

The Mentorship Program to Strengthen and Improve the Quality Management System of Medical Laboratories in Togo

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Abstract

Background: Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) is an assessment checklist proposed by WHO for baseline assessment, supervision, monitoring, and evaluation of medical laboratory progress towards accreditation. **Objectives:** Strengthen the quality management system (QMS) of the medical laboratories in health facilities across Togo. **Methods:** A pool of auditors and mentors was trained on the

WHO SLIPTA and Laboratory Quality Stepwise Implementation tools. After baseline assessment in 86 labs, 35 of them with zero stars were selected and supported by the mentorship program. The impact of the program was evaluated after 6 months (follow-up I), and the sustainability was measured after 12 months (follow-up II) and 18 months (follow-up III). **Results:** Baseline scores ranged from 11-83% with an average of 32%. Over 90% of the labs had zero stars, and 1.2%, 2.3%, and 5.1% got one star, two stars, and three stars, respectively. A significant impact of the program was observed at the follow-up I assessment by an increased average SLIPTA score from 27.8% to 53.4%. Among 35 labs mentored, 45.7% got one star and 8.6% got two stars. The sustainability of the program was shown by an increase in the score from 53.4% to 58.2% between follow-up I and follow-up II and a slight decrease from 58.2% to 56.1% between follow-up II and follow-up III. **Conclusion:** This mentorship program remains an excellent approach used to help Togo medical labs to improve their QMS.

Keywords: Togo, SLIPTA, Quality management, mentorship, medical laboratories

Introduction

Laboratories form the backbone of health systems, providing health care workers with critical test results for numerous deadly diseases, yet in Sub-Saharan Africa (SSA), which carries a huge disease burden, laboratories are among the less-equipped and poorly resourced facilities everywhere (Mataranyika & Beukes, 2014; Mboera et al., 2015).

ISO 15189:2012 is a global initiative that aims at creating a standard measure of quality in medical laboratories. The standard has promoted competence and responsibility in medical laboratory processes, equipment and outcomes. ISO 15189:2012 was developed by the International Standards Organizations Technical Committee and has been implemented in over 200 countries (Aoyagi, 2004; Kawai, 2010; Kubono, 2007). There were 380 laboratories accredited to international standards in SSA. Ninety-one percent were in South Africa. Thirty-seven of 49 countries had no laboratories accredited to international quality standards (Schroeder & Amukele, 2014). Hence, few low-income countries and in particular Togo, have established laboratory quality standards that are affordable and easy to implement and monitor. To address this challenge, the World Health Organization Regional Office for Africa (WHO AFRO) established a stepwise approach, using a 0- to 5-stars scale, to the recognition of evolving fulfillment of the ISO 15189:2012 standard rather than pass-fail grading. Laboratories that fail to achieve an assessment score of at least 55% will not be awarded a star ranking. Laboratories that achieve 95% or more will

receive a 5-stars rating. This stepwise approach acknowledges to laboratories where they stand, supports them with a series of evaluations to use to demonstrate improvement, and recognizes and rewards their progress (Gershby-Damet et al., 2010). Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) is an assessment checklist that can be used for baseline, supervision, and monitoring and evaluation of laboratory progress towards accreditation. It is a framework for improving quality of public health laboratories in low-incomes countries to achieve ISO 15189:2012 standards (Hiwotu et al., 2014; Nguyen et al., 2014).

The approach to QMS implementation in medical laboratories varies in each country / facility. Mentorship programs, in which a cadre of laboratory scientists are trained to facilitate both assessment and quality improvement, has been shown to work well. Remote mentorship in Cambodian clinical labs significantly improved their audits scores (Donovan et al., 2020). (Burgess, van Diggele, & Mellis, 2018). Baseline assessments enable identification of the most critical quality gaps allowing a targeted approach to quality improvement that is measurable (Mothabeng et al., 2012). This approach is less used in African countries and the lack of approach makes it difficult to improve the QMS in our laboratories due to lack of financial resources et qualifications.

