International Journal of Medical Laboratory 2022; 9(2):110-121.

International Journal of Medical Laboratory
Shahid Sadoughi University of Medical Sciences

Original Article

Evaluation of the Quality Management System due to the Implementation of the SLIPTA Program at the Bamenda Regional Hospital Laboratory, Cameroon

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Article history
Received: 18 Sep 2021
Accepted: 29 May 2022
Available online: 30 Jun 2022

Keywords
Bamenda
Improvement
Laboratory
Quality Management System
SLIPTA
SLMTA

A B S T R A C T

Background and Aims: Improving the Quality Management System (QMS) of clinical laboratories and achieving accreditation are important in health care delivery. It can be achieved by implementing the World Health Organizaton Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA). The SLIPTA program was introduced to the Bamenda Regional Hospital (BRHL) in 2010. Our objectives were to identify improvements and evaluate the QMS at the BRHL. Training, mentorship, and improvement of laboratory infrastructure were considered for the program to succeed.

Materials and Methods: Secondary data from the WHO SLIPTA assessment reports of the BRHL between November 2009 and March 2018 were extracted. The assessments were conducted by the WHO African Society for Laboratory Medicine (ASLM) SLIPTA certified and competent auditors, using the SLIPTA checklist. The final percentage score(s)/star(s) of the assessments was/were identified as improvements, and the evaluation was done by taking the difference between an absolute score of the Quality System Essentials (QSE) of the baseline recent follow-up assessment.

Results: A total of nine SLIPTA assessments were carried out. The results indicated great improvements in the QMS from a baseline score of 18% (0-star) to 82% (3-stars) at the recent follow-up assessment. There were also significant changes in the QSE, with the final absolute scores ≥ 58% in all aspects and the greatest change registered in the management review (94%).

Conclusions: We identified incredible improvements and magnificent changes in the QMS at the BRHL that were due to training, mentorship, and improvements in infrastructure resulting from the implementation of the SLIPTA program.

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[DOI: 10.18502/ijml.v9i2.10019]

Introduction

Accurate, reliable, and timely results in clinical laboratories are vital in diagnosing and managing clients. For such results to be produced, it is important for these laboratories to improve on their quality management system (QMS) and to attain international recognition (accreditation) for competence and compliance with the International Organization for Standardization (ISO) 15189 standards for clinical laboratories [1]. It can be achieved by implementing Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) program. It involves, but is not limited to, continuous training, mentorship and infrastructure improvement [2, 3].

In order for African countries to improve on their QMS and attain accreditation, the World Health Organization's Regional Office for Africa (WHO - AFRO) 2008 launched the SLIPTA program to provide a framework for benchmarking progress using an audit checklist based on the ISO 15189:2007 requirements [4]. Much training was done to empower laboratory personnel and enhance management's ability to improve their laboratories by using existing resources, communicating with clinicians and hospital administrators, and advocating for quality system strengthening. Among these training were the Strengthening Management Towards Accreditation (SLMTA), Laboratory Mentorship, Laboratory Audit, safety, Quality Assurance, Continuous Improvement, and ISO 15189:2012 standards.

The SLMTA programme was launched in 2008 along with the launching of SLIPTA. The global implementation of the programme in 47 countries since 2009 has been an important benchmark in improving the quality of clinical laboratories. The SLMTA programme is a task-based framework, interactive curriculum, and checklist. It comprises a series of training modules in laboratory management that utilize workshops interspersed with site-specific, on-site quality improvement projects. SLMTA was introduced in Cameroon by the centre for disease control and prevention (CDC) Cameroon and implemented by Global Health Systems Solutions (GHSS) Limbe, Cameroon and the Ministry of Public Health Cameroon in 2010. Five pilot laboratories were selected for the implementation of SLMTA, among them, there were Bamenda Regional Hospital Laboratory, Douala Laquintinie Hospital Laboratory, Buea Regional Hospital Laboratory (BuRHL), Laboratoire d'Analyses Médicales du Centre Yaoundé and Yaounde Central Hospital Laboratory [5]. There is ample evidence reported of magnificent improvements in the quality of some clinical laboratories due to the implementation of SLMTA in Cameroon [4, 6-8]. Two of these five pilot laboratories have been accredited, including the BuRHL and BRHL [7].

