ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF ALLIED HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Major Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Government Hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia

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This is to certify that the thesis prepared by Mekonnen Girma, entitled: ***Major Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Government Hospitals of Addis Ababa, Debrebrhan, Bishoftu, Ethiopia*** and submitted in Partial fulfilment of the requirements for the Degree of Master of Science in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance specialty track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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List of abbreviations

CABs	Conformity assessment bodies
ENAO	Ethiopia national accrediting office
EQA	External quality assessment
FMHACA	Food, medicine and Heath Care Administration and Control Authority
IHR	International health regulations
ISO	International organization for standardization
LMIC	Low and middle income countries
LMIS	Laboratory management information system
LQMS	Laboratory quality management system
NABs	National accrediting bodies
NHRL	National Health and research Laboratory
PFSA	Pharmaceutical fund and supply agency
PHC	Primary Health care
PT	Proficiency testing
QMS	Quality management system
QSE	Quality system essentials
SLIPTA	Stepwise Laboratory improvement process towards accreditation
SLMTA	strengthening Laboratory management towards accreditation
TAT	Turnaround time
UHC	Universal health coverage
WHO	World health organization
WHO-AFRO	world health organization regional office for Africa

Abstract

Background: Numerous global initiatives in Africa have focused on clinical laboratory harmonization and standardization, and accreditation. Though accreditation has many advantages and advocated largely, it is still challenging for the laboratories to fulfill all requirements and the criteria of accrediting bodies. So identifying the different challenges faced by the laboratories during the process of accreditation is important for proper planning and action to resolve those challenges.

Objective: To assess the major challenges of Medical Laboratories for ISO 15189 accreditation in selected government hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia.

Method: Cross sectional study design using qualitative and quantitative data collection approach was used from March to May 2017. The data for this study was gathered using structured questionnaire and in-depth interview. Stratified-proportional sampling technique was used. Data was entered, cleaned using EPI-Data 3.1 and exported to SPSS version 20 software for further processing and analysis. Simple descriptive statistics like percentages and frequency was used. The qualitative data from in-depth interview were categorized and discussed.

Result: In this research 175 questionnaire respondents and 24 key informants from 12 hospitals were included to identify the major challenges facing medical laboratory's accreditation process. All respondents had awareness about the accreditation process but only 79% of them have involved in the process in one or more ways. More than half of the respondents (51%) had training experience related to either laboratory LQMS or ISO accreditation. High turnover of trained and experienced laboratory professionals for better job opportunity and education was reported to mainly affect the accreditation process. Routine work load, poor equipment quality, shortage and quality of laboratory supplies, inconsistent mentorship and training, strict assessment process and low attention and commitment from top management were among the major challenges identified.

Conclusion: Even though there exists an effort to fulfil accreditation requirements, achieving and maintaining accreditation was still challenging for many facilities due to; trained staff turnover, training and mentorship inadequacy, low staff satisfaction, low quality and quantity of equipments, low top management support, and poor quality laboratory facility. This study highlights the need for stronger engagement, commitment and advocacy with all stakeholders to harmonize and lead accreditation program effectively.

Keywords: LQMS, accreditation, challenge, ISO 15189, SLMTA/SLIPTA, Medical laboratory

1. Introduction

1.1. Background

Many low- and middle-income countries (LMICs) are currently pursuing health care reforms to achieve universal health coverage (UHC). However, gaps in health care quality threaten this objective [1, 2]. Despite serious resource limitations, there is a growing belief that strengthening health care quality in LMICs can have an important impact [3]. A 2012 Salzburg Global Seminar identified priority challenges in ensuring healthcare quality and safety in LMICs and developed a consensus statement that calls for governments to adopt and promote quality improvement as a cornerstone for better health for all citizens [4].

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 [5]. Numerous global initiatives in Africa have focused on clinical laboratory harmonization, standardization, and accreditation [6].

Developed countries easily adopt their well-organized routine laboratory services [7]. However, for a long time, laboratory services were not considered a priority for most resource-limited health care systems in Africa due to poor infrastructure, low human resource capacity and inappropriate technologies [8]. The need for building laboratory diagnostic capacity in Africa has been well articulated over the recent past [9, 10].

International health regulation (IHR-2005) obligates World Health Organization (WHO) Member States to establish mechanisms for providing reliable and timely laboratory identification and characterization of infectious agents. Developed countries with well-organized routine laboratory services can easily meet this core capacity through existing systems. However, resource-limited countries, especially those in sub-Saharan Africa, need considerable capacity building [10].

Although there is a general improvement in infrastructure and service provision in sub-Sahara Africa challenges still exist, including the lack of sufficient numbers of well-trained laboratory scientists in public health service and inadequate laboratory management and leadership skills [11].

Little efforts have been made towards assisting laboratories to attain international standards such as ISO 15189 and hence slow progress to accreditation [12]. To provide quality clinical information, Laboratory accreditation is a widely accepted process of evaluating of a laboratory's quality in which an authoritative independent body gives formal recognition that the laboratory is competent to carry out specific tasks [13]. Accreditation also increases the credibility of the results and services delivered by a laboratory through providing recognition that it is compliant with quality [14].

Accredited laboratories can become more accountable and less dependent on external support. Accreditation may, thus, provide an effective mechanism for health system improvement yielding long-term benefits in the quality, cost-effectiveness, and sustainability of public health programs [15].

ISO 15189, a laboratory standard from the International Standards Organization (ISO), specifies quality management system and competency requirements for medical testing. Based on ISO/IEC 17025 and ISO 9001, it has gained widespread recognition as a reference standard for accrediting medical laboratories. For example, the recently launched WHO Regional Office for Africa has harmonized its assessment tools to ISO 15189, and laboratories working through the program will progressively develop compliance to this standard [15].

According to a review from sub-Saharan Africa, achieving practical and sustainable laboratory accreditation was a major challenge in Africa owing to lack of leadership, attention, resources and commitment across all management levels [16]. The accreditation approach has not yet been user-friendly, as most laboratories found it difficult to achieve quality improvement and accreditation as a package without employing a staged or stepwise approach [17].

As some researches done in Ethiopia suggest, almost all laboratories were not establishing quality management system according to expected standards and they were far from accreditation requirements. Even if most of the laboratory professionals believed in the benefit of accreditation for improvement of laboratory quality services, the practicing of quality system essential elements was poor and as result status of most laboratories towards of accreditation were below the minimum requirement by WHO-AFRO Accreditation Process [18]. Among the most important contributing factors that were reported for not scoring expected WHO-AFRO star level, were shortage of resource and lack of regular equipment service maintenance [18,19].

1.2. Statement of the problem

As many low- and middle-income countries (LMICs) pursue health care reforms in order to achieve universal health coverage (UHC), development of national accreditation systems has become an increasingly common quality-enhancing strategy endorsed by payers, including Ministries of Health [20]. According to the WHO Regional Office for Africa report, laboratories within the African Region need to expand in order to support the expansion of disease prevention and control services. However, most laboratories in the Region are not only poorly resourced but also operate with limited capacity [21].

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 gaps in the strengthening of laboratory services and systems in some African countries, such as poor laboratory infrastructure, lack of laboratory networks, equipment or their maintenance, shortage of well-trained laboratory staff and weak supply chain management systems [20].

Implementation of laboratory standards is verified through the process of accreditation [21]. However, achieving practical and sustainable laboratory accreditation was a major challenge in Africa owing to lack of leadership, attention, resources and commitment. So accreditation standards must encourage improved performance, while at the same time being achievable and not overly prescriptive [20].

Of over 340 accredited laboratories in Africa, 312 (92%) were located in South Africa. But outside South Africa, accreditation has mostly been achieved in private laboratories or where there is involvement of external funding [16, 21].

According to I-TECH 2015 success story report, until recently, the majority of Ethiopian public health laboratories delivered suboptimal service, and were thus not in a position to contribute to a quality health care system. Many of them performed poorly, hindered by dilapidated infrastructure, and poor development and implementation of laboratory quality-management systems (LQMS) [22]. Despite the availability of some researches done and the ongoing efforts, the accreditation of only few laboratories in the country calls for thorough assessment of the challenges of medical laboratories for ISO accreditation in order to act appropriately. So the current research tried to identify those challenges slowing medical laboratories from achieving ISO 15189 accreditation status.

1.3. Significance of the study

Though accreditation has many advantages, it is still challenging for the laboratories to fulfill the accreditation criteria of accrediting bodies. Patients, government bodies, and regulators must have confidence in the data generated by laboratories in order to make evidence based decisions in health care service delivery. An accredited laboratory can help to establish and assure this confidence. So identifying the different challenges faced by the laboratories during the process of accreditation is important to work on and resolve those obstacles. As this research aimed to identify the major challenges that medical laboratories faced to fulfill ISO 15189 requirements, the finding will be so informative and problem solving to be used by the laboratories and stakeholders to work on their challenges and strive to be accredited.

2. Literature review

2.1. Attitude and perceptions related to Accreditation process

A systematic review on the attitude of health care professionals towards accreditation reported that, most laboratory professionals felt that accreditation had resulted in better laboratory performance with more documentation and better safety and training procedures. Accreditation was believed to provide useful information by approximately 50 percent of laboratory professionals but was also felt by a significant proportion to be over-bureaucratic, inefficient and expensive. A large majority (85-90%) considered that their workload was increased by the accreditation process. In two laboratories, the technologists did not think that the accreditation process had improved the quality of the results. Accreditation was perceived to have increased paper work, discrepancies between the procedures and the reality, more attention is paid to the formalities than to the quality of the results [23].

According to a qualitative study in Iran on Assessors' attitudes toward and experiences of national quality standards, the most significant challenges were lack of motivation of laboratory professionals, shortages in both financial and human resources. Some believed that laboratory professionals were not adequately informed about the quality standards and its necessity. Some participants pointed out that lack of motivation in the laboratory staffs was due to lack of support from laboratory senior management and weak quality culture. A large majority of the assessors believed that more assessors are needed to increase both frequency of assessment and the hours spent by the assessors in the laboratories. Lack of incentives for the assessors and inadequate policy-level support for accreditation also perceived as important factors affecting the assessors' dissatisfaction. Building quality culture to encourage quality standards implementation, personnel involvement and motivation, paying high attention to laboratory personnel training, development of better interactions between assessors and laboratory professionals were the proposed solutions for the mentioned challenges [24].

According to a review in 2012, even if the percentage of accredited medical laboratories is still small in Europe, their accreditation is primarily according to ISO15189. The reviewer added, currently, accreditation is mandatory only in France. However, the added value of accreditation is recognized by more countries as indicated by the fact that it is obligatory for high-risk tests, i.e., molecular genetics in Belgium, newborn screening in Germany, and human genetics in Swiss. As revealed in a questionnaire sent to all European national accrediting bodies (NABs) in 2009, differences were noted in frequency of assessment, surveillance visits, as well as in the

hours spent by the assessment team. Some of the differences originate from the difference in the content of tests in different countries. Apart from the economic consequences, it is questionable if this is a real problem concerning the validity of accreditation. This review underlined that medical laboratory professionals should be involved in all levels of the accreditation process. It starts with working in ISO Technical Committees. ISO TC212, who prepares the ISO15189, started originally because of the need felt by the professionals for a specific standard for medical laboratories [25].

A qualitative study was done in Iran to compare laboratories directors' and Assessors' opinions regarding challenges and solutions of standardization. Both assessors and laboratories' directors had a positive attitude towards the standardization process and acknowledged it as a tool for quality improvement. Overly bureaucratic, time consuming, inefficient, costly, and increased workloads and stress for laboratory staffs were considered as major challenges by assessors. The laboratory directors rated, costly processes as the most challenging, followed by time consuming, high paper workload, and lack of shared. Solutions suggested by both groups include introducing strategies to raise better understanding of the standardization process and adopting a stepwise approach. They also indicated, revising and updating standards, related checklists and the technical guidelines based on the international standards considering the country's context and situation as well as learning from experiences of the previous assessment runs. Lack of motivation, inadequate information about the quality standards, lack of support from laboratory senior management and weak quality culture considered by the assessors among the major challenges. financial problem, high workload, inadequate number of laboratory personnel, and high rate of staff turnover were the most frequently mentioned factors by laboratories directors. [26].