Togo, after adopting ISO 15189:2012 as the quality standard for clinical labs, used a mentorship approach to implement and monitor the quality management systems in selected laboratories across the country. This paper presents the results of this first experience achieved.

Methods

Labs and selection criteria

The laboratory system in Togo is integral to the public health system architecture and has 3 main levels: central level (university hospitals and reference labs), intermediate level (regional labs) and district labs. The present study was conducted in public and confessional laboratories from central, intermediate and district level.

Method of assessment

Baseline assessment was performed from February to August 2016 using the WHO Stepwise Laboratory Improvement Process Toward Accreditation (SLIPTA) version 2.0 e-tool checklist developed by Global Scientific Solution for Health. The checklist and e-tool includes the 12 WHO SLIPTA sections which are organized according to the ISO 15189:2012 standard: (i) section 1: documents and records, (ii) section 2: management review, (iii) section 3: organization and personnel, (iv) section 4: customer and service, (v) section 5: equipment, (vi) section 6: internal audit, (vii)

section 7: purchasing and inventory, (viii) section 8: process control, internal quality control and external quality assessment, (ix) section 9: information management, (x) section 10: corrective action, (xi) section 11: occurrence management and process improvement, and (xii) section 12: facilities and safety. Each section has different questions and for each question there were 4 options: Yes, No, Partial and Non-applicable. The e-tool automatically calculates the score, in accordance with WHO SLIPTA criteria when a user responds to each question out of a total of 275 points. The lab is awarded zero stars if the score is 0-54%, 1 star for a 55-64 % score, 2 stars for a 65-74% score, 3 stars for a 75-84%, 4 stars for a 85-94% and 5 stars for a score of more than 95%.

The project was implemented in a series of stages, first, 31 biologists and lab technicians were trained as national assessors to the ISO 15189:2012 standard and on using the SLIPTA e-tool. The scope of the assessment and its plan were prepared and approved and 16 assessors conducted pilot assessments in 21 labs. Thereafter, this was expanded to 65 additional labs for a total of 86 sites.

Several days prior to the site visit, an informal letter describing the duration and scope of the assessment was sent to the labs. Each laboratory assessment lasted for one day and was conducted by a team of two assessors. Assessments began with opening meeting where the assessors explained the agenda of the visit including the evaluation plan, the scope and the aim of the assessment, the checklist and the standard to be used. Assessments concluded with a closing meeting where assessors shared the outcomes of the site evaluation, the recommendations for the lab personnel and lab administrative team. Following the assessment, a specific action plan was prepared for each lab.

Mentorship program

To support medical labs in setting up their QMS, a mentoring program was initiated in 35 labs. These labs were from the intermediate levels, public and confessional labs with no star after the baseline assessment.

Mentors were identified from the baseline assessors and selected based on those personnel who demonstrated regularity in conducting evaluations, compliance with the procedure when writing and prompt reporting, to support the laboratories. To complete the mentorship team, some quality managers (QM) of certain laboratories with proven and solid knowledge in quality management and / or who demonstrated a solid commitment to the implementation of the quality approach in their laboratories were also selected and added to these confirmed mentors. The capacity of all mentors is strengthened through a training on Laboratory

Quality Stepwise Implementation (LQSI) tool. One mentor was assigned to each of the 35 labs.

These mentors provided periodic on-site support and remote support via telephone, email, WhatsApp etc. to help the mentee laboratories to resolve the gaps identified during the baseline assessment and to improve their practices.

At each site, a total of 6 mentoring missions lasting 5 days each, were organized over a period of 6 months to bring the mentee laboratory to the level of at least "one star" for the follow-up audit.

Evaluation of the impact of the mentorship program

In order to evaluate the implementation of QMS and the impact of the mentorship, 35 mentee labs were reassessed using the SLIPTA e-tool. This follow up assessment (follow up I) was performed 6 months after implementation of the program.

Because of the lack of financial resources, the sustainability of the impact of the program was also evaluated during two follow up (6 and 12 months after the program) in 24 labs and three follow up (6, 12 18 months after the program) in 7 labs. Assessors of the mentee labs were different from the mentors.