The implementation of the SLIPTA program started in 2010 after the baseline assessment in 2009. The laboratory benefited from a series of training, including SLMTA, mentorship and infrastructural development that was intermittently spaced out with assessment to assess the progress. The laboratory evolved from a hazardous facility to a

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[DOI: 10.18502/ijml.v9i2.10019]

safe and convenient facility that produces quality and reliable laboratory results, which was done alongside the improvement of the infrastructure. The modest infrastructure that was not pre-constructed for a clinical laboratory practice was partially redesigned, renovated and more rooms were constructed to ensure efficient workflow and safety. Several studies have reported improvement in laboratory service due to improvement in infrastructure [3, 9].

After the BRHL exited the SLIPTA program in September 2012, it was assessed by the African Society for Laboratory Medicine (ASLM) in August 2013. Following its outstanding performance, ASLM made recommendations for the laboratory to apply for international accreditation. Some departments of the BRHL, including haematology, biochemistry, and serology, are now internationally accredited for their competence in compliance with the ISO 15189:2012 standard for clinical laboratories [10]. However, there is still limited literature on the BRHL [7]. This study aims to identify improvements and evaluate the QMS at the BRHL due to the implementation of SLIPTA.

Materials and Methods

Approval to use data from the BRHL SLIPTA assessment reports was obtained from the Regional Hospital Bamenda Institutional Review Board (approval No: 94/APP/RDPH/RHB/IRB). Consent to conduct the assessments was obtained verbally (the laboratory management accepted participating in the assessment).

The study site was the BRHL, a department of the Bamenda Regional Hospital (BRH). The BRH is a level II referral Hospital situated at Mezam Health District in Azire Health Area, North-West region, Cameroon. The BRHL was chosen because of the following reasons. Firstly, it was one of the pilot sites for the implementation of the SLIPTA program in Cameroon; secondly, it is a public laboratory that has demonstrated best practice and has achieved international recognition for competence in compliance with the ISO 15189:2012 standards for clinical laboratories by the South African National Accreditation System (SANAS) [11].

This is a retrospective study. Secondary data were extracted from the WHO SLIPTA assessment reports of the BRHL between November 2009 and March 2018. After the Baseline assessment of the BRHL in November 2009, the BRHL was selected as one of the five pilot laboratories to implement the SLIPTA program in Cameroon. The SLIPTA program was sponsored by the CDC Atlanta, through CDC Cameroon and implemented through Global Health Systems Solutions Limbe, Cameroon. At first, an advocacy meeting was held with the laboratory managers and hospital directors of all the pilot laboratories. The purpose of the meeting was to ensure their buy-in and commitment to improving laboratory service [5]. The BRHL bought the idea and bought in the hospital management to support the program. During the programme's implementation, there were a series of training, mentorships, improvements in infrastructure and evaluation.

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Different forms of training were carried out to translate knowledge to the laboratory staff, management, and hospital management. The training was either done on-site (internal and cross-trainings) or external at a site convenient to the trainers as workshops. Most of the training was carried out by trained and competent trainers from GHSS Limbe, CDC Cameroon or ASLM, following the needs to satisfy the ISO 15189 standards and recommendations from assessments. The training (external, on-site and in-house cross-training) on the 12 SLMTA modules produced 36 staff trained as SLMTA laboratory managers by March 2012, with one as trainers in 2014. During the on-site and in-house training on SLMTA, the hospital director was also trained on some modules. The other training produced four staff as mentors, four staff as certified SLIPTA auditors with one as an ASLM certified auditor, 38 staff on biosafety and biosecurity with four as managers, 34 on quality assurance and continuous improvement, 2 on the ISO 15189 standards and 36 staff on the information system with 2 as managers. Several studies have reported dramatic improvement in the quality of laboratory services due to training, particularly SLMTA training. Details of the specific type of training, date of training, number of staff trained and location are found in Table 1.

