LESSONS LEANRT OF THE FIRST PUBLIC SECTOR ISO 15189 ACCREDITED LABORATORY IN GHANA

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Abstract

***Background*:** Accreditation of public sector medical laboratories in developing countries such as Ghana have been described as an almost impossible task despite major efforts to establish and maintain efficient quality laboratory management systems. The Pathology Division of the 37 Military Hospital provides evidence of an efficient approach to accreditation to ISO 15189 in Ghana and the need to make medical laboratory accreditation an integral part of the national healthcare delivery system.

***Methods*:** The laboratory adopted the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme. After implementation the laboratory accelerated the process towards accreditation using an approach involving senior management in all accreditation activities, use of specific teams to focus on key improvement projects coordinated by an efficient mentorship programme. The laboratory was finally assessed by the Southern African Development Community for Accreditation Services to meeting the requirement of ISO 15189.

***Results*:** The Pathology Division of the 37 Military Hospital attained accreditation for its Haematology and Chemical Pathology departments making it the first public sector laboratory in Ghana to meet the requirement of ISO 15189. There has been an observed improvement in confidence of personnel and a culture for quality and meeting standards in support of quality healthcare delivery.

***Conclusion*:** ISO 15189 accreditation of medical laboratories is possible for all public sector laboratories in Ghana and the approach is scalable scalable especially for tertiary level laboratories. Accreditation ensures a culture for quality which is critical in support of quality patient care and must be an important aspect of national healthcare delivery systems.

Key Words: Accreditation, Laboratory, LQMS, Quality, ISO 15189

Introduction

Medical laboratories in Ghana and the world over are an essential component in the diagnosis, treatment and management of patients making reliable laboratory services, key to any efficient healthcare delivery system.[1,2] It is therefore quite unfortunate to observe that, in most parts of Africa, medical laboratory test results are generally distrusted for their accuracy and reliability. In the United States of America alone an estimated 94% of patient treatment and diagnosis are based on laboratory data.[3] The difficulty to accreditation of laboratories can be said to be highly influenced by the lack of prioritization of accreditation, inadequate allocation of resources for attaining and maintaining accreditation, poor understanding of the importance of accreditation by both laboratory personnel and health authorities and the high cost of the accreditation process.

In 2010 it was estimated that out of 380 laboratories accredited to international standards in sub-Saharan Africa, 91% (approx. 346) are in South Africa. Thirty-eight (38) out of the 49 countries evaluated, which included Ghana at the time had no laboratory accredited to any international quality standard.[4] In Ghana, there are an estimated 500 medical laboratories across the entire tier of healthcare service delivery in the public sector and yet not one of these is known to be accredited to any standard, local or international[4,5].

Implementation of SLMTA (Strengthening Laboratory Management Towards Accreditation) in Ghana started in 2010 with support from the US-Centres for Disease Control and Prevention under US-PEPFAR (United States President's Emergency Plan for AIDS Relief). In 2013, the Pathology Division with support from United States - Deployment Health Assessment Programme (US-DHAP) supported by the Jhpiego-Ghana was enrolled onto the SLMTA programme. Between 2010 and 2015, 15 laboratories including the Pathology Division of the 37 Military Hospital, grouped in three cohorts had been enrolled unto the programme[5]. Each facility benefitted from mentorship and logistics support over an eighteen-month period.

Until recently, the thought of a public sector medical laboratory meeting the requirement of ISO 15189 (medical laboratories: minimum requirement for quality and competence) and receiving accreditation was severely met with mixed feelings in Ghana. This article describes the experiences of the Pathology

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Division of the 37 Military Hospital in attaining and maintaining its laboratory accreditation status and the observed effect it has had on laboratory activities. It also presents an approach which is achievable and scalable in all medical laboratories. Furthermore, it describes the need to make accreditation of medical laboratories more relevant in particular tertiary level medical laboratories in Ghana.

