

## Factors Affecting Implementation of Laboratory Quality Management System in Addis Ababa Public Health Laboratories, Addis Ababa, Ethiopia

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### ABSTRACT

**Background:** Laboratory quality management system is one of the most important initiative change taken place in the field of the medical laboratory as a comprehensive and transformational strategy to improve the quality of service to respond the needs and expectations of the society in Ethiopia since 2009.

**Objective:** This study aimed to assess factors affecting laboratory quality management system implementation among Addis Ababa health laboratories, Ethiopia.

**Materials and Methods:** A cross-sectional study design approach was used from September 2017 to February 2018 using both quantitative and quantitative data collection approach. Data were entered, cleaned using EPI-Data 3.1 and exported to SPSS version.20 software for analysis.

**Results:** Nine variables were found considerably associated with LQMS implementation ( $p < 0.05$ ) where method validation and verification, root cause analysis, laboratory equipment maintenance related issues, external quality assessment, professional competency, measurement uncertainty analysis, evaluation, and audit and trained staff turnover.

**Conclusion:** The overall findings illustrate that there is a need for facility management should set a specified budget for laboratory quality management implementation and should into consideration those factors while laboratory quality management system implementation.

**Keywords:** Quality management; System factors; Addis Ababa; Ethiopia

### INTRODUCTION

International evidence suggests that improving the quality of clinical laboratory service can directly positively impact on the health care service. Quality Improvement (QI) is a proven, effective way to improve care for patients and to improve practice for staff and also a driving force in health care [1-3].

More than 70% of clinical decision-making is predicated upon, confirmed by, or documented by medical laboratory test results. Despite this recognition, there is still a gap in the strengthening of laboratory services and systems in some African countries, such as poor laboratory infrastructure, lack of laboratory equipment or their maintenance, shortage of well-trained

laboratory staff and weak supply chain management systems [4-6].

The implementation of laboratory standards is verified through the process of accreditation. Although Continuous Quality Improvement has been widely adopted in health care, there have been significant problems in embedding the core approach in health care organizations [7,8].

Improving the quality of clinical laboratory at health facilities is a challenge that must be undertaken to reduce mistreatment, unreasonable long TAT and enable developing countries to achieve their targets for Sustainable Millennium Development Goals 5 (SMDGs 5) [9-12].

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Deficiencies in quality of care represent neither the failure of professional compassion nor necessarily a lack of resources. Instead, they result from gaps in knowledge, inappropriate applications of available technology, or the inability of organizations to change. Local health care systems may have failed to align practitioner incentives and objectives; to measure [13-15]. One of the major challenges in implementing health programs in Sub-Saharan Africa is the reliability of medical laboratory services. The diagnostic support of laboratories is essential for a wide range of diseases and testing purposes, both from clinical and public health perspectives [16,17].

Numerous global initiatives in Africa have focused on clinical laboratory harmonization and standardization, and laboratory accreditation [18]. As part of this effort, the reform in the Ethiopian health sector has been intensified through the application of a new concept known as Strengthening Laboratory Management towards Accreditation (SLMTA). Despite the implementation of Laboratory Quality Management System (LQMS) in Addis Ababa, Ethiopia, there is little literature data on continuous laboratory Quality management in the health system of Ethiopia. Hence this study was intended to assess factors affecting laboratory quality management system implementation among Addis Ababa health laboratories, Ethiopia, that will fill this gap and exploring the possible solutions.

## MATERIALS AND METHODS

### Study setting and period

The study was conducted in government health facilities found in Addis-Ababa city, capital of Ethiopia, with an area of about 540 square kilometers. According to the 2007 census report, the population is enumerated to be 3,384,569 [19]. There are six regional, five federal (including one university hospital), 2 NGO-supported, 30 private, one defense, one prison, and one police hospital laboratories. There are also 100 (currently functional) public and 4 NGO-supported health centers, 7 Public, 500 private, 31 NGO supported clinics, and 30 private hospitals [20,21]. A cross-sectional study design using qualitative and quantitative data collection approach was employed from September 2017 to February 2018.