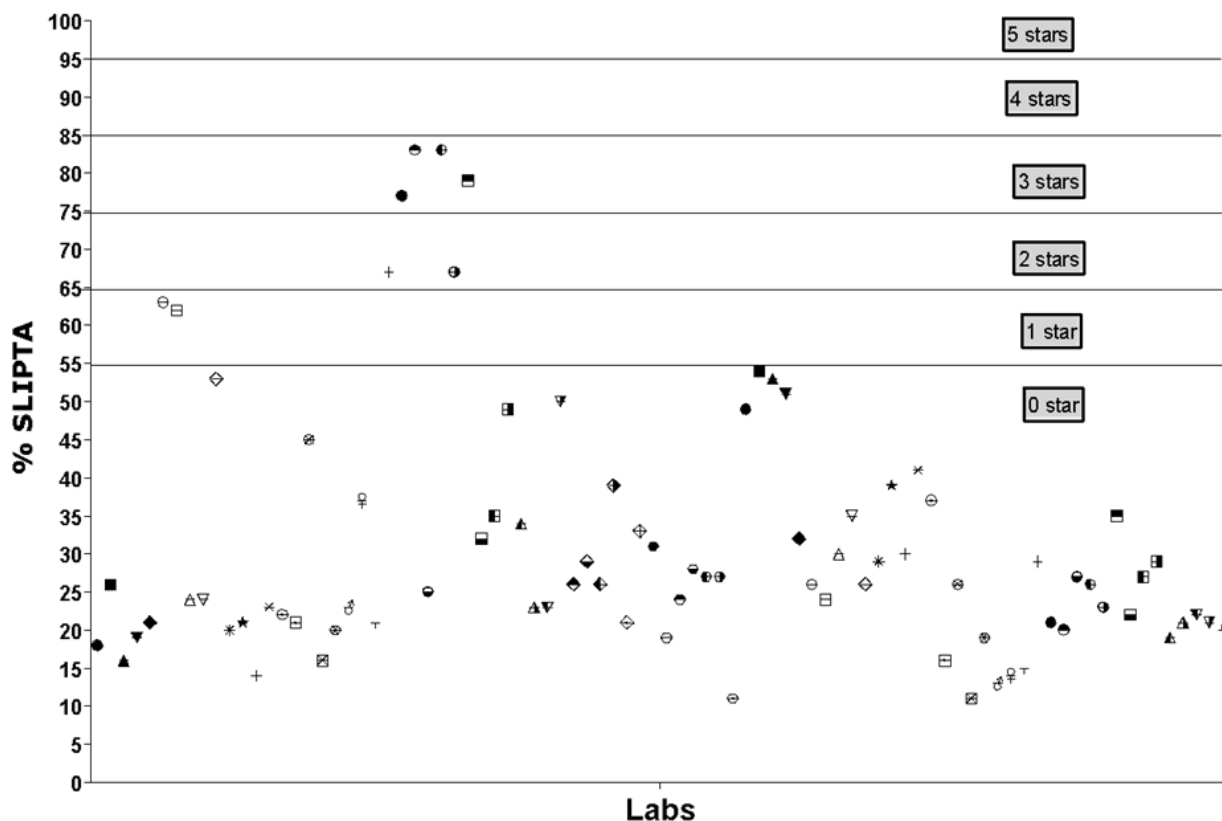
Data analysis

The SLIPTA e-tool was an Excel spreadsheet that was used to collect information and data were analyzed using GraphPad Prism 5.3. Data were entered for column statistics analysis and D'Agostino & Pearson omnibus normality test was performed to test their normality. Data were described as mean $\pm$ SD. The Kruskal-wallis test with Dunn's post-test was used to compare all the groups.

Results

Score during the baseline assessment

The average score across all (n=86) baseline SLIPTA assessments, was 32% (SD=17%, ranged 11-83%) (Figure 1). Out of 86 labs assessed, two (2.3%) got one star with a score of 62% and 63% respectively, two labs (2.3%) got two stars (67% score each) and 4 labs (4.6%) got three stars with a score of 77%, 79% and 83% respectively. None of the labs assessed got five stars and over 90% (78 out of 86) of the labs got zero star (Figure 1). Thirty-five labs that received zero stars were then enrolled in the mentorship program.