Methods

Setting

The 37 Military Hospital is a 400 bed specialist hospital located on the Liberation Road between Kotoka International Airport and Central Accra. It is one of the largest hospitals in the Republic of Ghana after the Korle-Bu Teaching Hospital.[6] It is the main clinical laboratory service provider for staff of the Ghana Armed Forces (GAF) and the general public. The laboratory operates the Haematology and Chemical Pathology departments in addition to other departments such as Microbiology, Histopathology and Serology, and a Blood Transfusion Service.

Ethical Considerations

We used data from the laboratory's quality management system. No patient information was used. Therefore no ethical review was required for this article.

Baseline Assessment and Accreditation Process Initiation

The laboratory quality improvement process of the Pathology Division started in February 2013 when it was selected with 4 other public sector laboratories to form the third cohort of SLMTA laboratories in Ghana. Implementers of the SLMTA programme in Ghana, Global Health Systems Solutions (GHSS), utilized the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist to identify gaps and opportunities for improvement and to measure progress based on the zero to five star grading system[7,8].

Nonconformities identified during the assessment included; inadequate knowledge on the ISO standard and laboratory quality management systems, lack of staff training programme, poor quality control systems, lack of method validation/verification system among others.

Developing the Quality System: Management Commitment

At the helm of affairs was a structured laboratory management team which had the sole responsibility of supervising and ensuring that the Laboratory Quality Management System (LQMS) was duly implemented and maintained. Specific roles were defined for the laboratory manager, quality manager and laboratory director which were otherwise not clearly documented.

Hospital management initiated monthly meetings with laboratory management to discuss the quality improvement process and the progress to accreditation. At these meetings, quality indicators, improvement projects, outcomes of assessments were discussed; gaps were identified and opportunities for improvement were uncovered. Hospital management was therefore very much informed and conscious of the quality requirement of the laboratory, the ISO standard and the accreditation process.

Developing the Quality System: Team Formation

To ensure the effective implementation of the quality process new appointments were created by laboratory management. These appointments included; Logistics Officers, Health and Safety Officers, Training and Development Officers and Quality Officers. These officers with the Quality Manager constituted the Quality Steering Committee (QSC). The QSC had the sole responsibility of monitoring the LQMS, coordinating and advising laboratory management as appropriate.

During the implementation process seven (7) specific teams were also formed; audit team, document review team, equipment maintenance team, method validation/verification team, quality control team, external quality assessment (EQA) team and client satisfaction team. Each of these teams with a team leader, had the responsibility of ensuring that the laboratory was meeting set goals defined by the QSC and the LQMS. To ensure closer monitoring of team activities, the teams provided regular reports to the QSC and to laboratory management.

Developing and Maintaining the Quality System: Mentorship

An in-country resident mentor from GHSS-Ghana was assigned to the laboratory to provide guidance and coordinate the activities of the quality system while providing the needed technical support. The facility-based embedded mentorship programme design, ensured continuous training for both technical and management personnel including one-on-one coaching. Some areas of training included; internal audit, quality control, specimen management, safety among others. It also ensured laboratory staff personally carried out most tasks to build their capacity in performing assignments and making the quality process sustainable.

The mentorship programme guided the development of policies, processes and procedures; development of quality control programmes, laboratory training programmes, audit programmes, safety programmes, equipment and inventory management programme and management review processes.

Quality Indicators

The laboratory used quality indicators to measure the strength and performance of its quality system. These quality indicators included; Turnaround Time (TAT), specimen rejection and external quality assessment (EQA). TAT measured the time between specimen receipt by the laboratory until result validation. Specimen rejection measured the ratio of

specimen rejected to the total samples received per year. EQA performance measured the ratio of the acceptable results to the total number of tests run for a given EQA sample. Targets that were set for each indicator were; 90% TAT compliance (number of samples within acceptable TATs of 5hours) per month, less than 20 specimen rejections per month and 90% EQA performance pass rate. All quality indicators were monitored and reviewed by the QSC and laboratory management. Number of specimen rejections and turnaround times were collected and analysed on Microsoft excel. Recorded data was double checked and cleaned to ensure data quality.

