Original article

Quality management system of level II laboratories providing CD4+ T cell count and AFB microscopy services in Addis Ababa, Ethiopia

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Abstract

Background: Delivery of high-quality patient care depends on reliable and actionable test results. Laboratories in developing settings are, however, often under-resourced resulting in poor performance. WHO-AFRO has established the Stepwise Laboratory (Quality) Improvement Process towards Accreditation (SLIPTA) to strengthen laboratory systems of its member states.

Objective: to assess the quality management system of level II clinical laboratories in Addis Ababa that perform CD4+ T cell counting and AFB microscopy as per ISO 15189 standard.

Methods: A cross-sectional health facility-based descriptive study was conducted between February 2013 and March 2013 using structured questionnaire (SLIPTA checklist) as well as observation to elicit information on quality management system of laboratories in intermediate referral facilities (Level II) that provide CD4+ T-cell count and AFB microscopy in Addis Ababa, Ethiopia.

Results: A total of 29 laboratories (13 government-owned, 13 private and 3 non-governmental hospitals) were assessed. The overall implementation of the 12 quality system essentials was <35% and values slightly over 50% were observed only for equipment, purchasing, inventory and information management. The average point obtained by the 29 level II (district) laboratories was 44.6% (115/258). Only 19 of the 29 laboratories were involved in an accreditation process, and only seven of these (four public and three private) had achieved star level 1 or above.

Conclusion and recommendations: The quality management system of level II laboratories performing CD4 count and AFB microscopy in Addis Ababa does not yet meet the ISO standard 15189. More intensive effort is needed to address quality while expanding laboratory services. [*Ethiop. J. Health Dev.* 2014;28(2):96-104]

Introduction

Laboratory testing is an essential component of improved healthcare delivery. Accurate and rapid diagnostic tests are required to diagnose illness, identify causative factors, monitor the effectiveness of treatment, and perform surveillance for key diseases (1). Delivery of high-quality patient care depends on reliable and actionable test results. Laboratories in developing settings are, however, often under-resourced resulting in poor performance (not only under resource but lack of system and accountability are also contributing factors to poor performance.) Clinicians often distrust laboratory data resulting in cycles of underinvestment in laboratory systems (1). However, a well-defined quality system is a must for ensuring quality of products or services (2). It ensures the accuracy of test results, increases the confidence of patients, clinicians and communities in the value of laboratory testing (3).

Implementation of quality systems in clinical laboratories are required to control processes within acceptable limits (4). It ensures consistency, reproducibility, traceability and efficacy of products or services (2). A quality system, as defined by ISO, consists of the organizational structure, responsibilities, procedures and resources needed to implement quality requirements (5).WHO-AFRO has established the Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) to strengthen laboratory systems of its member states (6). It is a process that enables laboratories to develop and document their ability to detect, identify, and promptly report all diseases of public health significance that may be present in clinical specimens (6).

Although implementation of quality management system showed improvement in the quality and standard of the laboratories in Lesotho (7), studies in Kenya (8), Rwanda (9), and Uganda (10) indicated that lack of adequate funding, government support, skilled staff and appropriate training were among the major challenges in improving the performance of laboratories.

In Ethiopia, there are various laboratories which perform CD4 count for HIV treatment initiation and monitoring, and Acid Fast Bacilli (AFB) microscopy for the diagnosis of tuberculosis. It is believed that continuous monitoring of the performance standards of laboratories is critical to strengthen laboratory services that have extensive benefits for Ethiopia's health system (11). The Ethiopian Federal Ministry of Health has identified poor diagnostic skill as a major challenge in TB and HIV control; enhancing laboratories is stated as one of the

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strategies to curb this problem (12).As the association between HIV/AIDS and TB is very strong in the country and worldwide, efficient and timely laboratory diagnosis of the diseases is very important. To this effect, various organizations, including CDC, collaborate with the Federal Ministry of Health to strengthen, among others, capacity of laboratories used for the diagnosis of the two diseases. Quality performance in both types of laboratories is, therefore, of paramount importance. The objective of this study was, thus, to assess the laboratory quality management system of level II clinical laboratories in Addis Ababa that perform CD4 T-cell counting and AFB microscopy as per ISO 15189 standard. ISO 15189 is set by International Organization for Standards (ISO) and, among other things, specifies requirements for quality and competence in medical laboratories. The information obtained in this study may be used by laboratories which are in the process of implementing SLIPTA.