### Sample size determination and sampling technique

The source population N for the quantitative study was health professionals working in Addis Ababa public health facilities, and the source population for the qualitative research was all facilities head, Lab Managers, Quality Managers and Safety Officers working at the public health facilities in Addis. Public health facility laboratories found in the study areas, which were participating in LQMS, SLMTA/SLIPTA program/process and laboratory professionals who had at least six months of experience in that particular laboratory and who had consented to be involved in this study were included. Study participants required for this study were calculated by using the formula for a single population proportion: The sample size n of the quantitative research is computed as follows.

$$n = \frac{z^2 \frac{p(1-p)}{d^2}}{d^2}$$

Where the above symbols stand for:-

z: Z-score at 95% confidence interval 1.96; p: sample proportion; n: size of the sample; d: Marginal of error; e: estimate of the percent defective within 5% of the true value with 95% probability

Since there is no previous study to determine the portion, the ratio (i.e., 50%) that yielded maximum sample size was taken, a margin of error of d=5%, with 95% confidence interval (z=1.96) adding 10% for non-response rate, the required sample size of 422 health care providers. The sample size for the qualitative part: All facilities head, Lab Head and Quality managers in the referral selected health facilities were taken as a qualitative sample.

### Sampling procedure

For sampling all health facilities found in Addis Ababa was the sampling frame then using simple random sampling two public health centres from each sub-city, all regional public hospitals were included in the study. Similarly, the list of all the respective human resource profile of health care providers who are working in health centres and hospitals included in the study were retrieved from Addis Ababa city administrative health bureau/respective sub-cities to calculate the proportional allocation of sample size in each hospital and health centres. The numbers of respondent for the quantitative study was allocated to each health facilities using probability proportional to size sampling technique. Respondents in the selected hospitals were selected using simple random sampling Figure 1. A purposive sampling technique was used for the qualitative study (in-depth interview). The selection is based on the responsibilities and position of respondents.

Total 422 health care providers from hospitals and health centres

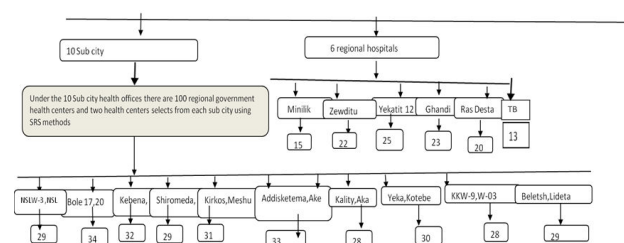


Figure 1: Schematic presentation of proportional sampling.

### Data collection procedure

A data collection tool comprising of a questionnaire and face-to-face interview guide was used. The survey was prepared based on a review of the literature on implementation of quality management systems and ISO 15189 standard. Qualitative data from technical laboratory professionals were obtained using open-ended questions to be written by them. Qualitative data from laboratory heads, quality officers and medical directors was

obtained by face to face interviews by level them as R1,R2... as chronological order as per their participation, and the information was captured using a simple tape-recorder, and the response and opinion of interviewee were transcribed to a written form by listening from the record. Similar ideas from the laboratory heads, quality officers and medical directors/CEO were organized accordingly; and individual opinions were held by a facility as it is differently said by that particular health facility key informant without mentioning the name. One data collector per health facility was deployed for collecting the quantitative data using a structured questionnaire while qualitative data were collected by the principal investigator to obtain adequate data.

### Data quality assurance

To ensure the validity of the data collection tool, a pre-test was done in one of the St. Paul hospitals before the study period which was not included in the main study. Appropriate modification of the data collection tool made accordingly before actual data collection made. Adequate orientation was given for data collectors and during the data collection period completeness of data checked through supervision by the principal investigator. After data collection, data entered, and cleaned using EPI-Data-3.1 (Epi Data Association, Odense, Denmark) and analysed by SPSS version 20 (IBM Corporation, Armonk, New York, USA) software. To protect data manipulation data was stored in a password-protected computer and backup was saved by flash and personal email.