Qualitative study was conducted in South Africa on 'The need for a quality standard for assurance in medical research laboratories'. The study participants commented that, training and competency areas require more flexibility. Certain aspects of the current ISO 15189 standard e.g. competency and external quality assessment as well as safety could be kept in a new standard which would be made more flexible for research laboratories. Comments about ambiguity included the standard is open to understanding depending on the implementer and accrediting assessor. This means auditors see things differently as opposed to people actually working in the laboratory and their interpretation as well as their checklists varies. As this article stated,

adopting laboratory standards and accreditation for their laboratories would entail more administrative work and thus leave less time for research work, additional documentation is required for accreditation and quality maintenance purposes. There have been also complaints regarding paperwork by scientists; they believe that all the paperwork decreases their productivity and personnel feel that accreditation or standardization will limit research capacity and creativity. As it has direct impact on patient management, ISO15189 is most appropriate and suitable for medical diagnostic laboratories whereas neither is relevant for research laboratories. [27].

2.2. Challenges (factors) affecting accreditation process

According to the review in Canada on the value and impact of accreditation in health care, achieving and maintaining accreditation status requires a significant investment of resources. For many organizations, there may be a question as to whether accreditation is worth the time, effort and cost, as well as whether or not it demonstrates a quantifiable improvement in healthcare delivery and outcomes. In this review the identified benefits of accreditation are viewed as: enhancing patient safety, ensuring an acceptable level of quality among health care providers, stimulating sustainable quality improvement, increasing reputation among end users. The review indicated the major challenges as accreditation process being stressful, time consuming, and requires a serious investment of resources. It was reported that accreditation takes time to adapt and changing the concepts of quality and performance [28].

Study conducted on the impact of SLMTA in improving laboratory quality systems in the Caribbean Region explained, ensuring a sufficient number of well-qualified laboratory workers is an ongoing challenge. This is exacerbated by high levels of attrition as staff that have benefitted from government-supported training leave the public sector for more lucrative jobs in the private sector, either locally or overseas. Thus, the remaining staff are overworked, reducing the amount of time available for training and quality improvement activities. The authors added that there is also a shortage of qualified mentors. Encouraging governments in the region to prioritize health system– strengthening strategies that lead to staff development and retention was mentioned to benefit not only laboratories, but the health system overall. The authors recommended, considerable funds needed to be invested. Establishment of in country or regional SLMTA trainers and mentors would build local capacity and help reduce program costs, especially as the program expands [29].

Another study done in Lebanon stated that improvements in quality were reflected by the increase in customer. As findings revealed, strategic quality planning, customer satisfaction and staff involvement were associated with better scores on quality results. The authors investigated, accreditation has been linked with improved staff satisfaction of quality management and planning. It has also been linked to leadership styles and training of staff members was mentioned to be essential for overcoming resistance for the accreditation process. Insufficient resources and staff, unpredictable drug supplies and faulty equipment were some of the key challenges facing the study groups. Furthermore, high staff turnover and workload, and the absence of a referral system were major challenges to implementing some of the accreditation standards [30].

A research done in china also showed that, when laboratories first established a management system according to requirements of ISO 15189, time is required for staff to buy in the idea of accreditation and be familiar with the requirements. In this research non-conformities were reported against issues of document control, use of obsolete documents, or carrying out procedures not as documented which shows time is required for some laboratory staff to change their usual practices. As the article clearly stated, some staffs still do not realize the usefulness of these requirements and consider them as only unnecessary extra work required by the accreditation body [31].

Various barriers to accreditation were reported by a study conducted in Jamaica including cost, lack of staff motivation, unclear requirements and challenges with the interpretation and implementation of ISO 15189:2007 standards, lack of support from management, and absence of a quality manager. The most significant barrier was unclear requirements and challenges with interpretation and implementation of ISO 15189. As it is stated in the specified research article, the costs involved in accreditation can be cause for serious concern for all laboratories, particularly for smaller laboratories or laboratories that offer a broad range of testing services. One of the major costs involved is the acquisition of new equipment especially auto-analyzers due to majority of laboratories in this study had acquired new equipment in their preparation for accreditation [32].

Another study on implementation of the WHO-AFRO Stepwise Laboratory Quality Improvement Process towards Accreditation reported that, of 159 laboratories, 145 (91%) achieved at least one star, 57 achieved two stars and 2 (1%) received five stars as per the

SLIPTA checklist. According to this research, two SLIPTA-audited laboratories, the National Tuberculosis Reference Laboratory in Maputo, Mozambique and the Princess Marina Hospital Laboratory in Gaborone, Botswana, have since attained international ISO 15189 accreditation. This indicates laboratories in Africa still need to strive to fulfill accreditation requirements. The article also suggested, although the SLIPTA process has been widely accepted by most countries and notable improvements made, the majority of laboratories have yet to reach international accreditation readiness. To reach their goals, country specific strategic planning with committed resources for infrastructure, human resources and training in laboratory quality improvement and structured laboratory mentoring are all part of continuous quality improvement and accreditation preparedness [33].

Research article on Piloting Laboratory Quality System Management in Six Health Facilities in Nigeria showed that, only two of the laboratories attained 1- star rating at baseline while the remaining four were on 0- star level. During the follow up audit, one of the laboratory moved from 1- star to 2-star, one moved from 1- star to 4- star, two from 0 to 3- star and the remaining two from 0 to 4- star rating. Four of the labs at exit audit were on 4- star and two on 2-star rating. As this article stated, overall, there was a significant improvement in the assessed QSE over the entire period of intervention. The study identified attitudinal issues in the staff, demonstrated through reluctance to cooperate and comply as they consider LQMS implementation as an additional burden (especially paper work burden) and not part of routine work [34].

Study conducted in Lesotho on management towards accreditation showed that only one (4%) of the 25 enrolled laboratories had at least a 1-star status rating at baseline out of a possible 5 stars. However, by January 2011, 17 (68%) had achieved a star rating, with four of the laboratories reaching three-star status. The results indicate that there was a measurable improvement over the 12-month period of SLMTA. One laboratory had a negative improvement of 6% because of unexpected staff departure: the supervisor, who was in the SLMTA program was transferred to another duty station which shows the impact of trained laboratory professional on the accreditation process. As stated in this research, laboratories were weaker in some areas than others. In particular, internal audits, management reviews, corrective actions and process improvement, showed the lowest average scores. The program also faced some challenges, from the perception of the participants to the process; it was indicated that improvement projects consumed a lot of time and could not be carried out during the course of their normal working day [35].

According to a research done in Kenya on ‘Attaining ISO 15189 accreditation through SLMTA’, at the baseline audit i.e., before SLMTA implementation, the laboratory scored 45%, corresponding to zero stars. After gaps were identified in all 12 QSEs and improvement projects were undertaken to address those problems, the laboratory more than doubled its score to 95%, earning five stars. Three years after initiation of SLMTA, the laboratory achieved accreditation to ISO 15189. As the authors of this article emphasized, the success was due to building a team with a shared vision and all strived to meet ISO 15189 requirements. The SLMTA trainees shared their projects with all staff, whom then took up responsibility which helped to prevent the mentality that quality improvement was ‘someone else’s job’ and ensured shared ownership of the process. Mentorship and continued focus on accreditation after SLMTA was also explained as key factors for the laboratory to reach even higher levels. Many critical challenges were mentioned in this article. Among serious problem that remains unsolved were staff attrition and cost; approximately US$36 500 used in pursuit of ISO 15189 accreditation, in addition to that spent by the Ministry of Health on SLMTA training and by partners for mentorship and additional training [36].

Another research done in Ethiopia by Eyob A. and his colleagues on “The status of medical laboratory towards of AFRO-WHO accreditation process in government and private health facilities in Addis Ababa” suggested, although majority of the laboratory professionals had knowledge on laboratory quality system essentials and accreditation and that they believed the laboratories have a capacity to be accredited, almost all laboratories were not establishing quality management system according to expected standards and they were far from accreditation requirements. As the authors added, even if most of the laboratory professionals believed in the benefit of accreditation for improvement of laboratory quality services, the practicing of quality system essential elements was poor and as result status of most laboratories towards of accreditation were below the minimum requirement by WHO-AFRO Accreditation Process. In this study majority of laboratories scored less than 50% in the quality system essential elements especially the situations were worst in the areas of internal audit, corrective action, occurrence management, document and records, management review, organization and personnel, and clients management. Absence of laboratory policy, poor management commitment, poor resource allocation, poor laboratory designing, lack of knowledge, and shortage of supplies were mentioned to be the possible causes [18].

In a study done to assess the outcome of Strengthening Laboratory Management Towards Accreditation (SLMTA) on laboratory quality management system in city government of Addis Ababa, 76% of the respondents disclosed that their facilities have no work plan and budget for laboratory specific purpose. Lack of resources accounted 24%, which is followed by absence of system for addressing laboratory issues in the health system. Lack of enough equipment was stated by 105(73.4%) of the participants while 115 (79.9%) of them disclosed the laboratory equipment were not serviced according to the schedule in the laboratory because of poor resource allocation. Laboratory design and size was observed as not adequate enough for laboratory operation due to the poor engineering lay out of the laboratory. Due to lack of motivation it was reported that 27(18.8%) the laboratory did not communicate regularly with upper management. Moreover, 54(37.5%) of the laboratory professionals did not conduct their customer satisfaction survey because of poor staff communication and poor resource allocation. The authors reported that, there is a statistically significant association between the outcomes of SLMTA with regular staff meeting, getting adequate training on how to implement SLMTA, coaching and mentoring, assessment of customer satisfaction, availability of enough equipment, equipment routinely serviced, and workload [19].

According to a research article by Tilahun M. *et al* on "Laboratory system strengthening and quality improvement in Ethiopia", laboratory managers and quality officers pointed out several challenges to successful implementation of improvement projects. Of the challenges, poor awareness of the program by upper management and regional health bureaus (i.e., SLMTA was not budgeted), lack of harmonization with other hospital improvement programs, inadequate awareness of quality management systems and insufficient commitment amongst non-SLMTA-trained staff, high workload relative to available staff; lack of quality manuals prescribing laboratory policies and procedures, and inadequate supportive site visits are the most ones mentioned in this article [37].

A research done by Yemisrach R. on the 'Assessment on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Implementation Progress in Public Health Facility Laboratories from 2013 to 2015" stated greatest improvements during 18 months were in corrective action (66%), organization and personnel (55%) and purchasing and inventory (54%) while the least improvement were process control (18%), occurrence management (25%), internal audits (30%) and equipment (36%). The researcher explained that, the presence of training based on SLMTA, LQMS and Safety were factors to have good progress. The main

identified factors or challenge in this study were, documents and records are not properly maintained and not easily in an up-to-date Master List with Archived records and results are not easily retrievable in a timely manner. Absence of annual management review meeting and not routinely performing a documented review are gaps on the management section (38).

Another research was conducted by Kefelegn B. on the 'Assessment on the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) Implementation in Selected Public Hospital Laboratories in Ethiopia'. The main challenges identified by the study were; high turnover of trained laboratory professionals, especially those who had a skill in quality-management, in SLIPTA, in biosafety and high attrition rate of dedicated staffs that cause a delay in the SLIPTA process which leads to stretching of the laboratory head and quality officer due to more assignment. According to this study the numbers of staffs were enough for zero star laboratories, but there was a skill gap and individuals did not contribute their time, effort, knowledge, due to demotivation. Reasons identified were low salary, no risk payment, no overtime payment; and no good laboratory equipment and no enough training (39).

Despite some researches done in Ethiopia, the information is still limited regarding the major challenges of medical laboratories for ISO accreditation. This study tried to address this gap.

3. Objectives

3.1. General objective

To assess major challenges of medical Laboratories for ISO 15189 accreditation in selected government hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia from March to June 2017.

