



Progress towards Accreditation in Ethiopian Public Health Institute National HIV Molecular Reference Laboratory, Addis Ababa, Ethiopia

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Abstract

Background: Quality management system in Ethiopia implemented more than one decade and training was provided in different seasons. Meanwhile, there is no encouraging implementation in the system even in the center of excellence national reference laboratory.

Objective: This study is aimed to assess progress towards accreditation, the case of Ethiopian Public Health Institute national Human Immunodeficiency Virus (HIV) molecular reference laboratory.

Methods: Retrospective record review was applied from January 2016 to December 2017. After being finalized all the documents based on required standard, baseline audit and bi-annual intensive internal audit conducted, and action items developed regularly. Advanced molecular technique is used for testing of HIV viral load and early infant diagnosis. Findings were described thematically.

Results: During the base line assessment using the ISO15189 checklist, the main challenges identified were inadequate human resource, turnaround time out of range, lack of Inventory system, lack of awareness, poor sample management, and lack of address for referring sites, lack of appropriate safety measures, calibration & traceability. To address those aforementioned bottlenecks, additional staff members were recruited, training provided, the required safety measures fulfilled. For those occurrences identified, detailed root cause analysis was performed and notified for all staff members and respective management. As of August 16, 2017 the laboratory was accredited.

Conclusion: Accreditation was successful with all challenges in the national HIV molecular reference laboratory. All staff and management commitment is crucial to resolve challenges and oversee changes on accreditation. Continual follow-up and maintenance of accreditation in the laboratory is recommended.

Keywords: Accreditation; HIV; Molecular laboratory; Ethiopia

Introduction

Accreditation is a perfect means toward building quality medical laboratories in a diverse workforce environment and improving patient safety while laboratories seeking accreditation in early operational stages may face a number of challenges [1].

Cognizant to various challenges and limitations, 340 laboratories were accredited in Africa, only 28 (8.2%) are in sub-Saharan Africa; the other 312 primarily private laboratories are located in South Africa [1]. Ethiopia is one of the African countries with various bottlenecks for accreditation while around 14 medical laboratories were accredited by the Ethiopian National Accreditation Office (ENAO) in the year 2012 to 2017 [2] of those Bethzatha Advanced Medical Laboratory is one of private health facilities accredited [3]. With challenges, active accreditation practices enable their entry into or development of elements of a framework of continuous quality improvement [4]. To easier for everyone to crouch the quality management system, the staff knowledge and attitude, culture changed will result from a three phase approach: mentorship in accredited laboratories, training on ISO 15189, and training on Good Clinical Laboratory Practice [5]. Quality assurance seeks the certainty indicated by compliance with minimum

standards and Non-complying practices are assumed to have poor intentions [6].

Precision, Accuracy, and Short Turnaround Time (TAT) are important in effective laboratory services. The types of laboratory errors are classified as pre-analytical, analytical, and post-analytical, depending upon the time of presentation, and mainly pre-analytical error is high based on different evidences. To minimize the error, job aid describing rejection or acceptance criteria is established besides to giving training [7]. It is important that countries introduce their own standards for accreditation based on the best interests of their health system in order to safeguard primary health care principles of universality, equity, quality, efficiency and sustainability [8].

The World Health Organization Regional Office for Africa (WHO-AFRO) accreditation process is not intended to replace established International Organization for Standardization (ISO-15189) accreditation schemes, but rather to provide an interim pathway to the realization of international laboratory standards. Laboratories that demonstrate outstanding performance in the WHO-AFRO process will be strongly encouraged to enroll in an established ISO 15189 accreditation schemes [9]. Many laboratories in the developing countries are now opting for accreditation protocols with the advantage that accreditation is improving their standards and at the same time these standards are making the results globally acceptable

and one of the Quality indicators is Sample rejection aimed to comply with the standards [10,11].

Accreditation provides a guide to external stakeholders to how quality and safety is managed within an organization while various findings also depicted that accreditation program is time consuming, costly, difficulty in meeting standards and collecting data, and also perceived to add little value to patient care [12,13]. Low volume of samples, import and access to reagents, equipment and technical support were challenges during quality system implementation [14].

In 2010, a National Laboratory Strategic Plan was set forth in Ethiopia to strengthen laboratory quality systems and set the stage for laboratory accreditation. As a result, the Strengthening Laboratory Management toward Accreditation (SLMTA) program was initiated in most of Ethiopian laboratories [15]. Continual follow up and mentorship program improved scores of health institute laboratories [16]. The center of excellence laboratory Ethiopian Public Health Institute has also participated in SLMTA program more than a decade and now very few departments were accredited by the Ethiopian National Accreditation Office (ENAO) using ISO15189:2012 standard checklist with various challenges encountered. This is, therefore, the current study is aimed to assess the progress of HIV molecular reference laboratory towards accreditation and to address the lesson learned through fast fact towards accreditation.