### Analyses and interpretation

Data was first entered and cleaned using EPI-Data-3.1 and exported to SPSS version.20 software. The quantitative data

were analysed using simple descriptive statistics: percentages, frequency and summarized using tables and graphs. The qualitative data from in-depth interviews and open-ended questions were organized, categorized, summarized, and finally discussed by narrating the findings thematically.

### ETHICAL CONSIDERATION

Ethical clearance was obtained from Addis Ababa Health Bureau Ethical Review Committee, with reference # AAHB/2058/227 and letter of support were obtained from Health Bureau and HFs participated in the study were informed. Participants were informed that all data collected would remain anonymous treated statistically and remain confidential.

### RESULTS

#### Socio-demographic characteristics of the study participants

A total of 401 laboratory professionals working in the sampled 20 health centre and six regional hospitals were participated in this study with 5% non-response rate, with the majority (45.9%) of the participants were found between 30-39 years age group. Most of the respondents 234 (58.3%) were female, and regarding education, the majority of the respondents 284 (70.1%) were at the B.Sc. Degree level. From the sampled health facilities, only two laboratories were accredited against ISO 15189 requirements. The detail is depicted in Table 1.

**Table 1:** Socio-Demographic determinants of Laboratory quality management system in Addis Ababa, Ethiopia, 2018.

Variable	Category	Category	Frequency (n)	%
Age (Years)		18-29	94	23.4
		30-39	184	45.9
		40-49	104	25.9
		>50	19	4.7
Sex		Male	167	41.7
		Female	234	58.3
WHO SLMTA/SLIPTA star status (n=26)		I	3	11.5
		II	8	30.8
		III	11	42.3
		IV*	4	15.4
Working Health Facility type (n=26)		Health Center	22	76.9

	Hospital	06	23.1
Educational status (n=401)	Diploma	51	12.7
	B.Sc. Degree	284	70.1
	M.Sc. Degree and above	66	16.4
Working Experience ( in year)	1-2	32	8.0
	3-5	41	10.2
	6-10	165	41.1
	10-15	126	31.4
	>15	37	9.2
Position held	Medical Director/CEO	24	6
	Laboratory head	26	6.5
	Quality manager	26	6.5
	Safety manger	24	6
	Laboratory bench work	301	75

\*From these health facilities only 2 laboratories were ISO 15189 accredited

### Participants' opinion on LQMS implementation

As indicated in Table 2 ,findings from perception and perspectives of the participants, even though majority of the professionals were aware on the day to day LQMS laboratory implementation, there is still significant amount of 20 (5%) unaware professionals are there and from the total participant of this study 98 (24.5%), did not ever take training related to laboratory continue quality implementation also almost half of the training participants were not satisfactory training 141 (46.5%) for the continuous quality management system.

116 (29%) were retort as their laboratory size and layout of the laboratory not convenient for quality management implementation and day to day laboratory activities and plus to these, even though the laboratory has a budget for routine operation, only 112 (28%) respondents respond as having a specific budgetary allocation for executing their laboratory quality management implementation and also the data reviled as using consultant is not the habit of the laboratory.

**Table 2:** Participants' opinion on Laboratory quality management system in Addis Ababa, Ethiopia, 2018.

Variable	Frequency (%)
Awareness of the organization's effort for the implementation of laboratory Quality Management System	
Yes	381 (95%)
No	20 (5%)
Involvement of professionals in the Quality management implementation process	
Yes	299 (78.5%)
No	82 (21.5%)
Area of involvement in Quality management process	