3.2. Specific objectives

- To describe the perception of laboratory professionals about degree of implementation of LQMS
- To describe the perception of laboratory professionals on the factors affecting accreditation process
- To identify recurrent hindrance for ISO 15189 accreditation process across studied laboratories
- To describe suggested solutions for the identified challenges

4. Materials and methods

4.1. Study Setting

The study was conducted in government Hospitals found in Addis-Ababa city, capital of Ethiopia, with the area of about 540 square kilo meters. According to 2007 census report the population is enumerated to be 3,384,569 [40]. There are 6 regional, 5 federal (including one university hospital), 2 NGO-supported, 30 private, 1 defense, 1 prison and 1 police hospitals 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 [41, 42]. The study also included those hospitals in close proximity of Addis Ababa, namely, Debrebrhan Hospital and Bishoftu Hospital. Debre Berhan town is the capital city of North Shoa zone and it is located 130 kilometers from Addis Ababa to the North East, with total population of 94,829. In the town there are about 22 health facilities, two hospitals (one private and one referral governmental hospital), 3 health centers, and 17 private clinics [43]. Bishoftu Hospital is located 47 Km away from Addis Ababa. It provides health care services for outpatient, in-patient and comprehensive services for three towns (Bishoftu, Modjo and Dukem) with more than 1.2 million catchment population [44].

4.2. Study Design and Period

A Cross sectional study design using qualitative and quantitative data collection approach was used from March to June 2017.

4.3. Population

4.3.1. Source population

Government Hospital laboratories that are found in Addis Ababa city, Debrebrhan town, Bishoftu town and laboratory professionals working in those hospitals were source population for this study.

4.3.2. Study population

Government hospital laboratories found in the study area, that were participating in SLMTA/SLIPTA program and applied or received ISO 15189 accreditation and laboratory professionals working in those laboratories were the study participants.

4.4. Inclusion criteria

- Government hospital laboratories found in the mentioned study area, volunteer to participate in this study, and which were participating in ISO 15189 accreditation process directly or in a stepwise approach were included.

- Laboratory professionals who had at least 6 months of experience in that particular laboratory and who had consented to be involved in this study were included.

4.5. Study variables

4.5.1. Dependent variable

ISO 15189 accreditation process

4.5.2. Independent variables

- Trained staff turn-over
- Mentorship
- Staff training in LQMS
- Management commitment, support and awareness about ISO accreditation process
- Resources
- Work load
- Staff Attitude
- Infrastructure

4.6. Measurement and data collection

4.6.1. Sample size determination

Government hospital laboratories that were found in the study area and fulfilled the inclusion criteria were studied. Laboratory department heads, quality officers, and medical directors were selected purposively. The sample size for questionnaire respondents aiming to point out the determinant factors for the challenges of accreditation was determined by using single population proportion formula. Because of the lack of related previous studies, p=50 % was taken, Level of significance = 0.05 Marginal of error (d) = 5%, Z-score at 95% confidence interval = 1.96.

$$n= \frac{(Z\alpha/2)^2 P (1-P)}{d^2}$$

$$n= (1.96)^2*0.5*0.5/ (0.05)^2=384$$

where: n =is initial sample size

$Z\alpha/2$ = Z score in a normally distributed curve at 95% confidence interval

P = proportion of the cases

d = maximum allowable error

Based on current information from each hospital laboratory, a total of 295 laboratory professionals were available in 12 selected hospitals. Since the calculated sample size was

greater than the total respondents, correction factor was done based on the finite population formula (nf), therefore the sample size was reduced to;

$n_{corrected}$ = n/1+n/N= 384/ (1+384/295) = 167, adding 10% non-response rate total sample size was 184.

4.6.2. Sampling Method

Purposive sampling technique was used to select the hospitals by considering their participation in the accreditation process. For the reason of confidentiality code was assigned for each hospital using English alphabet from A-L. From each hospital, the laboratory head, quality officer, and medical director were selected purposively for in-depth interview considering those key informants had better information on accreditation process and the questions raised. The number of questionnaire respondents taken from each Hospital laboratory was calculated using stratified proportional sampling technique. So, from each hospital the sample was taken conveniently by multiplying the number of all laboratory professionals in a given hospital by the ratio of total sample size to total laboratory professional (184/295). Figure 1 summarizes how questionnaire respondents were selected.

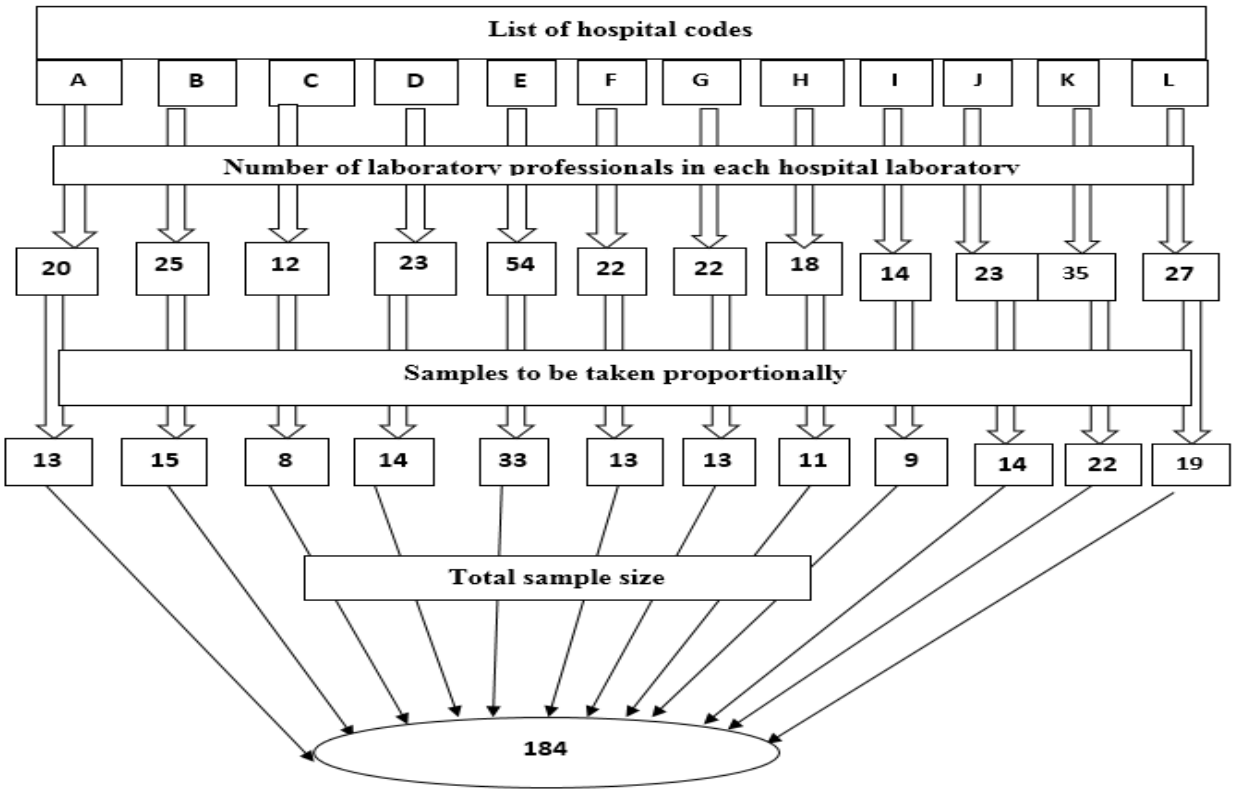

Figure 1: Diagrammatic representation of sampling technique

4.6.3. Data collection procedure

Data collection tool comprising of a questionnaire and face-to-face interview guide was used. The questionnaire was prepared based on review of the literature on implementation of quality management systems and based on ISO 15189 standard. The questionnaire consisted of four parts; part one: Information about the respondents, part two; Awareness, Participation, support by mentors, and training experience of study participants related to accreditation process, part three: perception of respondents about degree of implementing LQMS; part four: perception of respondents regarding factors affecting accreditation process. Quantitative data was collected using structured questionnaire. Qualitative data from technical laboratory professionals was obtained using open ended questions to be written by themselves. Qualitative data from laboratory heads, quality officers and medical directors was obtained by face to face interview and the information was captured using a simple tape-recorder and the response and opinion of interviewee was transcribed to a written form by listening from the record. Similar ideas from the laboratory heads, quality officers and medical directors were organized accordingly and unique opinions were organized by facility as it is differently said by that particular hospital key informant without mentioning the name. One data collector per hospital was deployed for collecting the quantitative data using structured questionnaire while qualitative data was collected by the principal investigator to obtain adequate data.

4.7. Data quality assurance

To ensure the validity of the data collection tool, pre-test was done in federal police hospital before the study period which was not included in the main study. Appropriate modification of the data collection tool was made accordingly before actual data collection was made. Adequate orientation was given for data collectors and during the data collection period completeness of data was checked through supervision by the principal investigator. After data collection, data was entered, and cleaned using EPI-Data3.1 and analyzed by SPSS version 20 software for further processing. To protect data manipulation data was stored in a password protected computer and backup was saved by flash and personal email.

4.8. Data analyses and interpretation

Data was first entered and cleaned using epi-data-3.1 and exported to SPSS version 20 software for further processing and analysis. The quantitative data was analyzed 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.

4.9. Ethical consideration

Ethical clearance was obtained from Addis Ababa University, College of Health Science, School of Allied Health Science, Departmental Research and ethics review committee (DRERC). An official letter of cooperation was also written to the study sites and Addis Ababa health bureau and permission was obtained from them. For the Hospitals under Addis Ababa health bureau (AAHB), ethical clearance was obtained from Addis Ababa Public Health Research and Emergency Management Core Process and a letter of cooperation was written to the respective Hospitals to get permission. The information collected was stored in a file, without mentioning the name of the study site (institution), but a code (letter) was assigned to assure confidentiality of the hospitals, laboratories and respondents.

4.10. Dissemination of the results

The result will be communicated to the department of medical laboratory science, Addis Ababa Public Health Research and Emergency Management Core Process, the studied hospital laboratories. Findings will be communicated to the scientific community through presentation on annual conferences of professional associations. The result will also be sent for publication to make it more available to be used by any stake holder and other researchers.

4.11. Operational definition

Challenge: The different obstacles that medical laboratories face to achieve ISO 15189 accreditation like: inadequate training, lack of resource, poor management and staff commitment

Trained staff turn-over: High attrition rate of laboratory professional who had training and experience on LQMS and accreditation.

Mentorship status: To what level that particular laboratory was supported by mentors to institutionalize and assist the laboratory accreditation process from regional or national team

Staff training: training experience of laboratory professionals related to medical laboratory QMS and accreditation.

Resources: The various resources that contribute for implementation of medical laboratory QMS or accreditation process like; human resource, financial, time, equipment, and supplies.

Work load: The routine laboratory work that makes the professionals full of activities and prevent them from accomplishing tasks that accreditation requires.

Staff Attitude: The awareness, acceptance, commitment, and engagement of laboratory professionals in the accreditation process.

Infrastructure: The design and quality of laboratory facility/set up that contribute for the quality of laboratory service and then for accreditation process.

Other technical laboratory professionals: laboratory professionals working different laboratory procedures/tests other than the laboratory heads and the quality officers.

Organizational culture: is a system of shared assumptions, expectations, experiences, and philosophy of the organization which affects medical laboratory accreditation process.

Organizational structure: how activities such as task allocation, coordination and supervision contribute for the achievement of accreditation status.

5. Result

5.1. Background characteristics of the study sites

The data was collected from 12 government hospital laboratories and laboratory professionals. Of these, 10 were hospital laboratories found in Addis Ababa while the rest 2 were at Debrebrhan and Bishoftu towns. According to the recent national and ASLM SLIPTA assessment result of each hospital laboratories, their star level is from zero star to 4 stars. Three laboratories had no star level, 2 laboratories had a star level of 4, 4 laboratories scored 2-star, and the rest 2 laboratories were at 3-star level. Of 12 laboratories visited by this study, only one was accredited by ENAO in selected tests of hematology, TB smear microscopy, and gram stain tests. As confirmed during the study period of this study, 7 laboratories were at document preparation to apply directly for ISO 15189 accreditation. Figure 2 summarizes the accreditation status of medical laboratories visited by the current study.