Methods

Study site and period

A retrospective record review was conducted from January 2016 to December 2017, meaning from the inception of document preparation and baseline assessment till final accreditation in the Ethiopian Public Health Institute (EPHI), National HIV Molecular reference laboratory, Addis Ababa, Ethiopia. This institute is under the Federal Ministry of Health (FMOH) and served more than ten decades on research and various laboratory activities valid for patients and the public in general. Accreditation is one of flagships not only for EPHI but also by FMOH to deliver quality service for clients.

Laboratory testing, data collection procedure and analysis

Advanced laboratory molecular technique was used for testing of HIV viral load and early infant diagnosis in Ethiopian Public Health Institute, National HIV Molecular reference laboratory and all professionals in the laboratory are well trained in and out of country training for this diagnostic modality. Available data from various records of implementation of ISO15189:2012 standard (Figure 1) was taken and narrated thematically.



Figure 1: Various documents and records for implementation of ISO 15189: 2012 and available platforms

Ethical clearance

This study was ethically cleared by the Scientific and Ethical Review Office of Ethiopian Public Health Institute (EPHI-IRB). Data confidentiality was maintained and access is limited, only authorized and responsible bodies access documents and records (Figure 2).



Figure 2: Accreditation certificate/Award.

audit using ISO 15189 checklist in April 4, 2016; there were too many non-conformances identified while during internal audit within three months period, improvement was observed and only identified gaps were shown in Table 1. A subsequent internal audit conducted within six months in December 2016 and great improvement observed, and preparation for external audit by ENAO continued. In April 2017, external audit conducted by ENAO and few major and minor non-conformances identified and cleared within the recommended time period. In-line with internal and external audit; daily, weekly and monthly record review by quality manager have been conducted and immediate discussion with all staff members were made to resolve any gap identified. The findings in each audit captured via action item format and shared for responsible bodies with due date, and those activities that need continuous follow up were managed using improvement plan, Plan Do Check Act (PDCA) and detailed root cause analysis performed as indicated in Figure 3. Overall performance and challenges were presented in annual management review meeting. In August 16, 2017; the success for accreditation achieved, particularly by HIV early infant diagnosis technique (Annex I). This success was achieved with various challenges including; an inadequate human resource to cascade the activity, turnaround time out of range mainly for HIV viral load determination, inventory system, poor sample management, lack of appropriate safety measures, lack of address for referring sites, service and calibration schedule, calibration and traceability problem, lack of appropriate sample storage facility, and lack of awareness on ISO standard and accreditation scheme in general.

Results

The basic of accreditation is continual assessment or audit to identify opportunities for improvement. By the time of the baseline

ISO Clause #	Gaps identified and activities not done
5.1	Competence evaluation : blind samples range must be defined
	Justification of samples used as a competence evaluation tools
	Vaccination of personnel not done
	Competency for lab aid or cleaner
	Safety manual, handbook, specimen management were not available
	Daily appraisal evaluation not done
5.2	Equipment identification format must be standardized
	Implementation of safety issue is serious problem
	Unauthorized personnel enter into lab
	Monthly Safety monitoring using checklist not consistent
	Eye wash log sheet not be complete and refill it
	Fire extinguisher expired
	Lab process map and floor design must be done
5.4	Request form must align with ISO requirement
	Sample retention period must be defined clearly
5.5	Summarizing verification data and UoM are need asap
5.6	Sop for conducting IQC
	SOP for monitoring quality control out of range

	Quality indicator must be presented
5.7	Review of results: procedure must be develop and practice
	Result review job aid must be prepared
	Specimen tracking log sheet must be merged
4.9	IAR using and implementation lack
	SOP for root cause analysis must be done
5.1	LIS procedures must be updated and ready
	LIS verification procedure must be prepared
4.13	Quality and technical retention time must be defined
	Customer survey satisfaction
4.6	Reagent verification procedure and its application
	Regular reagent verification must be kept
	Bin card variables must be completed
4.5	Develop list of referral labs
	Agreement between referral labs must be done
4.6	Vender selection and monitoring and evaluation must be done
4.7	Advisory service practice not done
4.12	PDCA format –quality improvement planning must be used and practice
4.8	Resolution of compliant not done

Table 1: Identified gaps during initial internal audit.

To address those aforementioned bottlenecks, pertinent discussion with the responsible bodies conducted so that, additional staff members were recruited, training provided, the required safety measures fulfilled. Due to lack of certified companies, calibration and traceability issue is a bottleneck for additional scopes in the laboratory yet.

Discussion

This study is first of its kind to assess challenges and lesson learnt in the progress of accreditation at national HIV molecular reference laboratory. Not only staff members but also any stakeholders in touch of this laboratory are satisfied for the success of accreditation. Accreditation is valid to assess the quality and safety of health care and ensure continuous improvement in the quality of overall patient care, and also to involve professionals at all stages of the quality initiatives, to provide external recognition of the quality of care in health care organizations and enhance public confidence [17]. Accreditation of medical laboratories provides international acceptance on test result and recognized reliability of test, operational performance, quality management and competence [18]. Achievement of accreditation in

laboratories is a challenge in Ethiopia like in most African countries [19] while baseline and continual assessment is very crucial for the success. Like other African countries, lack of laboratory networks, equipment or their maintenance, shortage of well-trained laboratory staff and weak supply chain management systems were bottlenecks in our setting [20], and also calibration and traceability were the main challenges observed [3].