Decision making (Management)	19 (6.3%)
Sensitization/Awareness	76 (25.4%)
Document preparation	112 (37.5%)
Auditing	52 (17.4%)
Coordination	14 (4.7%)
Addressing non-conformities	26 (8.7%)
Laboratory Professionals who had training related to continuing Quality Implementation	
Yes	303 (75.5%)
No	98 (24.5%)
Sufficient and adequate of training given	
Yes	162 (53.5%)
No	141 (46.5%)
Adequacy of size and layout of your laboratory as per the standard	
Yes	285 (71%)
No	116 (29%)
Availability of work plan and budget for a laboratory for implementing quality management	
Yes	112 (28%)
No	289 (72%)
The extent of organization use of consultants/mentors to assist with laboratory quality management system implementation.	
I don't know	210 (52.4%)
On irregular bases	179 (44.6%)
On regularly and fixed interval	12 (3%)
Permanently appointed	0

### Factors affecting LQMS implementation processes

The following potential determinates were summarized as per the opinion of the respondents' feedback rate towards LQMS implementation. The analysis was made between different factors with LQMS, the outcome variables. From those who report laboratory quality management system is implemented and having a regular proficiency testing participation was 87 (16.1), but it has 1.1 times more likely affirmative effect on LQMS implementation than laboratories with incomplete and irregular EQA participation [1.103 (1.102-2.231)].

Laboratory Professional is having B.Sc. degree and above holders were good than having a diploma for LQMS implementation in

their health facilities. Laboratories who are staffed with trained professionals and following with high turnover were found 1.3 times more likely affected to implement a laboratory quality management system as per the standard than not trained turnover staffs [1.379, CI (1.014-1.613)].

Regarding specific allocated budget for equipment maintenance, from laboratories which did not have projected budget for adequate equipment maintenance were 217 (66.2) from the total sampled of the study, and also the result revealed that being a laboratory did not allocate a budget for equipment maintenance were 0.7 times more affected their laboratory quality management system than laboratories having a projected budget for equipment maintenance [0.742, CI (0.472-0.975)].

Among laboratory professionals who are having good adherence on the available quality documents 135 (52.7), were 0.5 times more likely best implement laboratory quality management system than laboratory professionals not comply to their quality management documents [0.522, CI (0.351-0.874)] and also laboratory professionals competent with method validation/verification and meteorological traceability were more likely have a good laboratory quality management system implementation relative to incompetent on this.

Among the participants' laboratories having good practices and knowledge of continual improvement activities like internal audit and root cause analysis were much better laboratory quality implementers than laboratories which don't have practices regularly and continual improvement monitoring system [2.763 (1.297-5.715)], [0.393 (0.171-0.9410)] (Table 3).

**Table 3:** Variables associated with the laboratory quality management system in Addis Ababa, Ethiopia, 2018.

Variables	Affect LQMS Implementation		Crude odds ratio (95%CI) COR	Adjusted odds ratio (95%CI) AOR
	Yes (%)	No (%)		
Staff turnover				
contracted staffs	0	12 (11.2)	1	
untrained staff	72 (24.5)	67 (62.6)	0.865 (0.537-1.699)	1.630 (0.945-3.168)
Trained staff	222 (75.5)	28 (26.2)	0.637 (0.300-0.997)	1.379 (1.014-1.613)**
Professional educational level				
Diploma	20 (5.8)	34 (54.8)	0.532 (0.354-0.787)*	1.164 (0.825-1.563)
BSc degree	109 (32.2)	15 (24.2)	0.601 (0.455-0.821)*	1.432 (1.010-2.012)**
MSC degree and above	210 (62.0)	13 (21.0)	0.752 (0.544-0.966)*	1.957 (1.318-2.948)**
Resource managing related				
Projected budget	59 (18.0)	11 (15.1)	1	1
Lack of adequate equipment Maintenance	217 (66.2)	45 (61.6)	2.620 (0.968-4.056)*	0.742 (0.472-0.975)**
Regents and supplies	52 (15.8)	17 (23.3)	1.048 (0.555-1.979)	0.684 (0.540-1.073)
Adherence on the available Quality documents				
Good	135 (52.7)	76 (52.4)	0.606 (0.245-0.901)*	0.522 (0.351-0.874)**
Fair	93 (36.3)	29 (20.0)	0.741 (0.479-1.047)	
Poor	28 (11.0)	40 (27.6)	1	
Knowledge and skills (competency) on				
Document preparation	37 (13.3)	16 (25.4)	1	
Method Validation and verification	131 (26.6)	27 (42.9)	0.088 (0.046-0.168)*	0.085 (0.044-0.166)**
Measurement Uncertainty	151 (45.3)	16 (25.4)	0.574 (0.318-0.099)*	0.621 (0.284-0.984)**
Meteorological traceability	19 (14.6)	4 (6.3)	0.798 (0.461-1.308)	0.733 (0.423-1.560)
Work load				