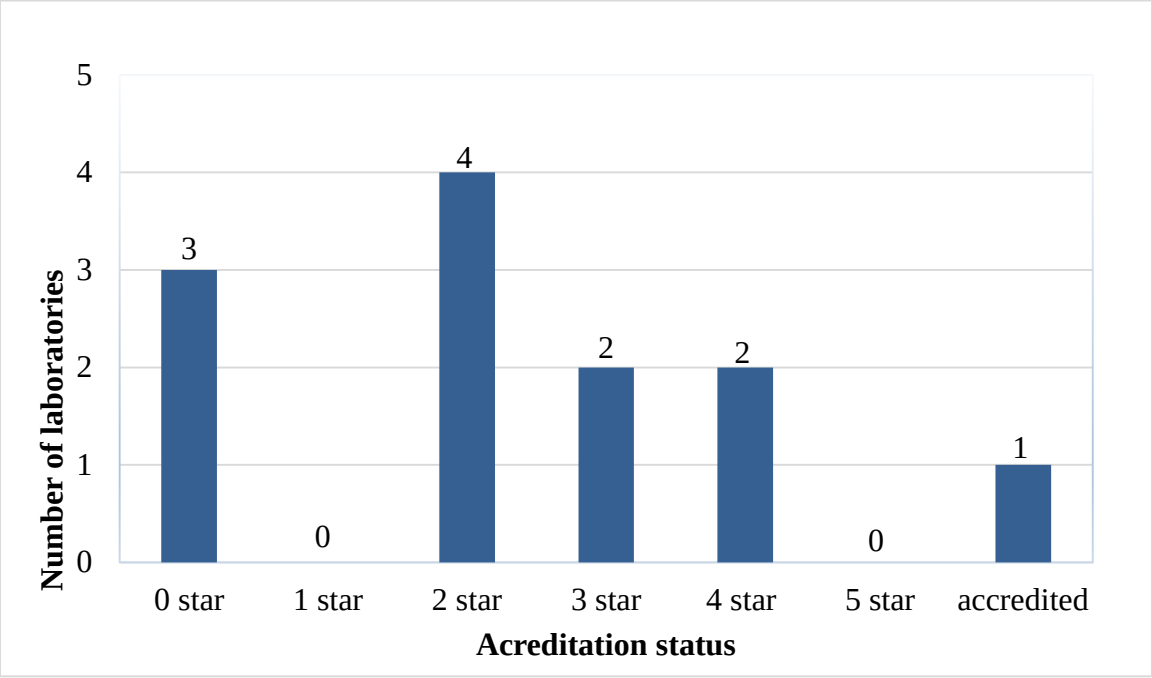

Figure 2: Accreditation status of 12 government hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia, from March to May 2017.

5.2. Background characteristics of the study participants

The population under study had varying demographic and background characteristics including sex, age, educational level, length of service, position, and distribution by department. Out of 184 questionnaires distributed, 175 were completed and submitted back to the principal investigator giving a response rate of 95 percent. For qualitative data collection, 11 laboratory head, 10 quality officers' and 3 medical directors were interviewed to forward their opinion regarding challenges of medical laboratories for ISO 15189 accreditation.

From the total respondents, 111(64.4%) were males. The age of respondents ranged from 21 to 57 of which 56 respondents belong to the age group of 26 to 30 followed by 31 respondents from 21 to 25. Majority of the respondents (55%) were BSc degree holders followed by diploma holders 28%. Working experience of the study participants in that given organization ranged from 6 months to 35 years. Regarding position of respondents in the organization, 123 (70%) were technical staffs followed by section heads 23(13.1%). Table 1 summarizes demographic characteristics of respondents.

Table 1: Background characteristics of study participants government hospitals of Addis Ababa, Debrebrhan, and Bishoftu Ethiopia, from March to May 2017 (n=175)

Variable		Number of respondents	Percentage (%)
Sex	Male	111	64.4
	Female	64	36.6
Age group of respondents	21-25	31	17.7
	26-30	56	32.0
	31-35	19	10.9
	36-40	16	9.1
	41-45	9	5.1
	>46	10	5.7
	Not recorded (missing)	34	19.4
Educational level	Msc and above	26	14.9
	Bsc	97	55.4
	Diploma	50	28.6
	Certificate	2	1.1
Experience in current organization, in years	<1	11	6.3
	1-5	95	54.3
	6-10	36	20.5
	11-15	14	8
	16-20	7	4
	≥21	7	4
	Missed	5	2.9
Position	Section head	23	13.1
	Lab manager	10	5.7
	Quality manager	11	6.3
	Technical staff	123	70.3
	Safety officer	3	1.7
	Section supervisor	5	2.9

5.3. Awareness, Participation, mentorship, and training related to accreditation process

Results of this study showed that all respondents (100%) had awareness about their laboratory's effort to seek either ISO 15189 accreditation or involvement in SLMTA/SLIPTA process. Of 175 questionnaire respondents, 138(79%) replied that they have been involved in the accreditation process, while 30(17%) of them replied that they have not been involved in the process. Of 138 study participants involved in the accreditation process, 70(40%) of them said, they were involved in document preparation followed by 36(20.6%) involved in more than one way.

Almost half of the respondents 90(51.4%) said, they had training experience related to LQMS. With regard to the extent of use external consultants/mentors, 45(25.7%) responded that external consultant engagement was at most at “very small extent” while 74(42.3%) responded consultant/mentors were used moderately and the rest 36(20.6%) perceived that their engagement was at least at “large extent’.

For low level of consultant engagement, different reasons were given but majority of them believe it was due to low support and commitment from top management. Of 36 study participants who responded that consultant engagement was large extent and very large extent, 30 of them said the support was as good as expected. Table 2 summarizes Awareness, involvement, mentorship, and training related to accreditation process.

Table 2: Awareness, participation, mentorship, and training related to accreditation process at government hospitals of Addis Ababa, Debrebrhan, and Bishoftu Ethiopia, from March to May 2017 (n=175)

Variable		Number of respondents	Percentage (%)
Awareness about accreditation process	Yes	175	100
	No	0	0
Involvement in the process	Yes	138	79
	No	30	17
	No response	7	4
Ways of participation	decision making	2	1.1
	Sensitization	4	2.3
	document preparation	70	40.0
	Auditing	1	.6
	Coordination	16	9.1
	Addressing non conformities	6	3.4
	more than one way	36	20.6
	Missing	3	1.7
Training experience	Yes	90	51.4
	No	85	48.6
To what extent your lab use external consultants/mentors	I do not know	20	11.4
	not at all	17	9.7
	very small extent	28	16.0
	moderate extent	74	42.3
	large extent	32	18.3
	very large extent	4	2.3

5.4. Perception of staffs on degree of implementation of LQMS

This section highlights the perception of staffs on the degree of implementation of some of the activities with regard to quality management system.

Slightly over 46% of the respondents affirmed that awareness creation and sensitization of staff on the benefits of accreditation was at least at “large degree”, while 25% of them said, moderately and around 23% responded as awareness creation was at most at “very small degree”. About 40% of the respondents agreed that top management commitment of the hospital was evident at least at “large degree”, while 23% of them affirmed as moderately and the rest 30% perceived that top managements’ commitment and support was evident to be at most at “very small degree”.

Close to half of study participants (48.6%) responded, the establishment of laboratory logistic systems to avoid under stock and overstock was at least at “large degree” while 28.6% of them said it was at “moderate degree” and 18.3% responded, it was at most “very small degree”. Almost 31% of respondents perceived, conducting of internal audit at planed intervals was at least at “large degree” while the other 31% of them responded it was at “moderate degree” and the rest 35.4% responded the implementation was at most “very small degree”.

The implementation of training and continual education was perceived by 43.4% of the respondents to be at least at “large degree” while 28.6% believe it was at “moderate degree” and 21% of them said it was at most at “very small degree”. Table 3 summarizes perception of staffs on degree of implementation of QMS.

Table 3: Perception of staffs on degree of implementation of LQMS at government hospitals of Addis Ababa, Debrebrhan, and Bishoftu Ethiopia, from March to May 2017 (n=175)

Questions(cases)	**No. of responses (n=175) indicating respective extent of implementation**					
	Do not know	**Not at all**	**Very small degree**	**Moderate degree**	**Large degree**	**Very large degree**
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Adequate awareness creation and sensitization	10(5.7)	13(7.4)	27(15.4)	44(25.1)	63(36)	18(10.3)
Management commitment	13(7.4)	17(9.7)	35(20)	40(22.9)	46(26.3)	24(13.9)
Quality manual development and communication	5(2.9)	4(2.3)	11(6.3)	27(15.4)	73(41.7)	55(31.4)
Laboratory logistic systems establishment	8(4.6)	14(8)	18(10.3)	50(28.6)	50(28.6)	35(20)
Conducting internal audit at planed intervals	5(2.9)	23(13.1)	39(22.3)	54(30.9)	46(26.3)	8(4.6)
Action plan development based on internal audit findings	8(4.6)	10(5.7)	14(8)	31(17.7)	75(42.9)	37(21.1)
Training and continual education implementation	12(6.9)	10(5.7)	27(15.4)	50(28.6)	58(33.1)	18(10.3)
Allocation of laboratory space designed to ensure quality	5(2.9)	9(5.1)	19(10.9)	52(29.7)	54(30.9)	36(20.6)
Adequate storage space for laboratory supplies	5(2.9)	7(4)	20(11.4)	40(22.9)	59(33.7)	44(25.1)
Adequate wash room for the staffs	7(4)	6(3.4)	13(7.4)	44(25.1)	61(34.9)	44(25.1)
Monitoring environmental conditions	7(4)	6(3.4)	11(6.3)	40(22.9)	60(34.3)	51(29.1)
System to select, purchase, and manage laboratory supplies	10(5.7)	9(5.1)	19(10.9)	45(25.7)	65(37.1)	27(15.4)
Perform independent equipment verification	7(4)	10(5.7)	21(12)	36(20.6)	72(41.1)	29(16.6)
Establishing a system to verify laboratory supplies before use	6(3.4)	6(3.4)	21(12)	44(25.1	64(36.6)	34(19.4)
Verifying new methods before introducing to routine use	10(5.7)	8(4.6)	20(11.4)	40(22.9)	64(36.6)	33(18.9)
Performing internal quality controls for all tests	1(0.6)	4(2.3)	8(4.6)	29(16.6)	70(40)	63(36)
Reviewing and releasing results by authorized personnel	3(1.7)	5(2.9)	14(8)	50(28.6)	53(30.3)	50(28.6)
Evaluating and verifying electronic LIS before using it	16(9.1)	18(10.3)	13(7.4)	48(27.40	44(25.1)	36(20.6)

5.5. Perception of staffs on factors affecting medical laboratory's accreditation process

From the study participants' opinions on the various challenges faced by medical laboratories in the accreditation process were collected and analyzed. There were divergent views on how different factors contribute to the implementation of LQMS and also on ISO 15189 accreditation process.

Of 175 respondents, 78(44.5%) stated that high cost of implementing LQMS affected ISO accreditation process considerably while 54(31%) responded moderately and the rest 36(20.6%) said, accreditation is affected by cost with a very small degree.

About 44% of the study participants responded that lack of staff participation affected accreditation process at most at "large degree", while 24% said moderately and the rest 26.8% responded it is at most at "very small degree" that lack of staff participation can affect accreditation process. Lack of support from top management was responded by 51.5% of study participants to affect accreditation process at least at "large degree", while around 27% responded moderately and the rest 20.5% said the effect in this regard was at most at "very small degree".

Regarding trained staff turnover, 40.8% of the total study participants perceived, high turnover of trained staff affected accreditation process at least at "large degree" whereas 24% of them said effect is moderate and 29.7% of them said it was at most "very small degree". On the other hand, 51.4% of the respondents said lack of adequate infrastructure affected accreditation at least at "large degree", whereas around 25% of them said the effect was moderate and the rest 21% responded it was at most very small degree.

As responded by about 51.4% of study participants, massive documentation requirements of the process affected accreditation at least at "a large degree", while 28% said moderately, and the rest 17.7% said the effect was at most at "very small degree". As also stated by 55.5% of the study participants, challenges related to mentorship contributed to slow accreditation process at least at "large degree", whereas 25.7% of them said mentorship related challenges contributed moderately and the rest 16.6% responded it was at most "very small degree".

Around 59% of the respondents said, challenges related to adequate equipment and supplies to provide uninterrupted laboratory service affected accreditation at least at "large degree" while it

was said to be moderate by 24% of them and at most at “very small degree” by the remaining 15.5% of the respondents.

Slightly more than 2/3rd of respondents believe that high burden of routine work load affected accreditation process at least at “a large degree”, while 42(24%) said moderately and 14(8%) of them perceived, routine work load affected accreditation at most at “very small degree”. Table 4 summarizes perception of staffs on the challenges affecting accreditation process.