The mentorship was done using the side-by-side approach by trained and competent laboratory mentors working with guidelines [12]. The mentorship was done using the ISO 15189 standards, SLMTA tool kit and the SLIPTA checklist. The mentors assisted the laboratory management and staff in closing identified gaps, writing standard operating procedures, preparing and implementing work plans, and others. One permanent on-site mentor was deployed to the laboratory by GHSS, with two additional on-site mentors on an alternating visits. The mentorship capacity was boosted by the training of two staff of BRHL, including the laboratory director, in March 2012 and two more in August 2014 as mentors making a total of seven mentors.

During the implementation of SLIPTA, the modest laboratory infrastructure that was not initially constructed for a clinical laboratory was modified to provide efficient workflow and safety. There was the construction of an additional building and other facilities, renovation of the existing modest building, and replacing some of the outdated instruments with modern and state-of-the-art instruments. These include the tiling of the floors, separating the testing rooms from dressing and eating rooms, upgrading the haematology and biochemistry manual analytical methods to fully automated methods (auto-analyzers), and relocating these departments. The Laboratory storeroom was relocated. The client reception area was relocated to a newly constructed site with a separate room for patient reception, registration, specimen collection, and issuing of results. Besides, four toilets for staff and clients, a good waiting space for patients, and a new storage room for storage of obsolete equipment were constructed. The blood bank was also separated from the laboratory. There was also the introduction of a

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[DOI: 10.18502/ijml.v9i2.10019]

basic laboratory information system and the purchase of computers and printers. The number of computers increased from one in 2011 to about 15 in 2017.

The evaluation was done by conducting assessments intimately during the training following schedules from SLIPTA, ASLM or BRHL. The assessments were conducted by the WHO, the African Society for ASLM, SLIPTA checklist [13]. This checklist comprises the 12 quality system essentials, and the results are based on a series of questions, with a maximum total of 258 points. The assessment score determined the stars rating as follows: < 55% = zero star, 55%–64% = one star, 65% –74% = two stars, 75%–84% = three stars, 85%–94% = four stars and 95% –100% = five stars. Assessments were conducted by certified and competent SLIPTA auditors. Recommendations from the assessment were used to improve the system.

Included in the study were data from assessment reports done by certified and competent SLIPTA auditors using the SLIPTA checklist between November 2009 and March 2018. The study excluded data from assessment reports that were not done using the SLIPTA checklist and those that certified and competent SLIPTA auditors did not do.

Secondary data were collected from SLIPTA assessment reports by two trained data collectors using a standard data collection format. Data were entered into Microsoft Excel 2010 spreadsheet (Microsoft Corporation, Redmond, Washington, United States). We also collected information on the implementation of the SLIPTA program from improvement plans, minutes of meetings, reports, key informants, and others.

Statistical analysis

The assessment's final percentage scores were used to identify the improvement, and the results were reported on a bar chart. The difference between the absolute scores of each of the Quality System Essentials (QSE) of the recent follow-up and baseline assessments were used to evaluate the QMS and the results reported on a Radar Chart.

Results

A total of nine SLIPTA assessments were carried out between November 2009 and March 2018. Our results revealed that there was a general improvement in the performance of the laboratory as indicated by the total percentage score(s)/star(s) assessment with the following score(s)/star(s) registered: Baseline in November 2009) 18% (0 – star), to the 4th Intermediate in February 2012 (85% (4-stars)), and finally to the 2nd Follow-up (recent follow-up) in March 2018 (82% (3-stars)) (Fig. 1). Workstations (working areas) were well organized, free from clutter, and safe, with an efficient workflow. One could see colleagues correcting each other in case there was an issue. Complaints, especially about "missing samples", were a thing of the past. There was even distribution of work, reduction in stock-out for reagents/materials, reduction in equipment downtime, and increased patient satisfaction.