Figure 1: Baseline SLIPTA assessment scores

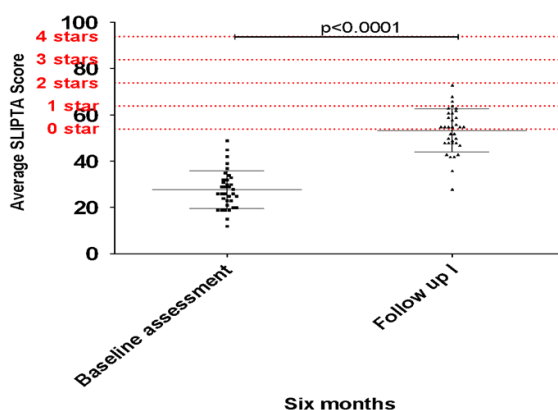
Bars show the SLIPTA percentage obtained by each lab after initial assessment (n=86).

Efficiency of the mentorship program

The efficacy of the conduction of the mentorship was satisfactory. None of the labs nor the mentors dropped out of the program.

Impact of mentorship program on SLIPTA score

Out of all 35 labs 16 (45.7%) reached one star and 3 (8.6%) reached two stars after follow up I, 16 (45.7%) labs remained at zero stars but achieved improvements in their overall score (figure 2).

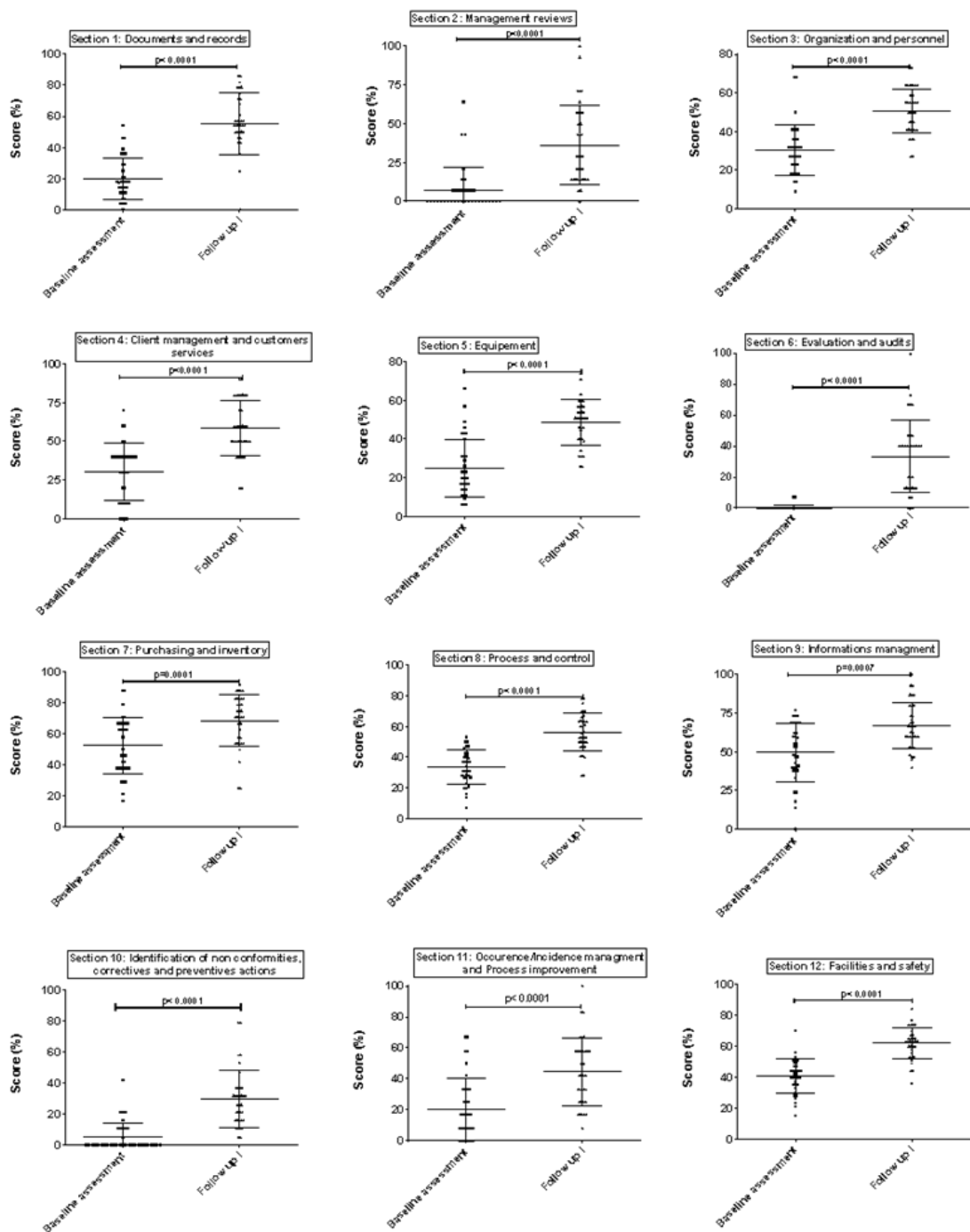
Figure 2: Impact of mentorship program on SLIPTA score