Table 4: Perception of staffs on factors affecting medical laboratory accreditation process in government hospitals of Addis Ababa, Debrebrhan, and Bishoftu Ethiopia, from March to May 2017 (n=175)

Questions (cases)	No. of responses(n=175) indicating respective extent of challenges					
	Do not know	Not at all	Very small degree	Moderate degree	Large degree	Very large degree
	n(%)	n(%)	n(%)	n(%)	n(%)	n(%)
Cost of implementing LQMS	7(4)	12(6.9)	24(13.7)	54(30.9)	51(29.1)	27(15.4)
Organizational culture	13(7.4)	8(4.6)	20(11.4)	51(29.1)	53(30.3)	30(17.1)
Staff resistance to change	13(7.4)	11(6.3)	23(13.1)	57(32.6)	47(26.9)	24(13.7)
Staff participation	9(5.1)	16(9.1)	31(17.7)	42(2	43(24.6)	34(19.4)
Support from top management	2(1.1)	13(7.4)	23(13.1)	47(26.9)	54(30.9)	36(20.6)
Continuous training on LQMS	8(4.6)	18(10.3)	23(13.1)	36(20.6)	56(32)	34(19.4)
Understanding of LQMS	10(5.7)	13(7.4)	26(14.9)	53(30.3)	41(23.4)	32(18.3)
Required standards and reference materials	7(4)	19(10.9)	30(17.1)	52(29.7)	36(20.6)	31(17.7)
Awareness on the benefit of LQMS and accreditation	8(4.6)	18(10.3)	24(13.7)	43(24.6)	50(28.6)	32(18.3)
Proper planning in implementing LQMS	6(3.4)	18(10.3)	26(14.9)	47(26.9)	50(28.6)	28(16)
Turnover of trained staff	10(5.7)	15(8.6)	37(21.1)	42(24)	49(28)	22(12.6)
Organizational structure	8(4.6)	17(9.7)	24(13.7)	43(24.6)	53(30.3)	30(17.1)
Complexity of the processes	7(4)	13(7.4)	30(17.1)	42(24)	57(32.6)	26(14.9)
Qualified personnel to lead the process	6(3.4)	22(12.6)	26(14.9)	38(21.7)	57(32.6)	26(14.9)
Management reviews	7(4)	18(10.3)	30(17.1)	50(28.6)	43(24.6)	27(15.4)
Sensitization on the Accreditation process	5(2.9)	16(9.1)	25(14.3)	44(25.1)	51(29.1)	34(19.4)
Funds to implement LQMS	8(4.6)	12(6.9)	26(14.9)	44(25.1)	49(28)	36(20.6)
Adequate Infrastructure	4(2.3)	17(9.7)	20(11.4)	44(25.1)	52(29.7)	38(21.7)
Massive documentation requirements of the process	5(2.9)	11(6.3)	20(11.4)	49(28)	65(37.1)	25(14.3)
Regular mentorship and technical assistant	4(2.3)	11(6.3)	18(10.3)	45(25.7)	68(38.9)	29(16.6)
Adequate equipment and supplies to provide Uninterrupted lab service	3(1.7)	5(2.9)	22(12.6)	42(24)	53(30.3)	50(28.6)
Work load	3(1.7)	4(2.3)	10(5.7)	42(24)	66(39.7)	50(28.6)

5.5. In-depth interview results

In this study, the reflection of 11 laboratory heads and 10 quality officers and 3 medical directors about challenges and suggested solutions of medical laboratories were taken. For the reason of confidentiality, instead of mentioning the name of the facilities, code was assigned from **A to L**.

5.5.1. Opinion of laboratory heads regarding the challenges facing ISO 15189 accreditation process

The laboratory heads participated, in this study raised various issues regarding the various challenges facing medical laboratory accreditation process and suggested possible solutions. Most of the points explained to be the barriers for accreditation process were shared by majority of the laboratory managers which is arranged as follows.

System for accreditation

Majority of those key informants believe that, the country's system does not support/facilitate the accreditation process. The laboratory head from hospital D, raised his unique belief for the reason of slow accreditation process as "*the low accreditation success of medical laboratories was due to hospital accreditation is not yet started in the country"*. As this key informant suggested, "*before dealing with laboratory accreditation, there should be an effort on hospital accreditation. If the hospitals or the parent organization was implementing QMS, the hospital itself can influence the laboratory to implement LQMS"*. He added also, "*yet, the hospital reform guideline is not being implemented which has its own negative effect on laboratory accreditation*". Laboratory head of hospital F also said, "*the country's system is not yet comfortable for the accreditation process; different offices have contradicting rules which negatively affect the accreditation process"*.

Staff commitment

As evidenced from laboratory heads of each hospital, Commitment and initiation of laboratory staffs regarding accreditation process varies from hospital to hospital. But majority of them agreed, the staffs are becoming supportive and contribute to the accreditation process. But it was reported that some staffs still lack consistent commitment to contribute for the success of accreditation process. According to the opinion of the laboratory head of hospital F, "*some laboratory staffs consider accreditation as extra burden that is imposed on them without any extra benefit"*. Laboratory head of hospital G also added, "*the commitment of laboratory staffs was not consistent to accomplish the tasks of accreditation. Some of the staffs consider*

accreditation as a one-time achievement that end after assessment process". Routine work load was also explained by majority of the laboratory heads as among the challenges that makes the staffs to be busy to accomplish the extra tasks that accreditation requires.

Top management awareness and commitment

As some of the laboratory heads believe, and emphasized by laboratory head of hospital F, *"in the country, laboratory tests and professionals were wrongly understood by the top management and other professionals and was not believed to be problem solving. Some understand laboratory as something that performs some tests in a small room*". It was believed by majority of laboratory heads that for successful accreditation process, commitment of top management was a key factor. Regarding hospital management awareness, commitment, and support, laboratory heads had different opinions. Some of them believe that, hospital top management was supportive for the accreditation process; specially, laboratory heads of hospital A, hospital K, and L said that "*the hospital management was highly supportive in any aspect that accreditation requires*".

Majority of the laboratory heads had explained that hospital management support fluctuates up and down with the accreditation status obtained. Laboratory head of hospital E said "*when the laboratory achieved better SLMTA star level, it was considered the manifestation of good management of the hospital but when the star level was below the previous one, the failure was assumed to be due to poor performance of the laboratory professionals which actually is not"*. As clearly stated by laboratory manager of hospital F, "*Low awareness and commitment of the hospital management system contributes to the slow accreditation status we have today"*. *Even if I am one of the member of the hospital management, my questions and voice is meaningless unless majority of management committee clearly understand the importance of having quality laboratory service and accredited laboratory. Whatever important issues I raised, the management was always focused on other clinical departments and issues while laboratory service was considered to be some others duty"*.

Medical Laboratory Equipment

All laboratory heads agreed that poor quality of equipment standard was the major challenges for compromised quality of laboratory service and in turn for slow accreditation process. It was specifically explained that, "*some of the equipment were difficult for verification because of absence of manufacturer claims on validation performance characteristics, some are bought*

without their calibrator, and for some others it is difficult to get controls and reagents". As clearly stated by the laboratory head of hospital E, "*PFSA has no consistent reagent supply for the equipment it mostly supplied; and laboratory supplies were bought from different suppliers which affected the laboratory to maintain consistent laboratory result and to develop LJ- charts for QC monitoring. Most of the equipment received from PFSA is incompatible to the actual laboratory set up*". Due to this and other challenges the laboratory head asked, "*why are we forced to buy equipment and supplies from PFSA? I believe that unless laboratories are out of PFSA channel, it is so challenging to participate in the accreditation process*". As majority of the laboratory heads explained, the Ethiopian National Metrology Institute (NMI) was not certified to calibrate some medical laboratory equipment including biological safety cabinets, centrifuge and balances. Bringing other accredited calibrating agencies outside the country was also a costly process for individual laboratories. Due to this calibration issue, one laboratory failed to score 5 stars.

Laboratory reagents and supplies

The other challenge felt and mentioned by all laboratory heads, were related to reagent quality and adequacy. As laboratory head of hospital D stated, "*Some reagents that are imported in the country are of poor quality which has negative impact on quality of service and accreditation process. There are some suppliers who have license from* Food medicine health administration and control authority (FMHACA) *and trade license but the reagent they supply is of poor quality. So as those suppliers have got the right to compete with other suppliers, the reagents from such companies are distributed to the laboratories via the national supply chain system which impose negative impact on the quality of tests and accreditation outcome".*

The laboratory head of hospital A also explained as, "*reagent purchasing is the most challenging part of the quality management system which mostly tend our laboratory to score zero in previous assessment experiences we had and it remained still our problem. The purchasing is also inconsistent; reagents are being bought from different companies which is uncomfortable to participate in proficiency testing program as well as to develop LJ-charts. For purchasing problem and inconsistent reagent supplies, the laboratory head suggested as solution that PFSA is better to plan and inform from which company and which method to supply for the laboratories for a specified period".*

As all agreed, and observed by the principal investigator of this study, the challenges related to laboratory equipment and supplies were the main reason for most test interruptions which predominantly prohibit laboratory accreditation. Although various factors contribute to the challenges related to laboratory equipment and supplies, majority of them suggested the problem was related to the country's supply chain system and professionals directly involving on the procurement process. As stated by the laboratory head of hospital I, *"Stock out of reagents mostly happen for a long period of time. Currently, we are not providing clinical chemistry tests due to reagent to machine incompatibility; the clinical chemistry automation bought needed human reagent but the reagents currently supplied by PFSA is EMS reagent which was incompatible to the machine we have now which is the reason for service interruption"*.

As the laboratory head of hospital D again suggested, *"The main reason for the persistent challenge we are facing related to laboratory equipment and supplies is because the procurement process is allowed to be handled by pharmacy professionals. But laboratory professionals have limited involvement in the procurement process. So that as pharmacy professionals are more concerned and interested on medicinal supplies but their concern, interest, and knowledge on laboratory supplies is limited. If there is under or over stock in laboratory supplies, who is accountable is the laboratory professional for the activity he/she was not involved. So I personally believe that there should be proper laboratory reagent consumption calculation and every activity related to laboratory supply/ equipment purchasing should be left for laboratory professionals"*.

Training and mentorship

Different laboratory heads had varying opinion regarding trainings related to LQMS and support by external consultants or mentors. The laboratory heads of hospital A and H said, "*for initiation and engagement of the staffs in the accreditation process, LQMS training was given to almost all the staffs specially on document introduction*". Another laboratory head of hospital F differently suggested his opinion as, "*trainings and mentorship were in up and down manner; there is no consistent consultation and training. As most of the trainings in our country are fund related, it is unplanned and it was not based on the actual gaps because trainers only consider the availability of funds to deliver training"*. Laboratory head from hospital E had also related opinion "*Trainings given by training providing offices is inadequate and even list of trained staffs was not disclosed to us in order to assign tasks based on the training experience of staffs. But during the assessment process we were asked to show list of trained staffs"*.

The laboratory head of hospital D also forwarded his opinion as "*trainings that are delivered related to LQMS should be updated because most of trainings are given using the document and power point which was used before 10 years. Training materials and manuals should nationally be updated even the examples in the training manuals does not consider the situations of our country"*. This laboratory head also continued as "*there is no training manual in the country for some tests like stool examination, urinalyses, blood film and some other specialized tests so that it is difficult to fulfill accreditation requirements ISO standard for this kind of tests"*. As laboratory heads of hospital B and C shared, most of their staffs including themselves lack training experience related to LQMS and accreditation.

Laboratory head of hospital I also added, "*Trainings given by training providing offices were difficult to apply in the real set up of the laboratory so our training manuals need to be revised and re-written again*". As emphasized by laboratory head of hospital B, "*only around four laboratory staffs including the quality officer only get trained but myself and other laboratory professionals lack formal training experience related to laboratory quality management system and accreditation. With regard to support by external consultants, there is no special support because of the mentors had the same training experience and knowledge with the staffs due to this we are not getting the expected support from external consultants(mentors)"*.

Laboratory head of hospital C added as, "*we were totally forgotten to participate in nationally organized trainings. It was a long time ago we were communicated regarding participation in accreditation process. Due to this low support, we are only trying based on our school knowledge*".