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Table 1. Training/Workshops between November 2009 and March 2018 at the BRHL

Type of training/ Workshop		Date	Number of BRHL staff trained	Site of training
Baseline assessment, November 2009 (Pre-SLIPTA)				
Safety	Bio-safety and Bio-security	June 2010	2	BRHL, Cameroon
	Bio-safety and Bio-security (Cross-training)	February 2012	34	BRHL, Cameroon
SLMTA	SLMTA 1	October 2010	17	Mutengene, Cameroon
	SLMTA 2	February 2011		On-site BRHL
	SLMTA 3	June 2011		On-Site, BRHL
	SLMTA 1(Cross-training)	March 2012	19	Bamenda, Cameroon
	SLMTA 2 (Cross-training)			
	SLMTA 3 (Cross-training)			
Information System	BLIS	March 2012	36	BRHL, Cameroon
Audit	Internal Auditor	February 2012	2	Limbe, Cameroon
	Internal Auditor (Cross-training)	April 2012	34	BRHL
Mentorship	Laboratory Mentorship	March 2012	2	Limbe, Cameroon
SLIPTA exist (5th intermitted Assessment)				
Quality Assurance	Quality control and method validation	November 2013	1	Johannesburg, South Africa
Safety	Bio-safety and Bio-security	March 2014	2	Limbe, Cameroon
	Bio-safety and Bio-security	December 2015	1	Yaounde, Cameroon
Audit	Internal Auditor	August 2014	2	Limbe, Cameroon
	Internal audit	December 2015	2	
	ASLM certified SLIPTA auditor	September 2014	1	Dar Salam Tanzania
Mentorship	Training of trainers for Laboratory mentorship	April 2014	1	
Quality Assurance	Principle and Practice of Quality Assurance and Training (Internal Quality Control, External Quality Control and method validation	February 2015	4	Douala, Cameroon
	Principle and Practice of Quality Assurance and Training (Internal Quality Control, External Quality Control and method validation (Cross-training)	April 2015	30	BRHL, Cameroon
Continuous Improvement	Continuous Improvement Process Training on Corrective Action, root cause analysis and preventive action	February 2015	4	Douala, Cameroon
	Continuous Improvement Process Training on Corrective action, root cause analysis and preventive action (cross-training)	April, 2015	30	BRHL, Cameroon
Information System	Basic information system (BLIS)	January 2015	2	Limbe, Cameroon
SLMTA	SLMTA TOT	February 2015	2	Yaounde, Cameroon
ISO 15189 Standards	Practical applications and understanding of ISO 15189:2012	October 2016	3	Limbe, Cameroon
Follow-up Assessment, March 2018 (Accreditation era)				

ASLM = African society for laboratory medicine; BLIS = Basic Laboratory Information System; BRHL = Bamenda regional hospital laboratory; ISO = International organisation of standard; SLIPTA = Strengthening laboratory improvement process towards accreditation; SANAS = South african national accreditation scheme; TOT = Training of trainers

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It attracted many patients to the facility, increasing the patient load and income. According to the balanced score card, the laboratory experienced an increase in income by 170%, a reduction in the average number of customer complaints on missing specimens to less than 1%, a reduction in the average turn-around-time by 50%, an increase in average customer satisfaction by 60%, an increase in average staff satisfaction by 40%, a reduction in the number of average specimen rejection by 80% and an increase in patients load by 150% between 2010 and 2017.

The greatest percentage improvements were in management review (94%), facilities and safety (87%), documents and records (83%), purchasing and inventory (82%), evaluation and internal audit (69%), client management and customer service (65%), identification of non-conformities, corrective and preventive actions (58%), organization and personnel (57%), occurrence/ incident management and process improvement (54%), information management (53%), equipment (49%) and process control (38%). The finial absolute scores were greater than or equal to (≥) 58% in all aspects (Fig. 2).

Discussion

Our objectives were to identify improvements and evaluate the QMS. SLIPTA assessment results conducted by certified and competent ASLM SLIPTA auditors between November 2009 and March 2018 were used. Improvements occurred in all the areas of the QMS from baseline results of 18% (0 – star) in November 2009 to 82% (3-stars) in March 2018. There were also great changes in the QSE, with the highest score for QSE registered in the management review. All the QSE registered greater than 58% in all aspects. These improvements were due to the implementation of the SLIPTA. During SLIPTA, there was training, mentorship, and infrastructure improvements. Several studies have reported dramatic improvement in the quality of laboratory services due to training, including SLMTA [4, 6-8, 12, 14-17]. Firstly, the knowledge acquired from training was used to develop and implement the QMS leading to tremendous results. The training motivated the staff as most laboratory staff became aware of their expectations, making them more organized and excited about the quality culture. Secondly, the laboratory had seven laboratory mentors, which made mentoring easier. Coupled with this, the laboratory director was also trained as a laboratory mentor. The hospital director was trained in some SLMTA modules, which was an added advantage since it was easier for policies to be developed in compliance with the ISO 15189 standard, validated and implemented promptly.