Methods

Study Setting:

The Step-wise Laboratory Improvement Process towards Accreditation (SLIPTA) checklist was used to gather data for the study. The Federal Ministry of Health (FMOH), Ethiopian Public Health Institute (EPHI) and appropriate NGOs support all medical laboratories to follow the SLIPTA standards and achieve WHO/AFRO accreditation. The regulatory body for the implementation of these standards is the FMOH. A cross-sectional health facility-based descriptive study was conducted between February 2013 and March 2013.SLIPTA check list was used to elicit information on quality management system of the laboratories in CD4 counting and AFB microscopy in Addis Ababa. Addis Ababa is the capital city of Ethiopia with an estimated population of 2,738,248 (CSA, 2008). It is divided into 10 sub-cities and 99 *woredas*. There are more than 800 health facilities consisting of 50 hospitals, 50 health centers and more than 700 clinics, with laboratories found at different levels. According to the Health Sector Development Program IV 2010/11 – 2014/15, Ethiopia has a three-tier healthcare delivery system: primary hospitals, health centers and health posts form a primary healthcare unit. The second level in the tier is a general hospital and the third a specialized hospital (12).

Study Units:

In this study, the study units were all level II laboratories which are located in Addis Ababa and provide CD4 T-cell count and AFB microscopy. A total of 27 health facilities (14 government and 13 private hospitals) and three Non-governmental organizations (NGOs) were involved in providing antiretroviral therapy (ART) services and, thus, perform AFB microscopy and CD4 counting on-site. All 30 level II laboratories (District Hospital Laboratories) were approached and 29 of them were evaluated after consenting to be part of the study.

Data collection instrument:

Latest SLIPTA checklist which was developed by WHO (6) was used to gather information through interview as well as observation. This checklist specified requirements for quality and competency aimed at developing and improving laboratory services to raise quality to meet established national standards. The elements of this checklist were based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guidelinesGP26-A4 (6). Recognition was provided using a five star tiered approach, based on a bi-annual on-site audit of laboratory operating procedures, practices, and performance. The 12 quality system essentials (QSEs) used in the checklist and the maximum achievable points are as follows (6):

1. Document and records (25 points);
2. Management reviews (17 points);
3. Organization and personnel (20 points);
4. Client management and customer service (8 points);
5. Equipment (30 points);
6. Internal audit (10 points);
7. Purchasing and inventory (30 points);
8. Process control and internal & external quality audit (33 points);
9. Information management (18 points);
10. Corrective action (12 points);
11. Occurrence/incident management & process improvement (12 points); and
12. Facility and safety (43 points).

Quality indicators: the following six quality indicators, which must be monitored regularly and evaluated for opportunities to improve testing service, were also assessed:

1. Are stock counts routinely performed?
2. Are audit outcomes used to improve lab performance?
3. Does the lab participate in external PT test?
4. Are turnaround time (from sample collection to dispatching of results) monitored regularly?
5. How many specimens are rejected during errors? Are these reviewed regularly?
6. Is customer feedback regularly collected and acted upon?

Data Collection:

Three laboratory technologists who had taken assessor training were involved in completing the SLIPTA checklist for different facilities under the supervision of the Principal Investigator. During the data collection, the laboratory managers (i.e. heads) of each health facility were interviewed and observation of documents was done by the same laboratory technologists as to whether or not internal quality control procedures were routinely conducted for CD4 count and AFB microscopy and whether or not the laboratory achieved acceptable proficiency testing (PT) results of at least 80% on the two most recent PT challenges for AFB microscopy and CD4 counting. During the evaluation of the quality

management system of the various laboratories, scores were given for each of the 12 quality system essentials. Moreover, the degree of implementation of the following major quality indicators was assessed to conduct gap identification and analysis: Laboratory quality manual, standard operating procedures (SOP), staff meeting, external quality assessment scheme, waste segregation system, vaccination of laboratory personnel, performance and review of internal quality control, and availability of quality officer and safety office among others.