Scatter dot plots represent the average SLIPTA score (mean $\pm$ SD) of each lab six months after (follow up I) the implementation of the mentorship program

Impact of Mentorship on each SLIPTA section

Compared to the baseline score, all the 12 sections of SLIPTA were significantly improved during the program (figure 3).

Before program implementation, the average SLIPTA score of management review across all sites was 7.1%. This section improved post-mentorship from 7.1% to 36.2%. Information management scores increased from 30.3% to 58.3%. Client management and customer services baseline scores increased from 49.5% to 66.9%. The documents and records subsection improved from 19.6% to 55.3%. The same trend was observed for the subsection 3: organization and personnel (from 30.4% to 50.5%). The mentorship program impacted significantly the SLIPTA sections 5 and 7. This was indicated by the improvement of the average score from 24.9% to 48.6% for the section 5 (equipment). The section 7 (purchasing and inventory) improved from 52.4% to 68.6%. Only 0.4% of the labs were performing evaluation and audit (section 6). After the implementation of the program, a great evolution to 33.1% was observed. About 33.5% of the mentored labs implemented the requirements of the section 8 (process and control). After the program, the follow up assessment showed an improvement of this section to 56.1%. Few mentored labs (4.9%) could identify non conformities and perform corrective and preventive actions (section 10). After implementation of the program, these requirements were globally performed by 29.8%. The section 11 (occurrence/Incidence management and process improvement) was implemented by 20.4% of the labs globally. This was improved after the follow up (44.5%). The impact of the mentorship program on the implementation of facility and safety requirement was significant. The global score improved from 40.5% to 62.0%.