These made communication and mentoring between the Laboratory Director and the hospital director easier as decisions could easily be reached since the standards understood by both directors were used as the reference document to justify proposals and decisions.

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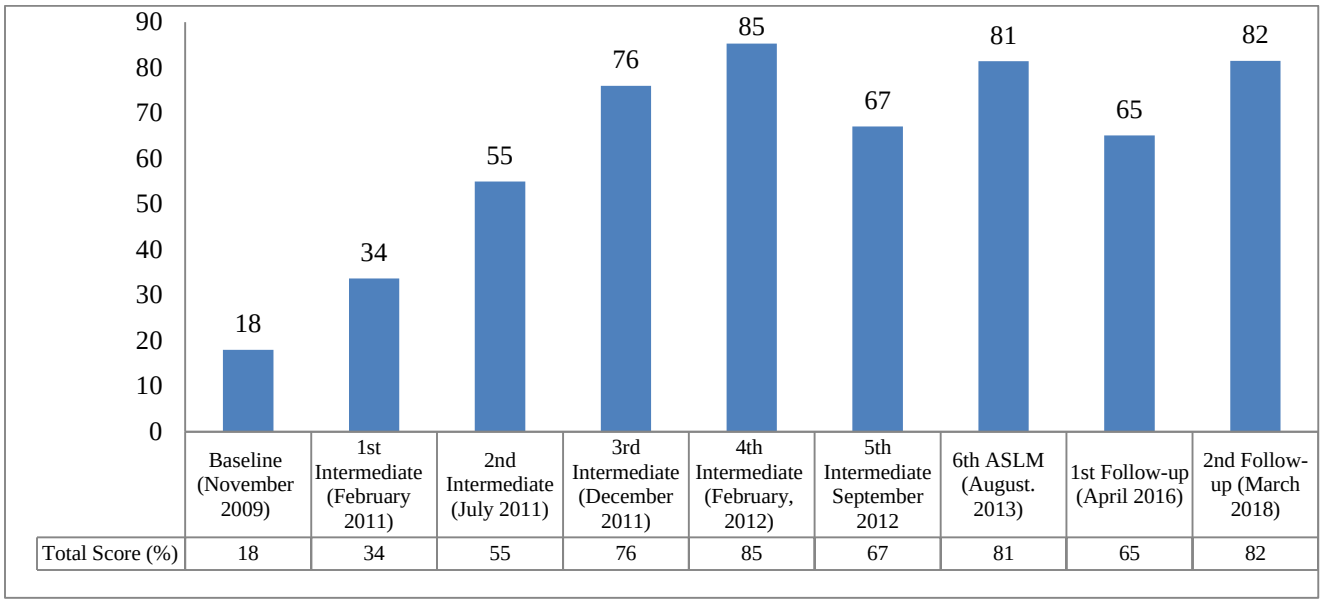

Fig. 1. Total scores/stars of SLIPTA assessment of the BRHL between November 2009 and March 2018