Data Analysis:
Variables of main interest were quality management systems for CD4 counting and AFB microscopy and factors that were thought to affect the target outcome variables included being private hospital laboratory (Yes or No); being involved in WHO-AFRO Accreditation program (Yes or No); whether or not the laboratory technologists/ technicians have taken training in quality management system (Yes or No); if it has quality assurance officer (Yes or No);if it has safety officer (Yes or No), and if it implements the 12 quality system essentials as per the ISO standard 15189 (Yes or No).

Data were computerized using Epi Data version 3.1 and was exported to STATA version 11 for analysis. As a measure of quality in different dimensions, scores were generated from responses and/or observations obtained to questions included under each domain. These scores were used as continuous or binary parameters to assess the quality of each laboratory. Means and proportions were used to summarize the scores. Proportion of "yes" answers to each question was also used to summarize each question.

Ethical clearance was received from Addis Ababa University, Aklilu Lemma Institute of Patho-biology. Consent was obtained from all participating laboratories. Data were coded to keep confidentiality of results.

Results
Different laboratories had varying human resources size, the highest being 55, in one of the private laboratories and the lowest 7 observed in one of the NGO owned laboratories. The highest achievement of 85.3% (220/258) was obtained in one privately-owned laboratory and the lowest achievement of 17.8% (46/258) was also in another privately-owned laboratory. The average score of all laboratories was 115 points (44.6%). Based on WHO-AFRO star level assignment of step-wise quality improvement of laboratories, four public and three privately-owned laboratories (24.1%) qualified for star level 1 to 4 and none of the NGO-owned laboratories qualified for any star level (Table 1).

The overall implementation of the 12 quality system essentials was <35% and values slightly over 50% were observed only for equipment, purchasing, inventory management and information management (Table 2).

Table1: **Mean achieved points and star levels of level II laboratories performing CD4 count and AFB microscopy in Addis Ababa**

Type of lab	Total no	Star level*														
		0 star			1 star			2 star			3 star			4 star		
		Nº	Pts	%	Nº	Pts	%	Nº	Pts	%	Nº	Pts	%	Nº	Pts	%
Public	13	9	112.6	43.6	2	152.5	59.1	1	186	60.5	1	203	78.7	-	-	-
Private	13	10	80.6	31.2	1	156	60.5	1	190	73.6	-	-	-	1	220	85.3
NGO	3	3	85.7	33.2	-	-	-	-	-	-	-	-	-	-	-	-

*No stars= 0 – 142 pts(< 55%); 1 star=143 – 165 pts(55 – 64%); 2 stars=166 – 191 pts(65 – 74%); 3 stars=192 – 217 pts(75 – 84%); 4 stars= 218 – 243 pts (85 – 94%), 5 stars=244 – 258 pts (≥95%)

Table2: **Average quality system achievement of all level II laboratories in Addis Ababa, Ethiopia 10/2013.**

Quality System Essentials	WHO/AFRO standard point	Average points (%)
Documents and Records	25	9.5 (38%)
Management Reviews	17	5.8 (34%)
Organization and Personnel	20	7.7 (39%)
Client Management and Customer Satisfaction	8	2.6 (32.5%)
Equipment	30	15.5 (51.5%)
Internal Audit	10	1.9(19%)
Purchasing and Inventory	30	16.4(54.8%)
Process Control and Internal and External Quality Assessment	33	15.5(47.5%)
Information Management	18	9.3(51.9%)
Corrective Action	12	3.4(28.3%)
Occurrence/Incidence Management and Process Improvement	12	1.5(12.2%)
Facilities and Safety	43	18(41.8%)
Total	258	107.1(41.5%)

Scores obtained in quality system essential stratified by the ownership of laboratories are summarized in table 3. Private and NGO laboratories both scored higher than 50% in equipment and information management. Government laboratories scored higher than 50% in documents and records, organization and personnel, process control and audit, and facilities and safety. NGO-owned laboratories scored markedly high points (79%) in purchasing and inventory. All of the different groups of laboratories scored lower than 50% in management reviews, client management and customer service, internal audit, corrective action, incidence management and process improvement.