Non-conforming events

Following the Non-conforming events (NCEs) identified by the Accrediting Body (AB), laboratory management through the laboratory quality steering committee ensured the investigation of each NCE to identify the root cause. Upon identification of the root cause, action plans were developed for elimination by way of corrective action. Plans were also developed and monitored to prevent recurrence of the identified NCEs.

Results

External Quality Assessment (EQA)

The outcomes of Chemistry EQA runs after 26 runs recorded an average of 89% pass rate whereas Haematology recorded 88% after 21 run (table 1). The laboratory commenced preparations towards its accreditation in 2016. Performance target score was 80% in 2016 and 2017 and was increased to 90% in 2018.

Table 1: EQA performance for Haematology and Chemical Pathology (2014 to 2018).

	2014 (%)	2015 (%)	2016 (%)	2017 (%)	2018 (%)
Chemical Pathology	74	80	84	80	89
Haematology	82	67	71	87	88

Specimen Rejection

The laboratory recorded a specimen rejection rate of 0.28% in the years 2017 (69,295 sample runs) and 2018 (80,272 sample runs) in Haematology. Rejection rate in Chemical Pathology was 0.14% (n=56,518) in 2017 and 0.20% (76,195) in 2018.

Turnaround Time (TAT)

The turnaround time (figures 2 & 3) for Haematology and Chemical Pathology recorded gradual improvements from 56% to 92% and 63% to 85% respectively from August 2018 to January 2019.

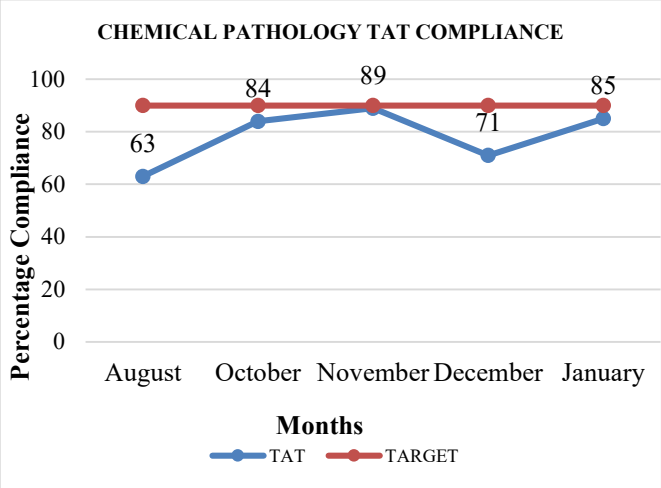

Fig. 2 Turnaround Times (TAT) for Chemistry tests monitored from August 2018 to January 2019. Percentage compliance was measured as the ratio of the number of test results sampled which were completed within laboratory stated TAT to the total number of tests sampled.

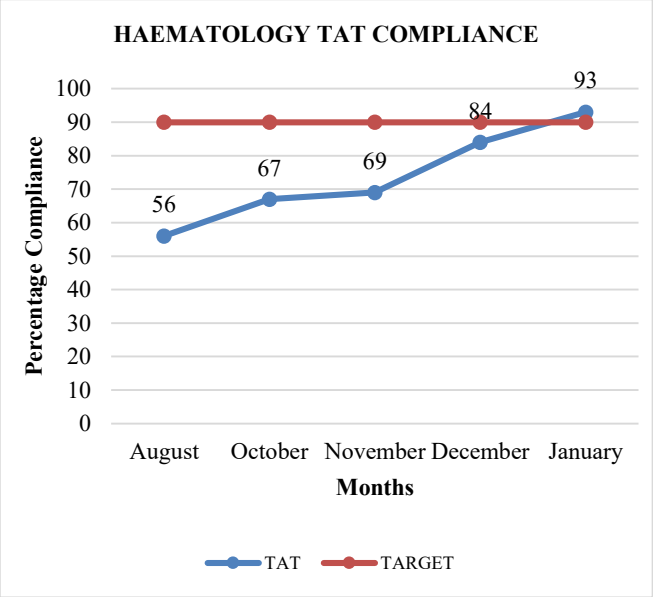

Fig. 3: Turnaround Times (TAT) for Full Blood Count test in Haematology.