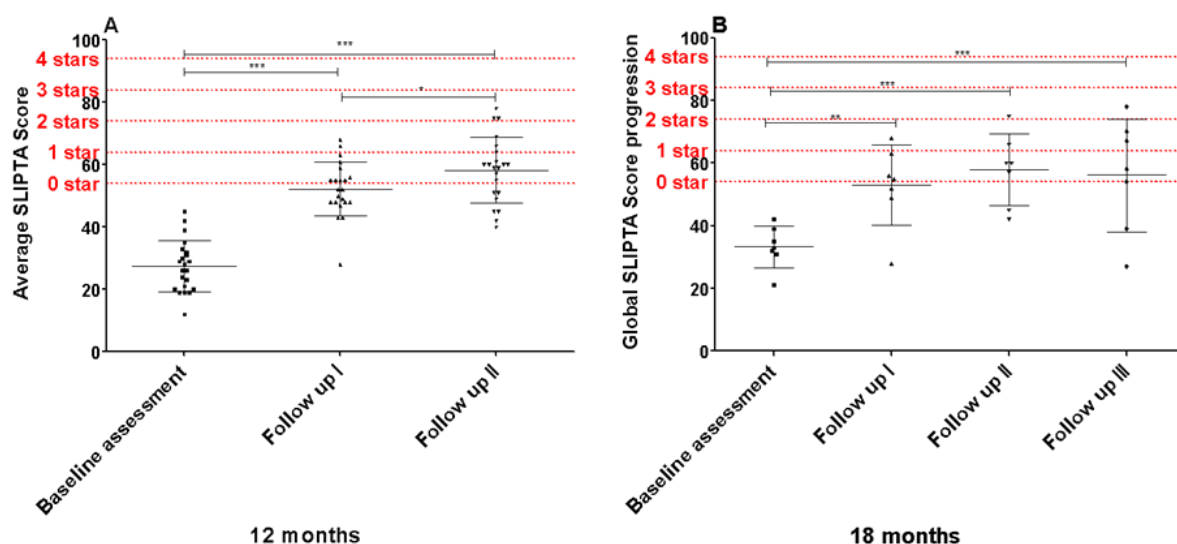
Figure 3: Impact of mentorship program on SLIPTA sections

Scatter dot plots represent the average score (median±IQR) for each section of the SLIPTA across all mentored labs

Sustainability of the mentorship program

Of the 22 labs assessed during follow up II, 9 (25.7%) reached one star, 2 (5.7%) two stars and 3 (8.6%) reached three stars 12 months after the mentorship. Eight (22.9%) remained without stars. Of the 7 labs assessed during follow up III, 2 labs remained at zero stars, 2 (5.7%) reached one star, 2 (5.7%) reached two stars and 1 (2.9%) reached three stars (figure 4).

Figure 4: Follow up I and II assessments. The sustainability of the impact of the mentorship was evaluated after 12 months (follow up I and II, A) and 18 months (follow up I, II and III, B)



Scatter dot plots represent the average SLIPTA score (median±IQR) across all mentored labs

Discussion

Clinical laboratories play a critical role in the health system (Kalra, 2004; Kubono, 2004; Yagi, 2010). For this reason, it is important for them to implement a quality management system which will help to improve the quality of their results (Kalra, 2004; Masamha et al., 2014). ISO 15189:2012 is an international standard designed for clinical laboratory management (Kubono, 2004; Perrone et al., 2016; Safadel et al., 2014). Stepwise Laboratory Quality Implementation Process Towards Accreditation (SLIPTA) tool was developed by WHO to monitor the labs during the process (Mbah et al., 2014; Mesfin, Taye, Belay, & Ashenafi, 2015; Nguyen et al., 2014). This approach was adopted by Togolese Ministry of health in order to improve its lab system. Baseline assessment conducted in 2016 in the central and intermediate levels of Togo's public health system structuration, using the SLIPTA e-tool developed by Global Scientific

Solution for Health (GSSHealth), showed that the medical lab area in Togo presents many shortcomings and needs to be strengthened. The second step concerned the mentorship program that aimed to accompany the labs to implement the quality management system.

This study has some limits linked to the lack of financial resources. Only 7 labs benefited from three follow up assessments. This explained the variation of labs numbers between baseline assessment, follow up I, II and III.

This baseline assessment underscored that the assessed labs lack infrastructures, supplies and equipment. It also showed a lack of high-qualified staff. The same finding was obtained in other Sub-Saharan African and resource limited countries and thus represents a significant barrier for the implementation of QMS in the region (Petti, Polage, Quinn, Ronald, & Sande, 2006; Soares, 2012). *Ndihokubwayo et al.* in 2016, assessed 159 Laboratories from 17 African countries using WHO AFRO SLIPTA checklist and found an average of 69% (*Ndihokubwayo et al.*, 2016) whilst *Yao et al.* in 2014, got an average score of 39% after assessing 617 laboratories in 47 countries in Africa, Caribbean, Latin America and Southeast Asia (*Yao, Luman, & Authors*, 2014). *Guevara et al.* in 2014, found baseline audit scores ranged from 19-52% in Caribbean region (*Guevara et al.*, 2014). In total out of 86 labs assessed during our baseline evaluation, 78 did not meet the requirement of the ISO 15189:2012 standard policies and got all zero star. This is in line with the findings on other African countries for example, district and central laboratories from Lesotho got also zero star after baseline assessment (*Talkmore Maruta et al.*, 2012).