Table 3: **Percentage of scores obtained by the different level II laboratories against each quality system essential, Addis Ababa, 10/2013**

Quality System Essentials	WHO/AFRO Standard Point	Mean Score (%)		
		Government labs	Private Labs	NGO labs
Documents and Records	25	14.1 (56.4)	10 (40)	4.3 (17.2)
Management Reviews	17	8.1 (47.6)	4.2 (24.7)	5 (29.4)
Organization and Personnel	20	13.7 (68.5)	8.8 (44)	0.7 (3.5)
Client Management and Customer Satisfaction	8	3.2 (40)	2.2 (27.5)	2.3 (28.8)
Equipment	30	14.6 (48.7)	16.1 (53.7)	15.7 (52.3)
Internal Audit	10	3(30)	2.6 (26)	0 (0)
Purchasing and Inventory	30	13.9 (46.3)	11.7 (39)	23.7 (79)
Process Control and Internal and External Quality Assessment	33	18.5 (56.1)	16.2 (49.1)	12.3 (37.3)
Information Management	18	8.8 (48.9)	10.2 (56.7)	9 (50)
Corrective Action	12	5.3 (44.2)	3.2 (26.7)	1.7 (14.2)
Occurrence/Incidence Management and Process Improvement	12	2.8 (23.3)	1.6 (13.3)	0 (0)
Facilities and Safety	43	25.2 (58.6)	19 (44.2)	9.7 (22.6)
Total	**258**	**131.2 (50.9)**	**105.8 (41)**	**84.4 (32.7)**

Assessment of Accreditation Process Involvement, PT Challenge Performance and QMS Training:

Of the 19 laboratories involved in accreditation process (12 public and seven private), seven laboratories (four public and three private) were at star level 1 or above. Proficiency test (PT) or EQA challenge performance assessment showed that 10 public, five private and one NGO laboratories accomplished >80% in two recent AFB PT challenges. Similarly, six public, five private and all NGO laboratories were able to attain >80% in two recent CD4 PT challenges. Despite the importance of training in the implementation of quality management system, laboratory technologists and technicians working in more than half of public and private laboratories and in all NGO laboratories did not have quality management system training.

Assessment of the Implementation of Major Quality Indicators:

The study showed that quality indicators were not always fully assessed and implemented to improve the quality of laboratory services except in a single privately-owned laboratory which achieved a 4 star level (Table 1).

To determine the development of a quality management system in a laboratory, the following quality indicators were considered in this study (Table 4).

Laboratory quality manual*:* This includes policies (processes and procedures) for all areas of laboratory service and addresses all the quality system essentials. It was observed that only a single public laboratory had a laboratory quality manual that was fully integrated in the laboratory functions and was revised and updated. Eleven public laboratories and seven private laboratories had laboratory quality manuals, but these were not revised annually or did not have up-to-date versions (Table 3).

Review of quality and technical records*:* Reviewing is addressing recurrent problems and evaluating new or redesigned activities by the laboratory manager or the quality officer. Of the 29 laboratories, technical records and quality control records were revised in only 2 laboratories.

Standard Operating Procedures (SOP*):* All procedures should be established, documented, and maintained up-to-date for all tasks. They should be available at the workstation for the relevant staff. Only one of the 29 laboratories considered in this study had Standard Operating Procedures which were fully prepared, updated and made available in CD4 testing and AFB microscopy workstations. Ten laboratories did not have any written SOPs. In the majority of the laboratories (18), the SOPs were not updated; were prepared either for AFB microscopy or for CD4 count.

Staff meeting: The laboratory should hold regular staff meetings to ensure communication within the laboratory. Meetings should be recorded to facilitate review of

progress over time. Only two private laboratories held regular (is there standard frequency to determine regularity? If so better to indicate frequency) laboratory staff meetings. The rest did not have regular staff meetings at all. If and when staff meetings were held, they were not recorded for subsequent follow-ups.