Specific on LQMS	94 (34.0)	78(62.4)	1	
Routine	182 (66.0)	47(37.6)	0.368 (0.268-.641)	
<b>Continual improvement activities</b>				
Internal auditing	119(39.8)	23 (22.5)	3.879 (1.399-5.924)*	2.763 (1.297-5.715)**
Risk assessment	42 (14.0)	17(16.7)	1.376 (0.843-3.213)	1.323 (0.592-2.629)
Management review	22 (7.4)	19 (18.6)	0.876 (0.371-1.795)	0.891 (0.439-2.231)
Root cause analysis	107 (35.8)	26 (25.5)	0.423 (0.164-0.813)*	0.393 (0.171-0.941)**
Monitoring quality indicators	9 (3.0)	17 (16.7)	1	
<b>Participation on EQA</b>				
Completely and regularly	87 (16.1)	25 (36.8)	2.289 (1.040-3.108)	1.103 (1.102-2.231)**
Incomplete and irregular	246 (73.9)	43 (63.2)	1	

\* Indicate  $p < 0.05$  in case of crud odds ratio; \*\* indicate  $p < 0.05$  in case of adjusted odds ratio

### Result summarized from the key informant interview

Considering to backing the quantitative data, key informants interview were conducted and collected from the quality manager and were health facilities of upper management members using an open-ended in nature and primarily focused factors affecting for the implementation of the quality management system, the involvement of professionals in LQMS implementation, accountability for LQMS system. Most of the participants (6 of 7) agreed as “laboratory quality management is a very important program but because of the erratic reagents, supplies and consumable supply system in the city ,plus there is no equipment service engineer or trained biomedical engineer for resolving our non-functional analysers, and there are clear gaps regarding method validation/ verification, performing a root cause analysis, measurement uncertainty and also on metrological traceability among our laboratory professional, despite these there is high alteration rate of trained staffs”.

They also respond as “We have irregular mentoring and coaching program from the regional laboratory, but it is not strong because we are involved in many duties including the routine and also the assigned mentors were come to as without preparation, so it should be prepared, and there should be a regular mentor or consultant”.

Even though most medical directors who participated in this study revealed that “...Even though we believe as the quality of laboratory tests is very vital for the medical decision, the current laboratory quality status is not in a good standard and should be enhanced into international standard, ISO15189”.

### DISCUSSION

This study was designed to assess the laboratory quality management system implementation status and identifying

factors affecting the implementation in Addis Ababa Public Health Laboratories. Addis Ababa, Ethiopia. This study reported that 381 (95%) respondents that had been an effort on the implementing laboratory Quality Management System in their laboratories which is not agreed a study done by Hamid's and Adino et al. did not have good awareness inadequate competency on the LQMS standards and related technical guidelines based on international standards fail to consider a country's context and fail to smooth the progress of accreditation and hard to apply in real laboratory settings [22-29].

Despite there is in need, and there was still a gap in the quality management system implementation ,the current study note a positive success on the laboratories scored as SLIPTA scoring star 1 to star 4 and also among them there were ISO 15189 laboratory accredited, and the performance in this context was relatively higher than laboratories in most East African countries, these may be the reason that the Ethiopian ministry of health set as a rule pushing SLMTA graduated laboratory to Ethiopian National Accreditation Office (ENAO) for ISO15189 accreditation [28].