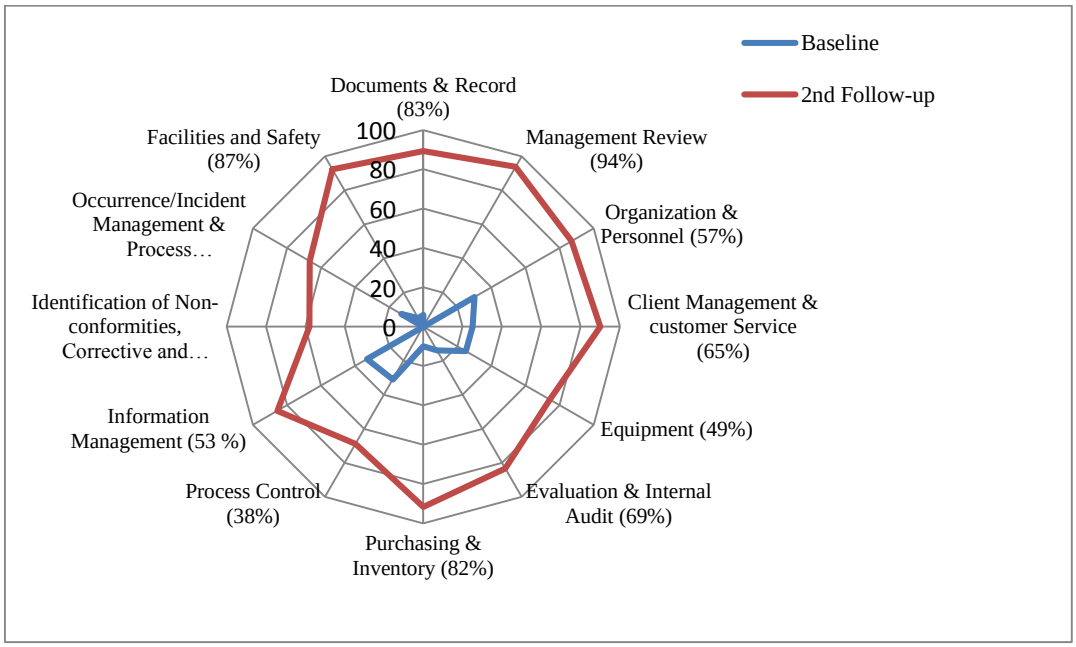

Fig. 2. Percentage differences in scores of the quality system essential assessment between baseline in November 2009 and 2nd follow-up assessment in March 2018 at the BRHL

Work was shared between the mentors, producing rapid results, including developing and implementing policies, standard operating procedures (SOPs), manuals, forms, work plans, and others. Gaps were identified and closed promptly since the mentors worked as a team. The team spirit became a laboratory culture as each mentor had a cohort of staff to mentor.

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[DOI: 10.18502/ijml.v9i2.10019]

Experience from other studies identified mentorship as a vital activity in the improvement of the QMS [7, 12, 18, 19].

Furthermore, the improvement of infrastructure contributed significantly to the observed improvement of the quality management system. Prior to the introduction of SLIPTA, the BRHL had modest buildings with very rough floors, potholes, and cracks and inadequate space for testing, storage, and staff facilities. The laboratory was hazardous, and the staff was unsatisfied with the working environment. With the introduction of SLIPTA, the laboratory management could use their knowledge from the training to make meaningful proposals to the hospital management that improved on the QMS. The innovations made in the laboratory improved patient and specimen flow, reduced turn-around time and increased patient satisfaction. The introduction and use of the information system facilitated the delivery of results, and clinicians could access patients' results in their offices or wards. Improvements in laboratory service because infrastructure improvements have been reported in several studies [3, 9].

Although there was a general improvement in the QMS as indicated by the assessment results, there was a drop from four stars in February 2012 to the SLIPTA exit assessment in September 2012. It was attributed to the fact that staff lost focus [7] and experienced difficulties sustaining the QMS. Most of the policies, procedures, manuals and partial implementation of the QMS were at their peak during the February 2012 assessment. The laboratory collected occurrences/non-conformities from complaints, audits, customer surveys, management reviews, and quality indicators which produced good action plans that were accepted. At the September 2012 assessment, most of the actions on the action plans had not been closed. The laboratory had gone through an entire year, and most of the activities such as management review meetings, internal audits, evaluation of quality indicators, customer surveys, up-date and archiving of documents and records were due. After the exit assessment, the laboratory staff redoubled their efforts to close most of the gaps identified. It is evidenced by the increase in performance in the ASLM assessment. After the ASLM assessment, the laboratory experienced new challenges such as an increase in the number of documents and documentation, increased workload, personnel migration (reduction in the number of trained staff) and the limited capacity of existing personnel to train newly recruited. Most of the personnel had gone on retirement, transferred, or terminated their contracts. Out of 36 staff trained on SLMTA, Basic laboratory information systems, internal audit and other disciplines before the ASLM assessment, only five were present during the follow-up assessment. The permanent on-site mentor and the two on-site alternating visiting mentors deployed to the laboratory by GHSS had been withdrawn. In addition, the two trained biosafety managers trained had also gone on transfer. Secondly, about 25 new personnel (locally hired or government recruited) passed through the laboratory. Some of this newly hired personnel received partial on-site

