLMTA and build local capacity, the ASCP also provide SLMTA TOT workshops for 344 participants, and targeted mentorship training for 214. Building on these efforts, the ASCP initiated a program to institutionalize the SLMTA curriculum at the preservice level by providing SLMTA training to medical educators in 2 countries: Vietnam and

Lesotho. To address gaps in the original SLMTA training program, the ASCP has offered numerous specialized workshops in quality control, document management, biosafety, external quality assurance, and internal audits. Likewise, 42 participants from Mozambique and Ethiopia have completed the follow-up SLMTA 2 curriculum (described later). In total, SLMTA programs in 13 countries have received direct support through ASCP's PEPFAR program.

## LESSONS LEARNED

Laboratories participating in SLMTA progressed more quickly when the laboratory manager and quality officer who were chosen to attend the SLMTA trainings returned to their laboratories and included the entire laboratory staff in the improvements and changes needed. When only the attendees to the training tried to implement the newly learned skills, there was often resistance to the changes by staff members who were accustomed to established routines. When mentors were assigned to sites and worked directly with staff in the implementation of modifications, they had the time to explain and convince staff members why the changes were necessary. At subsequent training sessions, laboratories shared their successes and how they overcame obstacles encountered during implementation.

Mentors as well as supervisory visits were key to success. On the occasions when a laboratory was remotely located and mentors were not accessible or available in the area and/or supervisory visits were difficult, a noticeable lag in improvement was noted. Time would be lost as laboratories that worked alone and isolated lost their training inspiration and even forgot or misunderstood what they had learned. It was important to keep up the momentum for improvement to have resources available for both clarification and encouragement.

The most successful laboratories during the initial phase of improvement were those facilities whose chief officers/administrator stakeholders were committed to the project. When this happened and the laboratory staff were encouraged and commended on progress by the chief operating officer, success continued to occur.

SLMTA teaches the development of many logs and checklists to document maintenance and all aspects of quality management with the warning that tasks not documented are not considered completed. After setting up procedures to accomplish these tasks, laboratories often failed to continue the record keeping. This failure was especially noted when a laboratory's WHO assessment was due and they had to wait a long time or if it was postponed. This long wait did not necessarily occur after the training sessions were complete, but sometimes occurred while awaiting an official assessment by the ASLM, which was initially backlogged with assessment requests.

It is noteworthy that SLMTA training, when completed successfully, provides laboratories the ability to implement changes necessary to obtain a 3-star recognition. The framework of tasks and the WHO SLIPTA checklist further guide the requirements necessary for 5-star recognition and for the requirements that need to be performed by countrywide policy changes, such health/safety and supply and capital equipment procurement. In addition, there are subject matters introduced in SLMTA training but not presented in depth:

- Quality control
- Writing SOPs (standard operating procedures)
- Management of documents and records

A supplemental SLMTA workshop focused on quality control was piloted in 2013 to partially address this gap. However, to address additional weaknesses identified in



SLMTA participants' SLIPTA postassessments, the SLMTA 2 program was launched in 2016. SLMTA 2 does not modify or replace the existing SLMTA curriculum but builds on it to provide the extra push laboratories need to achieve 5 stars. SLMTA 2 covers quality control, method validation, measurement analysis and improvement, internal audit, occurrence management, root cause analysis, and corrective action.

The SLMTA program, in combination with the SLIPTA checklist and process, has proved to be an effective tool to empower laboratorians and improve laboratory quality in developing settings. The SLIPTA checklist can provide useful program feedback to national and international partners, enabling them to create tailored education programs to address specific gaps. SLMTA, by providing practical tools and methods, has enabled thousands of laboratorians to implement quality system improvements in their laboratories, thus resulting in improved patient care. As shown by postassessment SLIPTA score, however, additional interventions after SLMTA are required for laboratories to reach the level of international accreditation. International partners should focus their efforts to address the specific needs of national laboratory quality programs and continue to support the adoption of quality standards and the establishment of national accreditation programs. Although the HIV/AIDS epidemic was the primary motivation for SLMTA and SLIPTA, the tools have been implemented in a wide variety of laboratories and disease programs. They can serve as a useful model for improving laboratory quality across pathology disciplines, and their content and training methodology can contribute to preservice laboratory training programs as well.

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