The lessons learned through the establishment of an accreditation program in EPHI national molecular reference laboratory may be useful to other nations, government and private health facilities seeking to develop a program through which to monitor service delivery during a period of rapid transformation or fast fact sheet for quality assurance implementation and providing service quality for customer satisfaction. These lessons are perhaps most relevant in settings where the government is seeking to assert greater control over a fragmented health system, particularly where there is a need to both ensure fulfillment of the required standards and introduce more comprehensive requirements that will set a high bar for quality of health care, and practice accreditation with all the foregoing challenges.

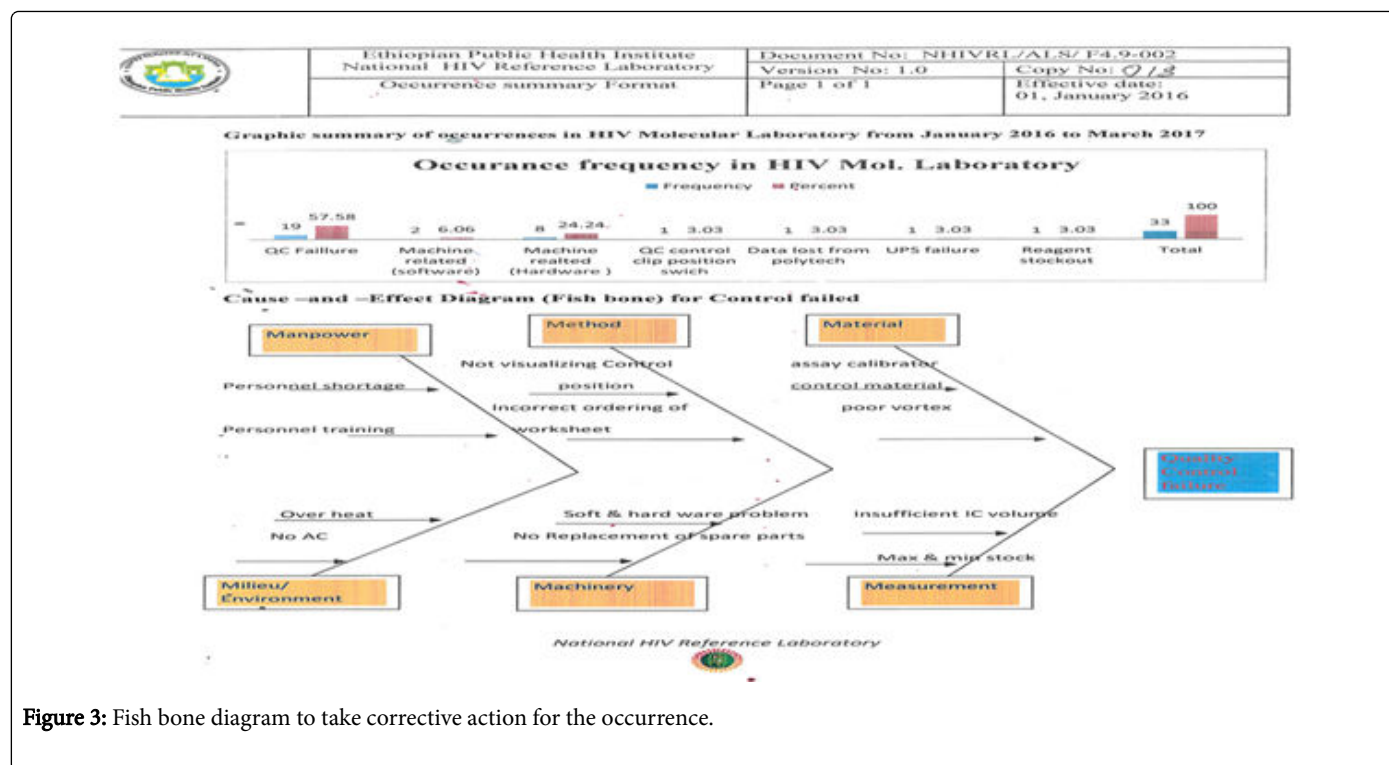


Figure 3: Fish bone diagram to take corrective action for the occurrence.

Strength and Limitation of the Study

The study was first of its kind in national level and indicated the real picture of medical laboratory quality improvement. Nevertheless, the nature of the data could not infer causal relationships.

Conclusion

Accreditation was successful with all challenges in the national HIV molecular reference laboratory and this might shed light on to other medical laboratories seeking for accreditation. Innovative and well-coordinated commitment of staff members and management is crucial to resolve challenges and oversee changes on accreditation. Continual follow-up and maintenance of accreditation in the laboratory is recommended.

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Conflict of Interests

All authors declare that they have no conflict of interests.

Author's Contributions

All authors contributed on accreditation activities. AL designed the study, collected data, analysis and wrote the manuscript. AJ, KZ, MG, RT, EK and SA participated in providing input for written proposal

and manuscript. All authors read, critically revised and approved the final manuscript.

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