Evaluation tool and follow-up*:* The laboratory should measure the satisfaction of clients, clinicians, and patients regarding its services either on an on-going basis or through episodic solicitations. A total of 18 laboratories did not prepare the evaluation tools and did not follow up the quality service of the laboratories. Only 5 laboratories had the evaluation tool and followed up the service quality in their respective laboratories. The rest of the laboratories created the evaluation tool but did not use them to monitor the quality of service.

Equipment preventive maintenance: Preventive maintenance by operators must be done on all equipment used in examinations including centrifuges, autoclaves, microscopes and safety cabinets. Two of the thirteen public laboratories and three of the thirteen private laboratories were the only ones to perform preventive maintenance for the laboratory instruments while none of the three NGO laboratories performed this activity.

Laboratory inventory system: This reliably informs the laboratory how much minimum and maximum laboratory stock must be kept to avoid interruption of service and to prevent expiry of reagents, respectively. The system for laboratory inventory was employed in eleven of the total assessed laboratories while fourteen laboratories of the total did not have a system at all for laboratory inventory.

Performance and review of internal quality control (IQC)*:* This verifies the attainment of the intended quality of results and must be reviewed routinely. Of all the laboratories considered in this study, only five performed internal quality control properly and documented and reviewed it in a timely manner. Implementation of internal quality control in 18 laboratories was only partial. Either they did not perform complete internal quality control or they did not document or review it in a timely manner. Six laboratories did not perform an IQC to improve the quality of CD4 count as well as AFB microscopy.

Participation in external quality assurance: Laboratories should handle, analyze, review and report results for proficiency testing by an external body. All of the public and NGO laboratories and eight of the private laboratories had been participating in External Quality Assurance (EQA) for AFB microscopy and CD4 counting. Four private laboratories did not participate at all in EQA for AFB microscopy or CD4 counting. Of the participating laboratories, only one of the public and private laboratories performed root cause analysis for unacceptable EQA results and took corrective action to improve the quality service of AFB microscopy and CD4 counting. The remaining laboratories did not use the feedback they got to improve the laboratory service quality for AFB microscopy and CD4 counting.

Result crosscheck system: Authorized personnel systematically review the results of examinations and evaluate them in conformity with the clinical information available regarding the patient, and then authorize the release of the results. Only 12 of the 29 laboratories had a system to crosscheck results before dispatch, which could be helpful in minimizing errors on the spot.

Cause analysis of occurrence reports: A laboratory ought to have a policy and procedures for the resolution of complaints or following up on other feedback received from clinicians, patients or other parties. When there was an occurrence report during laboratory examination, almost the majority of the laboratories (19/21) did not perform cause analysis which could help them to prevent the error from recurring. Only six of the assessed laboratories were able to perform this activity.

Use of quality indicators for quality improvement activities*:* Quality indicators need to be compared against a benchmark from an acknowledged guideline. Key indicators must be monitored regularly (how frequent is regular?) and evaluated to improve testing services. The implementation of the quality indicators to improve the quality of services was only been understood and fully performed by three laboratories. This indicates the majority (twenty three out of twenty nine) did not use quality indicators as a way of improving quality of (see comment) activities.

Adequate size of the laboratory*:* The laboratory floor plan should be configured to promote high quality work, personnel safety and efficient operations. Almost half of the assessed laboratories did not have adequate size for performing the activities required of them. On the other hand, 10 of the 29 laboratories had enough space and proper arrangement of paraphernalia which could create comfortable working environment.

Availability of safety manual*:* This manual should be readily available in work areas, by being specific to the laboratory's needs. It should also be reviewed and updated at least annually. A fully prepared and revised version of safety manual was only available in two of the twenty nine laboratories. The majority of the laboratories had safety manuals that were not fully prepared or revised.