Staff turnover

Majority of the laboratory heads agreed accreditation requires trained and experienced laboratory staffs who lead and involve in the accreditation process. But it was emphasized that high turnover of trained and experienced laboratory staffs majorly affected accreditation process. Specifically, as laboratory manager of hospital I explained, *"high turnover of trained staff is among our major challenges we are facing in our set up specially laboratory heads were repeatedly changed. Within 6 years around 8 laboratory heads were changed in this laboratory which has its own negative impact on accreditation results"*. For high turnover of laboratory professionals, most of the laboratory heads suggested that, low satisfaction level of the staffs highly contributed. Laboratory head of Hospital D suggested "*low satisfaction level of*

laboratory professionals is one of the major barriers to retain trained laboratory professionals. Even if LQMS implementation and participation in accreditation process requires well trained and experienced laboratory professionals, these experienced professionals always think about how to learn innovative medicine, master of public health, and join non-governmental organization for better earnings. So to have laboratory professionals who are loyal to their profession, the government and other concerned bodies should work to resolve this issue".

Lack of quality related budget

As some of laboratory heads raised, the reason for low accreditation success was also due to lack of quality related budgets. As clearly stated by laboratory head of hospital D, "*lack of quality related budget for, equipment calibration, preplanned training, equipment maintenance, service maintenance, and consultancy, hugely contribute for low success in accreditation*". This idea was supported by laboratory head of hospital I as "*there is no budget for quality system implementation; the hospital always orders the laboratory to prepare our own budget but it was limited on that level*".

Infrastructure (facility)

Premises of laboratory facilities were among the big challenges that all laboratory heads explained as the big challenge which is difficult to be solved easily. As clearly stated by laboratory head of hospital E, "*the laboratory buildings design and setups we have is too old which is difficult to fulfill requirements of ISO standards but during the assessment process, the assessors were even asking whether the building has smoke detector or not which was actually impractical even in the country*. As laboratory head of hospital I also added, "*facility and infrastructure highly contributes for low quality service provision and slow accreditation status. For example, in our setup, four different laboratory analyzers are running in a single room.* As added by laboratory head of hospital G, "*the facility we are working in is too old that did not consider the increasing patient flow and difficult to fulfill the ISO requirement. The laboratory store was too narrow which does not fulfill ISO standard"*.

Assessment process

In this regard some of the laboratory heads explained the assessment process and the assessors does not consider the real situation of the laboratory as well as the country. The laboratory head of hospital J suggested that, "*The laboratory is under the support of SLMTA and had current star level of 3 but the staff and the hospital management were expected more star levels could be*

achieved. The assessor was fault finders even enough time was not taken to assess properly; it was within a single hour the assessment was completed". As laboratory head of hospital F explained, "*Even if our laboratory was assessed and told it was on 2-star level, there was no any certificate for the star level we achieved; at least the staffs should have been acknowledged for achieving star 2 from nothing*".

Some of the laboratory heads believe, the assessment process does not consider the way the laboratories were supported and the staffs were trained. As laboratory head of hospital E raised, "*I personally believe capacity building offices should not at the same time be assessing office. During the assessment process our laboratory lost some points for the commitment we were not expected to accomplish. For example, it was that office selected, purchased, and delivered some of the laboratory equipments we were using but during the assessment process we were asked to show the documents how those equipments were selected from the company but the document of selection process and verification status was not communicated to us which is not actually the mistake of the laboratory but assessment points were lost due to this issue".*

Regarding the various challenges facing accreditation process, some of the laboratory heads point out they are always in trouble to sustain the accreditation status they achieved with a lot of effort.

5.5.2. Quality officer's opinion regarding challenges of ISO 15189 accreditation

Quality officers of 10 hospital laboratories were interviewed to forward their opinion regarding the various challenges facing medical laboratories during accreditation process. Most of the opinions suggested to be the challenge for accreditation process were shared by majority of the quality officers. The quality officers believe, there were many factors in one way or another contribute for low accreditation success.

Management awareness

As some of the quality officers emphasized, for better accreditation achievement, awareness creation regarding accreditation process should consider top management and other health professionals. As quality officer of hospital D said, "*Accreditation is impossible by the effort of laboratory professionals only; but it should be the task of all health professionals and top management. So that, during awareness creation and sensitization process, all staffs who either directly or indirectly contribute for the quality of the laboratory service should be considered".*

Different views were forwarded regarding commitment and support of top management to the accreditation process. Quality officer from hospital F explained as, "*the hospital mangers had limited knowledge regarding the importance of having accredited laboratory but they only require laboratory service to have only some support for their clinical management. Even if the building we have is of good standard which were built and renovated by partner organization, facility alone does not bring good accreditation result unless management support is accompanying"*. Quality officer of hospital I added that "*the hospital management awareness and commitment for accreditation process was low and unsupportive which has its own contribution for slow accreditation process*".

Staff commitment

All quality officers believe, for successful accreditation process, commitment of laboratory professionals is the major factor. Regarding staff commitment different quality officers had varying opinions. According to the quality officer opinion of hospital L, *"the main factor for a successful accreditation was staff commitment. Unless a laboratory has a committed staff, it is impossible to achieve even a single star level. Commitment of staff is among the good opportunities we have which helped us to achieve 4 star in our recent assessment"*. Quality officer of hospital A also added, "*at the beginning, the staff were resisting to accept additional tasks that accreditation process requires but gradually almost all staffs were becoming cooperative and still contributing for better achievement"*.

On the contrary, quality officer of hospital B responded, "*even if adequate awareness creation was made to the staffs, there is still inadequate staff commitment to involve in every process accreditation requires"*. Quality officer of hospital C also explained the staff as, "*resistant to record their work and the tasks assigned to them which imposed additional tasks on me to fill the gaps of other negligent staff members"*.

Quality officer of hospital F raised his opinion as, "*laboratory professionals consider accreditation as an extra burden and created some disagreements and conflicts between the staffs and the management. The hospital was using 3 shifts working hours per day which I believe as unsuitable for the laboratory routine work and specially for accreditation process. For instance, the morning shift leaves unfinished tasks to be accomplished by the afternoon shift, but this shift staffs still leave the tasks unfinished by considering it was not their duty which is*

totally obstacle for accreditation success. Eight hours shift method also made the staffs to be busy on the routine works".

Staff satisfaction

One of the reason mentioned for retarded level of accreditation in most of the laboratories was due to low level satisfaction of laboratory professionals. As quality officer of hospital E explained, "*most staffs mostly raise, what advantages accreditation can bring for us, rather an extra work load? For this concern, I believe there should be a mechanism to encourage laboratory professionals who have achieved better accreditation status"*. As most of the quality officers emphasized, for the development of the profession as well as for better accreditation achievement, there should be at least educational opportunity for the staffs to upgrade their educational and competency level. This was clearly sated by quality officer of hospital L as, "*even if our staffs sacrificed a lot with a limited resource and facility for accreditation success we achieved, there were no incentive mechanism to motivate the staffs. At least educational opportunity could have been given for some of model staffs. This is a barrier for professionals' satisfaction and retarded accreditation which prevents the staff to go forward for better success"*.

Training and support by external consultant/mentor

The quality officers have forwarded their opinion regarding training and mentorship adequacy and quality and had different views. As explained in detail by quality officer of hospital E, "*the quality and quantity of training regarding the LQMS is not as expected. Training should be inclusive; all staff either directly or indirectly contribute to the laboratory service including cleaners should be trained accordingly. The trainings provided also are theoretical which is power point based but it is difficult to apply in the actual set up. `So the trainings given should consider how the trainees can apply the trained methodology in the actual facility they are working in. Most trainers lack facility based knowledge"*.

The quality officers of hospital D also believe, "*the support by external consultants/mentors is important for the laboratory to at least fully implement quality management system. In our regard, we had a foreign external consultant who was employed by partner organization and the support was important and helped us to achieve the accreditation status our laboratory reached. Although external consultants are important until getting something stable, it is not a must to always depend on. For example, our laboratory is currently able to maintain the accreditation*

status without external consultant". Quality officer of hospital I also said, "*External consultants/mentors were supporting us but there was a gap on updating new information and major changes in the accreditation standards and check lists"*.

Laboratory equipment and reagent

Quality of laboratory equipment and reagents were also considered among the very challenges explained by almost all quality officers. Even it was evidenced by the principal investigator of this study there were a number of interrupted tests in most of the hospitals visited by this research. As explained by quality officer of hospital A, "*supply chain management (purchasing) is the most critical barrier to implement LQMS or ISO accreditation process. The procurement system itself is also highly criteria based which makes our laboratory was mostly suffering from stock outs which in turn brings service interruption followed by failure in accreditation success"*. Quality officer of hospital B also added, "*laboratory reagent stock outs is the most challenging one for our hospital laboratory; currently, our clients are being referred to other laboratories which is expected to have negative impact on test quality and patient satisfaction and in turn on accreditation result"*. Quality officer of hospital D strengthens the opinion of other quality officers as, "*even if ISO does not allow any test interruption and even needs 3 months more stocks, supply chain management remained among most of the challenges we are always suffering.*

The other area mentioned as one of the obstacle for ISO accreditation was PFSA as a system. Quality officer of hospital E said, "*PFSA buys and dumps equipments without validation data and without any study and need but there was no any response when we were asking for reagents and controls for the equipment supplied by this organization itself"*.

As clearly explained by quality officer of hospital D, "*equipment handling system is not available as a policy in the country like; equipment purchasing, calibrating, and disposing but during the assessment process points are lost even if not applicable in the country. For example, the problem we actually faced in our accreditation status in CD4 count is suspended currently due to pipette calibration issue which is the office calibrated our pipette was not itself accredited"*.

Laboratory infrastructure

Poor laboratory infrastructure was also mentioned as one and major obstacle for accreditation process by quality officers of all hospital laboratories. Quality officer of hospital B said that,

"*ahead of anything else the quality of laboratory facility (infrastructure) should be emphasized because previous thoughts do not consider laboratory service to require a qualified facility and set up. For example, from its nature of the tests done, microbiology department requires high quality set-up starting from the design of the building but the reality in our facility and other laboratories is the reverse so this issues tend us to fail before applying for accreditation*". Quality officer of hospital E also supported that, "*the quality of laboratory facility and set up was poorly constructed that have a negative impact on the assessment result but as to me the assessment process should consider the actual infrastructure the laboratory has and it should not be taken as the poor performance of this particular laboratory service"*.

Assessment process

The assessment process was also mentioned by some of quality officers as a challenge for accreditation especially in laboratories assessed by WHO-AFRO check list. As quality officer of hospital E stated, "*there were no both baseline assessment and mentorship in between the previous assessment and the current one. The capacity building office was itself the assessing body, due to this dual power of the office it created disagreement during the assessment process about whose mistake was the identified non-conformity"*.

According to the quality officer of hospital L, "*most areas that we lost points during the assessment process were out of the scope of the laboratory. for example, as it was costly to bring internationally certified calibrating agencies out of the country, biological safety cabinet was calibrated by the national calibrating office but due this office itself was not accredited by other authorized body, points were lost in this part. I personally believe any concerned body is better to think over it and modify theoretical questions that are not applicable in the actual facilities. So some non-realistic requirements should be considered by any stakeholder for quality laboratory service as well as better accreditation status. If those nonconformities due to the mentioned challenges were fulfilled, we could have been on 5-star level because in our current assessment result our laboratory is 5 points below the 5-star requirement"*.

As general comment, it was suggested by some of quality officers as, "*the standard of ISO accreditation is so challenging to be achieved by developing countries, but if there is organizational and professional commitment, it is possible to reach at some level of quality and accreditation status*". And the other quality officer said, "*before medical laboratories deal about accreditation, we have to be sure that our set up allows the implementation of ISO standards and*

our staffs can clearly understand the standard and the check list". One of the quality officers also underlined that *"the country's ministry of health should take the assignment to accredit at least tertiary hospitals"*.

5.5.3. Other technical staffs' opinion related to challenges of ISO 15189 accreditation

The opinion of technical laboratory professionals other than laboratory head and the quality officer were collected using open ended questions and different important points were suggested regarding challenges of medical laboratories for ISO accreditation. The various points written by the respondents were organized and summarized as follows.