The data obtained in this study showed that information management, purchasing and inventory were more satisfied by the assessed labs. The SLIPTA requirement regarding management review (section 2), internal audit (section 6) and corrective action (section 10) were less performed by our labs. Same finding was noted by WHO which assessed 159 laboratories between 2013-2015 and found that sections 6 and 10 were the lowest scoring sections (*Ndihokubwayo et al.*, 2016). Absence or lack of assessors could explain that. For instance, in Togo first assessors were trained by Global scientific for health in 2015.

This initial evaluation highlighted the weakness of the assessed labs. This situation is common in the majority of the labs in Togo. Therefore, it is important to find a strategy to improve this situation. We then initiated the mentorship program and initially enrolled 35 labs. The impact of mentorship in health professions is widely recognized (*Burgess et al.*, 2018) for example, a mentorship program was implemented at four labs in Lesotho, after 10 weeks the labs improved from zero to five SLIPTA stars (*T. Maruta et al.*, 2012). Here the labs were evaluated after 6 months mentorship

implementation, even 18 months after the program, an improvement in SLIPTA scores was observed.

The impact of the program in the mentored labs could also be seen on each SLIPTA section. For instance, the requirements for the section: evaluation and audit were very low (0.4%) but this was improved up to 33.1% after the first follow up. Evaluation and audit help to identify non conformities in order to improve the overall quality system. We could observe the improvement of the identification of non-conformities, preventive and corrective actions. Facility and safety are a big challenge. Here, our program, significantly improved facilities and safety. This improved biosafety and biosecurity issues in our labs. The lack of procedure and documents characterized our quality management system in our labs (Katawa et al., 2011). The impact of the program on SLIPTA section 1, documents and record, was very significant, from 19.6% to 56% after the follow up III. The process control is important to ensure the quality of the results in the labs. The baseline assessment showed weakness for these requirements. This was also improved from 33.5% to 64.2% after 12 months (follow up II). This became a culture and encouraged lab managers in Togo for the improvement of the process. For instance, the division of labs of Togo undertook the external quality assessment of thick and thin blood smears for the diagnosis of malaria (Dorkenoo et al., 2021). At CHU Campus of Lomé, the validation of the emergency anemia screening was performed after the mentorship program (Kafui Codjo. Kouassi Codjo, Micheline, Gnatoulma, Agboka, & Damintoti, 2020).

The implementation of mentorship program in MOH at Mozambique, increased the audit score from 37% at baseline to 57% after the follow up (Masamha et al., 2014). Globally, we could observe a significant improvement of the SLIPTA score after the follow up I assessment. There was an overall average decrease from follow up II to III and this could be explained by the state official allocation which make instable labs technicians in a given labs for long time. Some of the labs remained at zero stars even after the program. This was mostly due to the less implication of their top managers during the program. There is a need to increase sensitization strategies in order to get their adhesion. Also, most of the labs were public sector and the personnel trained moved a lot during the staff assignment.

This shows the impact of the program on the improvement of the quality management system in our laboratories.

Conclusion

The implementation of the mentorship program in 35 selected labs in Togo lead to a great improvement of the application of the requirements of

all SLIPTA-WHO-AFRO sections. The follow up assessments showed the sustainability of the impact of the program 18 months after. The implementation of the program in labs will help to increase the quality of our lab services and therefore to a better healthcare system.

Author contributions

AMD, GK and AKK designed and organized the mentorship program. SE, EM and GK analyzed the data. KK, PF and MA designed the training program of assessors and mentors. KK and MA trained the auditors and mentors.

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Conflict of Interest: The authors reported no conflict of interest.

Data Availability: All data are included in the content of the paper.

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