The current study found significant association between laboratory quality management system and the resource allocation for adequate equipment Maintenance laboratory did not allocate a budget for equipment maintenance were 0.7 times more affected their laboratory quality management system than laboratories having a projected budget for equipment maintenance ,which is concordance view with study done in Ethiopia Waju Beyene , Challi Jira, Morankar Sudhakar which is 86 (62.8%) of major equipment requirement were not comply with the national standard and also done by Gershy et al. [16,18].

This study revealed a positive attitude and only 112 (28%) respondents respond as having a specific budgetary allocation for executing their laboratory quality management system implementation on laboratory quality management system as they thought it produced valuable change at all levels of the health system. However, there were several concerns including the bureaucratic, prescriptive nature of the accreditation process, not using a consultant as well as the financial burden, it imposed on health care facilities as a similar study done by Alkhenizan et al. and Adino et al. [22,29].

In this study, 87 (16.1) participated regular proficiency testing which had 1.1 times more likely positive effect on LQMS implementation than laboratories with incomplete and irregular EQA participation as comparable study done by Ashebir et al as EQA failure rates of 63.8% and there was no continuous improvement raised from it other than participation, which is contrary to the ISO 15189: 2012 requirement [30,31].

Contrasting the importance of consultant mentorship, in this study there is little utilization of consultant mentor, 12 (3%), summarized from this study as irregular mentoring and coaching program from the regional laboratory but it is not strong because we are involved in many duties including the routine and also the assigned mentors were come to as without preparation, which is comparable finding as facilities getting adequate mentorship were found 2.5 times more likely to get good LQMS implementation than which did not get it by Abay et al. and Hamid et al. [6,23].

Laboratories are having good practices of continual improvement activities like internal audit, measurement uncertainty, method validation/verification, and root cause analysis were much better laboratory quality implementer than laboratories which doesn't have practices regularly and continual improvement monitoring system [2.763(1.297-5.715)], [0.393(0.171-0.9410)], which aligned with study conducted by Guevara G et al., Bella H et al., and Donovan M et al. and also there is backing data of qualitative finding demonstrate that these are critical and most challenging factors for implementation of LQMS, thus, laboratories should work on these ahead for to establish and solidify laboratory quality management systems and to help laboratories achieving quality laboratory service to the users [25-27].

Finding from this study revealed that adherence to laboratory quality management documents and regular monitoring of their activities as per the quality indicators were found directly related to the laboratory quality management system implementation, that the findings may be given detailed by the presence of such a system may augment the high participation of trained laboratory professionals in reviewing and monitoring of quality indicators by adhering their stated quality policy manual which is the most splendid drive for the implementation of LQMS in their facilities [6,11,13].

In this study workload was not found significantly associated with laboratory quality management system implementation, they wondered what advantages accreditation could bring for them, as data gathered from the qualitative part, as similar finding noted by both Hamid in Iran in 2014 and Donovan et

al. in Jamaica in 2010 found lack of motivation of laboratory professionals to be a significant obstacle for laboratory quality management system [23,24,27]. In contrast, a study from Lebanon by Fadi et al., found that accreditation was a driven force for to better quality performance [32].

## CONCLUSION

The study was conducted laboratory quality management system implementation status and identifying factors affecting the implementation in Addis Ababa Public Health Laboratories. Addis Ababa, Ethiopia and the finding revealed that method validation and verification, root cause analysis, Equipment maintenance related issues, participation in an external quality assessment program, measurement uncertainty analysis, evaluation and assessment (internal audit), trained staff turnover had a significant association with LQMS implementation of Addis Ababa health laboratories. Hence, investing and due attention should focus on identifying factors that can intensify and improve laboratory quality management system implementation that can direct opportunities to excel in the performance of quality laboratory service to the beneficiary in the city.

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