Non-conforming Events

The number of non-conformities significantly dropped from 30 at the initial accreditation assessment in 2017 to nine at the first accreditation surveillance assessment in 2018.

Accreditation

The laboratory was accredited to ISO 15189 by the Southern African Community for Accreditation Services (SADCAS) with registration number MED019.

Maintaining Accreditation

Consistent, complete and comprehensive technical and management reviews were a critical contribution to the maintenance of the accreditation process. These reviews were otherwise ineffective prior to the accreditation acquisition. A Quality Assurance Office was established to support the management of the quality system. The effective commitment to the maintenance of the quality system is evidenced in the significant drop in the number of non-conformities at the surveillance assessment and the maintenance of its accreditation status.

Discussion

High quality laboratory testing is critical for patient care, disease prevention and disease surveillance.[9] Although the majority of laboratory testing are done in public sector laboratories, no medical laboratory in the public sector in Ghana had been accredited to ISO 15189[4,5].

The journey to accreditation was met with several challenges which required intense commitment and effort. The use of teams offered the opportunity for more personnel to be involved in the quality improvement process. Collective involvement therefore proved to be an effective tool in the change process[10]. This helped to eliminate the erroneous notion that the change process was "someone else's job".

At the core of the quality improvement process and accreditation was an effective mentorship program. The effective use and impact of mentorship on the accreditation process can also be seen in the experience of Bugando Medical Centre Clinical Laboratory-Mwanza Tanzania[1].Contrary to their method however, where external Clinical Laboratory Standards Institute (CLSI) mentors were used, the Pathology Division used an in-country mentor in the establishment of their quality system and the attainment of ISO accreditation. This is clear evidence of how countries like Ghana have the capacity to establish and technically support their own laboratory quality management system.

The outcomes of EQA for Chemical Pathology tests increased from 74% before accreditation to 89% after accreditation acquisition. Haematology also saw significant increases from 67% to 88% before and after accreditation respectively. The consistent increases in EQA scores is associated to the critical attention; quality control, equipment servicing, maintenance and personnel competence, given to testing procedures. The drop in performance in Chemical Pathology was due to changes in test units which was undetected. This was however identified and corrected resulting in the recovery of better scores. Annual specimen rejection rates was below 0.5% for 2017 and 2018. The number of samples rejected however saw increases as the laboratory further strengthened its specimen acceptance and rejection criteria. The laboratory did not only strengthen its specimen acceptance and rejection criteria, but also met with its clients to explain and train them on the specimen requirement for testing in the laboratory. The laboratory further provided sample requirement guidelines to all wards and emergency units to inform the choice of samples for laboratory testingand its associated requirement in improving sample rejection. Turnaround Time in Haematology showed gradual increases from 58% compliance in August 2018 to 93% in January 2019. Chemical Pathology also showed improvement in TAT from 63% compliance in August 2018 to 83% in January 2019. The observed drop in TAT compliance for Chemical Pathology in December 2017 was associated with ongoing equipment maintenance procedures.

It was evidenced in the implementation that, management commitment is critical at two levels in public sector laboratories: hospital management and laboratory management. This form of commitment is consistent with the published work of Viegas et al (2017) who described institutional commitment, staff motivation, strong laboratory leadership, adequate infrastructure and a comprehensive action as key pillars to accreditation acquisition. Medical laboratory accreditation should form part of a national agenda, particularly in Ghana, to ensure that the medical laboratory, a key aspect of diagnostics, is supported to offer the most accurate and reliable outcomes for efficient patient management.

Conclusion

The attainment of ISO accreditation in the public sector medical laboratory in Ghana is a possibility. Using the SLMTA programme and the SLIPTA approach coupled with management commitment, team work and efficient mentorship, more laboratories can attain accreditation and increase the quality of laboratory service delivery in Ghana and in Africa. Laboratory accreditation must be a national agenda for all countries, especially Ghana, particularly all national and regional level facilities.

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