Waste segregation system: Waste should be separated according to biohazard risks, with infectious and non-infectious waste disposed of in separate containers. Seven of all the laboratories considered in this study had a properly implemented waste segregation system. Ten laboratories labeled the waste bins as "infectious" and "non-infectious", but did not strictly follow labels or the

waste was mixed up when discarded. The majority did not have such system.

Vaccination of laboratory personnel*:* Laboratory staff should be offered appropriate vaccinations, particularly that of hepatitis B. Since all the assessed laboratories perform CD4 count, vaccination against hepatitis was mandatory. However, of the 29 laboratories considered in this study, 20 did not have their laboratory personnel vaccinated against hepatitis. Laboratory personnel working only in seven laboratories had been vaccinated by their respective organizations or took a prior vaccination on their own.

Availability of quality and safety officers*:* There should be a quality officer with delegated authority to oversee compliance with the requirements of the quality management system. A trained safety officer should also be designated to work with the laboratory manager to implement the safety program. All the public laboratories and six private laboratories had properly trained quality officers as well as safety officers. Two private laboratories had these officers but they did not receive the appropriate training. The NGO laboratories had no quality and safety officers at all. (Table 4).

Table 4: **Quality indicators and their implementation in the assessed laboratories, Addis Ababa, 10/2013**

Quality Indicators	Public labs (n=13)			Private labs (n=13)			NGO labs (n=3)			Total		
	Yes	No	Partial	Yes	No	Partial	Yes	No	Partial	Yes	No	Partial
Laboratory Quality Manual	1	1	11	0	6	7	0	3	0	1	10	18
Policy & SOP accessibility	0	3	10	1	5	7	0	2	1	1	10	18
Review of quality & technical records	2	2	9	0	9	4	0	2	1	2	13	14
Staff meeting	0	2	11	2	7	4	0	3	0	2	12	15
Evaluation tool &follow-up	3	6	4	2	9	2	0	3	0	5	18	6
Equipment preventive maintenance	2	2	9	3	3	7	0	1	2	5	6	18
Laboratory inventory system	5	4	4	4	9	0	2	1	0	11	14	4
Performance & review of Internal quality control	2	2	9	2	3	8	1	1	1	5	6	18
Participation in External quality control	1	0	12	1	4	8	0	0	3	2	4	23
Result cross-check system	3	5	5	7	4	2	2	1	0	12	10	7
Cause analysis of occurrence reports	5	5	3	1	11	1	0	3	0	6	19	4
Use of QI for quality improvement activities	2	10	1	1	10	2	0	3	0	3	23	3
Adequate size of laboratory	5	5	3	5	6	2	0	3	0	10	14	5
Availability of safety manual	2	0	11	0	4	9	0	3	0	2	7	20
Waste segregation system	5	1	7	2	8	3	0	3	0	7	12	10
Vaccination of lab personnel	2	11	0	4	7	2	1	2	0	7	20	2
Availability of safety officer	13	0	0	6	5	2	0	3	0	19	8	2
Availability of quality officer	13	0	0	6	7	0	0	3	0	19	10	0

Yes- if labs scored yes in all questions under the section; **No**- if labs scored no in all questions under the section;
Partial- if labs scored at least one NO response under the specific section

Discussion

The observation that the majority of the laboratories considered in this study (>75%) were at no star level was indicative of a not well implemented quality management system in AFB microscopy and CD4 testing laboratories. There are no similar studies in Ethiopia on AFB microscopy and CD4 testing laboratories to make any valid comparisons. The number of laboratories in our study that achieved any star level was much lower than that observed in most East African laboratories (14), which were involved in the accreditation process. Although Zimbabwe and Ethiopia enrolled in similar time in the SLIPTA process, only very few laboratories considered in our study achieved one or more star levels whereas almost all laboratories in Zimbabwe achieved various star levels (15), mainly because they implemented improvement projects and mentor-embedded support.