Among the various opinions raised, almost all staffs said that there was no any motivation mechanism by the government or the organization they were working with regarding the profession and the achievements in accreditation. The respondents' added accreditation is an extra work other than the routine tasks that needs extra effort and time of the staffs but for that effort there were no any motivation mechanism that initiated the professionals to go to the next better accreditation status or to maintain the quality and accreditation level they achieved. Even different allowances that were paid for other professionals including professional risk allowance was not secured which discourages the profession and professionals, said the respondents. Routine work load was also mentioned as a big challenge for slow accreditation status.

The other major challenge raised by the staffs were high turnover of trained and experienced laboratory professionals for other job and education opportunities. This high turnover of laboratory staffs was observed in most of the laboratories during the study period; some of the laboratory staffs had joined other profession's education opportunity called new innovative medicine which was mentioned to have a negative impact on both professional development and in turn on accreditation process. For this, low or absence of continuous professional development and low satisfaction level of the professionals were taken as a reason by the respondents.

Majority of the respondents said that the facility or infrastructures of their laboratories are much more bellow the ISO standard that tends the laboratories to fail before assessment process. Quality of laboratory equipment, and reagent quality and shortage were mentioned among the challenges they were facing which taken as reason for most interrupted tests. Shortage of laboratory supplies was said to become beyond the control of laboratories which was considered

as a major headache in almost all laboratories visited by the PI. For this, poor and traditional reagent purchasing system was mentioned as a reason.

Inadequate training and poor follow up was also explained to contributed for slow accreditation process. It was also said, the follow up and mentorship was not consistent; due to this most staffs were considering accreditation as a onetime process despite the fact is it should be every times activity.

The other major challenge raised by the respondents was, low hospital management support and commitment related to laboratory service and accreditation. As most of the respondents stated the hospital management had no focus on the quality of laboratory service. This was due to low awareness regarding the advantage of having accredited laboratory for the hospital and the country as a whole. For accreditation to become practical and successful at least the hospital management should closely work with the laboratory management and staffs.

Even if there were various challenges that retarded accreditation process, the support from non-governmental organization and some partners were mentioned as good opportunity to go forward for better accreditation status of the laboratories.

5.5.4. Medical director's opinion regarding challenges of medical laboratory accreditation

In this study, we got a chance to contact three medical directors to forward their opinion regarding the challenges facing medical laboratories during accreditation.

The medical director of hospital A explained, "*Accreditation of medical laboratory is all about quality so that it is important to have accredited laboratory in our hospital laboratory service. Effective accreditation needs a huge commitment to change the existing trend of the hospital as well as the staffs"*. He also expressed his opinion as, "*accreditation highly needs renovation of various things including the building itself. Because many buildings for laboratories as well as the hospital itself were not built based on appropriate design, reconstruction might be needed which needs a big investment and commitment"*. The other challenge the medical director emphasized was, "*for accreditation it is difficult to have consistent laboratory supplies due to the procurement system is not suitable for the laboratories seeking accreditation"*. The medical director suggested as a solution for the mentioned and other challenges facing medical laboratories as "*the laboratory staffs should externalize their problems and plan accordingly how to perform their tasks and should know when to ask for something for their laboratory service*

and related to accreditation. Laboratory professionals should highly play a key role and be involved directly in PFSA equipment and reagent procurement system".

The other medical director of hospital C also believes, quality of laboratory tests is very important for the hospital he is working and for quality health care service as a whole. As the medical director responded, "*as a newly assigned medical director, I have no more information and knowledge regarding ISO 15189 accreditation but I promise to do what is possible in the future for better accreditation involvement*".

The medical director of hospital F also believes accreditation is highly important to have quality test results. He explained that, "*the competency, experience and commitment of laboratory professionals contribute for quality laboratory test results and accreditation as a whole. As to me some laboratory professionals lack commitment to do what accreditation deeds to be done*". The medical director added that, "*the universities and colleges should focus on practical aspect of learning to produce competent and committed laboratory staffs and the areas what accreditation and quality requires should be focused on the university or college level*". The other point raised by this key informant was, "*most of the laboratory equipment were obtained through donation so that these equipments lack quality as mostly complained by laboratory professionals to have negative impact on both qualities of test results and accreditation process*". He suggested also the country should have consistent reagent purchasing system at least for a planned period of time.

6. Discussion

This research aimed to identify the major challenges facing medical laboratories seeking ISO 15189 accreditation in a direct or stepwise approach.

It is reported by this study that all respondents had awareness regarding their laboratory's effort to seek either ISO 15189 accreditation or involvement in SLMTA/SLIPTA process which is one of the important factor for successful accreditation process. Even if all of respondent had awareness, the involvement of only 138(79%) of study participants, could have its own negative impact on the accreditation process.

According to majority respondents explained, the country's system does not facilitate the accreditation process which could be the reason for the absence of a single laboratory achieving star-5 after many efforts have been done. Ndihokubwa *et al.*, suggested that, although SLIPTA process has been widely accepted by most countries and notable improvements made, the majority of laboratories have not yet to reach international accreditation readiness [33]. Another research in Iran also supported that there is inadequate policy level support to facilitate accreditation process [24].

It was agreed that accreditation requires trained and experienced laboratory staffs who lead and involve in the accreditation process. But high turnover of those trained and experienced laboratory staffs majorly affected accreditation process. Low satisfaction level of the staffs highly contributed for high turnover of laboratory professionals. As it was evidenced from the respondents' opinion, those experienced professionals always think about how to learn innovative medicine, master of public health, and join non-governmental organization considering better earnings. A research done in Caribbean Region supported the current study as ensuring a sufficient number of well-qualified laboratory workers is an ongoing challenge, exacerbated by high levels of attrition as staff leave the public sector for more lucrative jobs in the private sector, either locally or overseas [29].

Most of the respondents raised what advantages accreditation can bring for them, rather than an extra work load. This perception demands a mechanism to encourage laboratory professionals who have achieved better accreditation status. The current finding is in line with similar research from Iran done by Hamid R *et al.* in 2014 and another research in Jamaica which also reported lack of motivation of laboratory professionals as the major challenge for the success of laboratory accreditation [24,32]. On the contrary, another study in Lebanon reported

accreditation has been linked with improved staff satisfaction [30] but the reality in the current study is different that accreditation is not evidenced to bring staff satisfaction.

Staff initiation and commitment was explained as the main actors for successful accreditation. In the current study, commitment and initiation of laboratory staffs regarding accreditation process varies from hospital to hospital. Some of the respondents agreed, the staffs are gradually becoming supportive while some laboratory staffs consider accreditation as an extra burden that is imposed on them without any extra benefit. Inconsistent staff commitment and considering accreditation as a one-time achievement that ends after assessment process were identified as challenges while the reality is accreditation needs every day's activity and effort. Similar research done in China supported the current study as laboratory professionals still did not realize the usefulness of accreditation and consider it as only unnecessary extra work required by the accreditation body [31]. Another study in Lesotho also reported that perception of accreditation participants affected the process [35]. A review in Canada also proved, accreditation process was considered being stressful, time consuming, and requires a serious investment of resources [28]. The current study proved consideration of accreditation as an extra burden by the staffs created some disagreements and conflicts between the staffs and the management which is a barrier for success in accreditation.

Routine work load was also identified to be among the challenges that makes the staffs to be busy to accomplish the extra tasks that accreditation requires which demands considerable number of laboratory professionals to be increased. A systematic review by Abdullah A. and Charles S. and another research in Lebanon also supported this study as workload was increased by the accreditation process [23].

Even if a little more than half of the respondents had training experience related to either LQMS or accreditation process or both, the rest half responded that they had no training engagement before. Training was believed to be the key for successful accreditation process which necessities all staffs to be trained accordingly. But the respondents believe, trainings were inadequate in terms of quality and quantity and training manuals were not updated to the current situation. A concordant qualitative study in Iran also suggested, revising and updating the standards, related checklists and the technical guidelines based on the international standards considering the country's context and situation was found to be important for improved accreditation achievement [26].

Most of the trainings in our country were suggested to be fund related. It was also believed to be unplanned which was not based on the actual gaps the accreditation requires as a system. Lack of training manual in the country for some tests like stool examination, urinalyses, blood film and some other specialized tests which is difficult to fulfill accreditation requirements for this kind of tests was identified as one of the challenges. As evidenced in majority of respondents, most of the trainings were difficult to apply in the real set up of the laboratory which needs training manuals to be revised and re-written again. Similarly, researches done here in Ethiopia by Tilahun M. *et al.* 2013 and Abay S. *et al.* 2015 reported that training inadequacy was a challenge for laboratories participating in SLMTA/SLIPTA programs [19,37]. But still lack of adequate training regarding LQMS and accreditation remain a challenge in the current research.

In most of the study sites, the quality and adequacy of mentorship/consultation was questioned as being not up to standard and in some of the laboratories it was not believed to be a special support because of the mentors had the same training experience and knowledge with the mentee staffs. Most of the respondents do not believe in getting the expected support from external consultants (mentors). It was confirmed that some of the mentors do not update new major changes on ISO standard and assessment check list. Researches done in the Caribbean Region and Kenya, supported the current study in that low adequacy and quality of mentorship contributed for slow accreditation process [29, 36].

As majority of the respondents confirmed, laboratory tests and professionals were wrongly undermined by the management as well as other professionals and were not believed to be problem solving. It was believed by majority laboratory professionals that for successful accreditation process, awareness and commitment of top management was a key factor. Even if hospital management support was evidenced in some of the laboratories visited by this particular study, still it was believed to lack full engagement and commitment. It was suggested that, the hospital mangers had no adequate knowledge regarding the importance of having accredited laboratory apart from only some support for their clinical management which discourages laboratory professionals to strive for better quality and accreditation success. It was also reported in Iran that the support from top management was low and considered to be a challenge for slow accreditation process [26]. Another research in Ethiopia by Tilahun M. also reported top management support was low regarding laboratory accreditation [37].

It was agreed by majority of the respondents, that poor quality of equipment was the major challenges for compromised quality of laboratory service and in turn for slow accreditation process. It was specifically explained that, some of the equipment were difficult for verification because of absence of equipment claim, some are bought without their calibrator. For some others it is difficult to get controls and reagents while, running controls becomes standard practice with automation [45]. Most of the equipment received from the country's equipment supplying agency were incompatible to the actual laboratory set up which demands equipment handling system to be available as a policy in the country for equipment purchasing, calibrating and disposing. A research done in Lebanon and Jamaica also explained that faulty equipments were reported among the challenges for accreditation success [30,32]. Due to this and other challenges, it was noted that the government should not necessarily force the laboratories to buy equipments and supplies from PFSA. As remarked by some respondents, unless laboratories are out of PFSA's channel for equipment and reagent purchasing, it is so challenging to participate in the accreditation process. In one WHO document stating the advantages and disadvantages of decentralization in drug supply, improved public sector efficiency in the provision of health services, stimulation of local participation in their own health care provision, improved quality of care through better response to local needs were listed among the advantages. Among the disadvantages were issue of accountability for meeting national policies and cost [46]. In the current study, respondents criticize the centralized system from the point of view of improving their provision of laboratory service in particular and their journey to accreditation at large.

Reagent stock outs followed by test interruption were the most challenging part in most of the laboratories visited by this study and explained by the respondents. These challenges contribute for the non-conformities they faced in the previous assessment experiences they had and remained still unsolved problem. For purchasing problem and inconsistent reagent supplies, it was suggested as solution that PFSA to have better planning and inform laboratories from which company to purchase and which method to supply for a specified period. Challenges related to laboratory supplies was also reported by the study done in Lebanon [30]. As all agreed, and observed by the principal investigator of this study, the challenges related to laboratory equipment and supplies were the main reason for most interrupted tests which was totally prohibited by accreditation requirements.

Majority of the respondents said that facility or infrastructures of their laboratories are much more bellow the ISO 15189 standard that tends the laboratories to fail before assessment process.

The laboratory buildings design and setups are too old which is difficult to fulfill requirements of ISO 15189 standards. Facility and infrastructure highly contributes for low quality service provision and retarded accreditation status. As observed in some laboratories, different laboratory analyzers were running in a single room. Researches done before, by Eyob A. and Abay S. also reported laboratory design and quality contributed for low success in accreditation process [18,19]. As observed by the researcher and majority of key informants suggested, ahead of anything else the quality of laboratory facility (infrastructure) should be emphasized and renovated as opposed to the past beliefs and practices which undermine the laboratory service to require a qualified facility and set up. This is supported by the report in Canada, achieving and maintaining accreditation status requires a significant investment of resources [28].