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[DOI: 10.18502/ijml.v9i2.10019]

training on the QMS and terminated their contracts for a better job or went on transfer before completing. The capacity of the laboratory also increased concerning the number of staff, tests, infrastructure, and activities. As of the recent follow-up assessment, the laboratory had a personnel capacity of 45. It was very strenuous for the five trained personnel trained before the ASLM assessment to effectively translate the knowledge to the rest, coupled with the fact that they are also involved in routine laboratory work. Other studies have shown that staff migration and inadequate training capacity have limited the progress of several institutions or programs. Mothabeng et al. (2012) reported a drop in the performance of SLMTA due to staff migration [20]. Hancock, in 2008, also reported a negative improvement in many programs due to personnel migration [21]. Change in management affected the improvement in the QMS. The hospital management was changed at the end of 2013, and it took time for the new management to understand the QMS, which created gaps in the QMS due to changes on the organizational chart which were not in compliance with the ISO 15189 standards, leading to delays in the implementation of many aspects of the QMS such as maintenance, purchasing, and decision making, increasing in equipment breakdown time, turn-around–time and out of stock for reagents and material. Change in management has affected some organizations' decision-making [22, 23].

The progress in the QMS between the first follow-up assessment in April 2016 and the recent assessment in March 2018 was boosted by the training of on-site training of the BRHL QMS using the quality manual and SOPs during the orientation of newly recruited staff and the training on the ISO 15189 standards in October 2016. Lastly, the fact that the goal of the laboratory staff was focused on the achievement of international recognition (accreditation) was also a motivating factor. Several studies have evidence that a goal-oriented focus enhances performance [24, 25].

Recommendations

Clinical laboratories are vital for the diagnosis and management of patients. Hence, we recommend that improving the QMS of clinical laboratories and achieving accreditation should be a joint endeavour of the government, institutions, laboratory management, laboratory personnel, and partners. The government should improve on the training of laboratory personnel to include aspects of the ISO 15189 standards. The policy on the transfer of personnel should be revisited to ensure that personnel are transferred or sent on retirement, considering the effective continuity of quality services. Personnel should be maintained at each post for at least five years before transferring. The organogram of the laboratories in Cameroon should be revised to match the ISO 15189 standards.

The institutions should respect the policies in the ISO 15189 standards and the budget for laboratories to include: training, infrastructure, and maintenance. The laboratory management should educate the institutions on the laboratory quality management system and ensure that

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[DOI: 10.18502/ijml.v9i2.10019]

training knowledge should be translated to all laboratory personnel and training and mentorship should be improved. Partners should educate the government and the institutions on the sustainability of laboratories' quality, especially those that had gone through the SLIPTA programme and are accredited. Occasionally, they should develop refresher courses and training of new SLMTA managers to sustain the quality of services. Generally, a training module on the laboratory QMS for hospital managers should be designed and have them trained to support effective implementation. Since this was a retrospective study, we were limited to the data available and information from records and key informants.

Conclusion

Our objectives were to identify improvements and evaluate QMS. We conclude that we identified incredible improvement and a magnificent change in the QMS at the BRHL. These improvements and changes were due to training, including SLMTA, mentorship and improvement of infrastructure results from the implementation of the SLIPTA program. The SLIPTA program is essential for improving the QMS for laboratories to attain accreditation.

Conflict of Interest

The author acknowledges and certifies that there were no affiliations with or involvement in any organization or entity with any financial interest such as educational grants, membership, employment, consultancies, or patent-licensing arrangements, or non-financial interest such as personal or professional relationships, affiliations, knowledge or beliefs in the subject matter or materials discussed in this manuscript.

Acknowledgements

We acknowledge the BRHL and the RHB staff and management for their collaboration towards the improvement of the QMS. We also acknowledge the Global Health Systems Solutions Limbe and CDC Cameroon, the hospital's management, and the Ministry of Public Health for their technical (training and mentorship) and financial assistance and material support towards the improvement and accreditation of the BRHL.

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[DOI: 10.18502/ijml.v9i2.10019]