The average point obtained by the laboratories considered in this study was 44.6% (115/258). This indicated that, on the average, laboratories in Addis Ababa fulfilled less than what was required of them in quality laboratory performance. Similar findings were also reported from a baseline assessment conducted earlier in Ethiopia (13) and in Lesotho (7). The average result in the current study as a whole was slightly lower than the findings in Kenya, Rwanda, Tanzania¸ Uganda and Burundi, where 29% of the sites achieved at least star level 1 (14). The higher values in the other African countries could partly be explained by the fact that all investigated laboratories were involved in the accreditation process in the respective countries. This was not the case in the current study where only 19 of the 29 laboratories were involved in an accreditation process. However, within the laboratories involved in the accreditation process, 35% (7/20) were able to achieve at least star level 1 or above which indicated that participation in the accreditation process could result in a better performance compared with the ones in the aforementioned study (14).

The laboratories included in this study also had various major drawbacks in most quality system essentials, which were worse than those observed in Lesotho (7), Kenya, Rwanda, Tanzania¸ Uganda and Burundi (14), where embedded mentoring was performed and refresher training sessions were given to the laboratory staff in the implementation of quality management system. However, the involvement of most laboratories in the accreditation process during our study resulted in some improvement in terms of achieving some star level, which was not the case during the course of a previous study (13). In Thailand, working towards accreditation made many laboratories markedly improve performance and quality system essentials (16)

The current study indicated that the quality management system implementation in the laboratories considered in this study was at the early stage as indicated by the score (<50%) in nine of the 12 QSEs. Thus, the process of SLIPTA implementation in Ethiopia was slower when compared to the performance of other African countries (14). The majority of the assessed laboratories in our study, thus, needed to implement the QSEs for the provision of quality and reliable service to the community (6).

The document and recording system in the laboratories considered in our study (38%) was notably lower than the scores reported for Uganda and Tanzania (14). However their performance was considerably higher than the score reported from Kenya, Rwanda and Burundi (14).The low score in our study was mainly because of lack of fully prepared quality manual, a document control system, unavailability of up-to-date SOPs in all workstations and absence of proper archiving and timely retrieval of results and records (4, 9).

Only a few laboratories in our study exercised management reviews. Although the average score for management review in most East African laboratories was also low (<50%), the score for the laboratories in our study (34%) was only higher than that for Rwanda and Burundi (14). The commitment of management, expressed in terms of clearly formulated quality policies, appropriation of adequate budget, and implementation of corrective action is crucial to maintain quality in the laboratories (4).

Organization and personnel were poorly handled by most laboratories in this study (39%), and the score for customer service was also low (32%). These scores were much lower when compared to laboratories in Kenya, Tanzania and Uganda, which scored >50% (14). For a better performance, laboratory service should be more customer-focused and the competency as well as the motivation of the staff should be raised (9).

On a positive note, the laboratories considered in our study scored >50% in equipment, purchase and inventory and the performance in these quality system essentials was relatively higher than laboratories in Lesotho (7) and most East African countries except for Uganda (>70%) (14). Performance in information management was also better than the laboratories in Kenya, Tanzania and Burundi (14).

Similar to the observations in all East Africa laboratories (14) (with the exception of Uganda), the majority of the laboratories in our study failed to implement internal audit as described in the quality manual (4). If and when performed, it was not done by properly trained personnel. These would result in bothed-up results due to

inaccurately identified and wrongly addressed analytical problems (9).

***Conclusion*:**

The quality management system of level II laboratories performing CD4 count and AFB microscopy in Addis Ababa did not meet the ISO standard 15189 at this point in time, although some improvements had been noted. Involvement of respective higher management of the institutions (e.g. hospitals) together with the mandated governmental authorities in providing proper training, performing timely assessment, using bidirectional feedback as well as providing mentoring is of paramount importance in the implementation of quality management system. Although involvement in an accreditation process is useful, it should be supported by a consistent assessment and follow-up. The management of the hospitals (clinics) should have a full involvement in the quality management system of the laboratory because without the effort of the upper managements, an attempt to implement a functional quality management system would only be a futile exercise. It is suggested that a huge advocacy/promotion on the need of quality management system be done in the health sector laboratories and in medical colleges. This would create better knowledge and a resulting change in attitude towards quality management system implementation. The different health associations can play an important role in this respect.

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