The assessment process was also mentioned as a challenge for accreditation process specially in laboratories assessed by WHO-AFRO check list. As it was confirmed by some of the key informants, most areas that points were lost during the assessment process were out of the scope of the laboratories. As some areas in the assessment check list does not consider the actual situation and capacity of the country's laboratories, it was suggested that any concerned body is better to think over it and modify theoretical questions that are not applicable in the actual facilities. So some non-realistic requirements should be considered by any stakeholder for quality laboratory service as well as better accreditation status. If those nonconformities due to the mentioned non-applicable challenges were fulfilled, some laboratories could had been at 5-star level. Some of the respondents emphasized that, some of the assessors were fault finders even there were no standard length of time to assess a given laboratory. A qualitative study in south Africa also reported, ambiguity as the standard is open to understand depending on the implementer and accrediting assessor. The authors stated that auditors see things differently as opposed to people actually working in the laboratory [27]. Another qualitative research in Iran also reported, inadequate time devoted for each assessment, lack of providing feedback or delayed feedback to the laboratories, over strict assessments, and inconsistent assessment results by different assessors [26].

7. Strength and Limitation of the study

7.1 Strength of the study

- The opinions of key informants to suggest the major challenges facing medical laboratories' accreditation process were extensively taken and analyzed in this study.
- This study used both qualitative and quantitative approach to collect and analyze data

7.2 Limitation of the study

- Due to administrative issues it was difficult to access the opinion of all medical directors.
- The result would be more informative if more laboratories outside Addis Ababa were included.

8. Conclusion and recommendations

8.1 Conclusion

Even though there exists an effort to fulfil accreditation requirements, achieving and maintaining accreditation was challenging for many facilities visited by this particular study. This study highlighted the need for stronger engagement, commitment and advocacy with all stakeholders to harmonize and lead accreditation program effectively.

According to this study, of 175 questionnaire respondents only 90 of them had training experience related to LQMS. It was also evidenced from face to face interview that there was still a gap in adequacy and quality of training provision and mentorship. As the accreditation status of most medical laboratories is not stable, it is possible to conclude that there is a gap and limited effort to support medical laboratory's accreditation program and the country's system is not yet fully ready to support/facilitate the accreditation process.

High turnover of trained and experienced laboratory professionals due to low satisfaction level, majorly affected accreditation process. Staff initiation and commitment was explained as the main actors for successful accreditation. Even if the commitment of the staffs was said to be improved, still staffs consider accreditation as an extra burden and some consider it as a one-time achievement that ends after assessment process.

Routine work load was among the challenges that makes the staffs to be busy to accomplish the extra tasks that accreditation requires. In most of the hospitals, the awareness and support of the hospital management for accreditation process was not as expected by the staffs. Laboratory equipments and supplies were among the challenges for accreditation process and found unavoidable challenge for almost all laboratories. The design and quality of most laboratories functioning was much more bellow ISO 15189 standard which is so challenging to resolve it in a short period of time.

8.2 Recommendation

Based on the findings of this study, the researcher suggested the following recommendation.

- The country's capacity building office is better to update the training manuals by considering the actual gap of the laboratories and professionals; and trainings are better to include practical aspect of learning. Any sort of support is better to be consistent.
- The regional laboratories are better to mentor the laboratories under and update new information related to accreditation.
- The hospital management is better to understand the importance of having accredited laboratory in their hospital and support it for better health accreditation outcome and better health care delivery.
- Although there might be different demotivating factors, laboratory management and the staffs are better to be loyal to their profession and strive to increase the reputation of their profession. The professional society could play a role.
- The country's equipment and reagent supply system is better to go beyond supplying laboratory commodities and give special consideration for medical laboratory' accreditation.
- Ministry of health is better to go beyond stating the importance of having accredited laboratories in the country in its health care transformation plan and should closely follow and support the accreditation process.
- Universities are better to revise their curriculum and incorporate the concepts of medical laboratory quality management system and accreditation to make laboratory professionals more informed and competent regarding the issue of LQMS and accreditation at undergraduate level.

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Annexes

Annex 1. Participant information sheet

Addis Ababa University, College of Health Sciences, School of Allied Health Science, Department of Medical Laboratory Science, Addis Ababa, Ethiopia

Title of the research: Major challenges of medical laboratories for ISO 15189 accreditation in selected government hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia

First of all, I would like to thank you in advance for your cooperation and consent to participate in this study. Please read or listen carefully about the general information of the study. If you have any question regarding the study, please ask freely.

Background

I am doing a research in partial fulfillment of the requirement of master's degree in laboratory management and quality assurance specialty at Addis Ababa university department of medical laboratory sciences. The research is on "Major challenges of medical laboratories for ISO 15189 accreditation in selected government hospitals of Addis Ababa, Debrebrhan, and Bishoftu Ethiopia"

Laboratory accreditation is a widely accepted process of evaluation of a laboratory's quality, performance, and reliability and efficiency, in which an authoritative independent body gives formal recognition that the laboratory is competent to carry out specific tasks. It is a means to promote and enforce better quality in laboratory testing and to ultimately reduce testing errors. Accreditation also increases the credibility of the results and services delivered by a laboratory through providing recognition that it is compliant with quality and competence standards considered necessary for accurate, reliable and safe testing. The value of accreditation lies in promoting the delivery of reliable results for patient management or generation of reliable data for critical public health interventions

The data for this study will be gathered using structured questionnaire and in-depth interview. You will be asked your socio-demographic information, challenges during the accreditation process, and possible solutions for those challenges.

Aim of the study

The purpose of this study is to assess the major challenges of medical laboratories for ISO 15189 accreditation and identify the possible future solutions for the identified challenges.

The information you provide can help to find out the level of participation of staff and management in the accreditation process, challenges and possible solutions.

Benefits for participants

Study participants will not have any financial incentives or other inducements from participating on this study.

Risks for participant

The proposed research will not have any known harm, social discrimination, physiological trauma and economical loss on study participants.

Confidentiality

I assure that all the information you provide during the interview and data collection process will be kept confidential by using codes instead of names. Your participation in this research is entirely voluntary. Your willingness to participate in this study is essential and highly appreciated.

Assurance of Principal Investigator

I put my signature below to confirm you that I take over the responsibility for the information that you give.

Mekonnen Girma (PI): Signature: _____Date: _____

Note: If you have any questions about this study, feel free to ask now or anytime throughout data collection and the study period by contacting:

Principal investigator: Mekonnen Girma (Mob. +251918060169 Email: mekonnen2302 @gmail.com

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Medical laboratory department (tel. +251112755170)

Annex 2 Consent form

I have been informed about the study which plans for the Assessment of the major challenges of medical laboratories for ISO 15189 accreditation in selected government hospitals of Addis Ababa, Debrebrhan, and Bishoftu, Ethiopia. The objective and the application of the study were briefly explained to me. I am also informed that all information contained within the questionnaire is to be kept confidential. Moreover, I have been well informed of my right to refuse information, decline to cooperate and drop out of the study if I want. It is, therefore, with full understanding of the situation that I agreed to give the informed consent voluntarily to the researcher to give my idea/ knowledge for the mentioned study.

I give my consent for giving of the requested information for this study.

Participant code: _____ Signature: _____

Date: _____

Annex 3: Data collection tool

I am a post graduate student at Addis Ababa University pursuing a Master of Laboratory Management and Quality Assurance. For my final thesis, I am carrying out a study on the Assessment of Major Challenges of Medical Laboratories for ISO 15189 Accreditation in selected government hospitals of Addis Ababa, Debrebrhan, Bishoftu, Ethiopia. I believe the findings of this study will have great benefit to your laboratory and other organizations seeking not only this particular accreditation but supporting the program and others as well.

If you choose to participate in this research, please answer all questions as honestly as possible. Participation is strictly voluntary and you may refuse to participate at any time. There is no compensation for responding or any known risk. The data collected will be for research purposes only.

Thank you for your cooperation!!!

Mekonnen Girma

This Questionnaire is divided into four sections

Section (A) - Information about yourself, **Section (B**) - Awareness, Participation, support by mentors, and training experience of study participants related to accreditation process, **Section (C)** Degree of Implementing LQMS, **Section (D)** Factors affecting accreditation process. Individual responses will be kept confidential. Kindly answer all the questions in this questionnaire to the best of your knowledge and if you have any queries do not hesitate to call on mobile number **0918160169** or send an email to **mekonnen2302@gmail.com.** Your participation is highly appreciated.

Thank you!!!

Hospital code _____ (to be completed by the researcher)

SECTION (A) – Information about yourself

Kindly encircle that best describes your answer

101. Sex **1**. Male **2.** Female
102. Age (in years) _____
103. Educational level **1**. MSc and above **2.** BSc **3.** Diploma **4.** Certificate
104. How long have you worked at this organization/hospital? _____(specify)
105. In which unit/department are you working? **1**. Hematology **2**. Clinical chemistry **3**. Microbiology **4**. Serology **5**. Parasitology **6**. Urinalysis **7**. _____ (**Other specify**)
106. Which of the following describes your position in your organization? **1.** Section Head **2.** Lab Manager(head) **3.** Lab Quality Manager **4**. Technical staff 5. others/specify_____

SECTION B: Awareness, participation, support by mentors, and training experience related to accreditation process

The following questions relate to your experience while your organizations seeking ISO 15189 accreditation of your laboratory directly or through step wise approach. Answer the questions below about the steps taken to gain quality systems certification by **encircling** below the appropriate item.

201. Are you aware of your organization's effort to seek ISO 15189 accreditation recognition? 1. **Yes** 2. **No**
202. If your answer in the question above is Yes, have you been involved in the accreditation process. 1. **Yes** 2. **No**
203. If your answer for question number **202** is **Yes,** how long have you been involved in the process? _____ (specify)
204. If your answer for question **202** is **Yes** in which way(s) have you been involved in the accreditation process? 1. Decision making (Management). **2.** Sensitization/Awareness. **3**. Document Preparation. **4.** Auditing. 5. Coordination **6**. Addressing non-conformities. **7**. Other (specify) _____
205. Have you ever taken training related to ISO 15189 accreditation? 1. **Yes** 2. **No**

206. To what extent did your organization use external consultants/mentors to assist with quality system implementation? **0.** I don't know **1**. Not at all **2**. Very small extent **3.** Moderate extent **4**. Large extent. **5**. Very large extent
207. If your answer for question **207** is not at all and very small extent, what is the reasons? **1**. Lack of competent consultants **2**. lack of adequate budget for external consultants **3**. lack of management support **4**. Other----------specify
208. If your answer for question **206** is at large extent and very large extent, have you got the expected quality assistance? **1.** Yes **2.** No

SECTION C. Perception regarding degree of Implementation of LQMS

To what degree was the following items implemented as part of your ISO 15189 accreditation effort? Please **encircle** (with the guidance of the key below) in column that best describes your implementation experience.

0 = Don't Know **1** = Not at all **2**= Very small degree **3** = Moderate degree **4** = Large degree **5** = Very large degree

Item implemented	Degree of Implementation					
301. Adequate awareness creation and sensitization of staff on benefits of ISO 15189 accreditation conducted.	0	1	2	3	4	5
302. Commitment of top management was evident to fulfill all ISO standards.	0	1	2	3	4	5
303. A Quality manual with clear Quality policy statement and objectives was developed and communicated	0	1	2	3	4	5
304. Laboratory logistics system is established to manage laboratory supplies to avoid over stock and under stock for essential laboratory supplies.	0	1	2	3	4	5
305. The laboratory is conducting internal audits at Planned intervals to check the compliance of all required standard	0	1	2	3	4	5
306. Action plan is developed based on internal audit findings.	0	1	2	3	4	5
307. Training and continual education is implemented effectively for all managerial, technical and supporting staffs.	0	1	2	3	4	5
308. The laboratory have space allocated for the performance of its work that is designed to ensure the quality of its work	0	1	2	3	4	5
309. The laboratory has adequate storage space for laboratory supplies which is regularly monitored including refrigerators	0	1	2	3	4	5
310. The laboratory has wash rooms for staffs and adequate sample collection space for clients.	0	1	2	3	4	5
311. The laboratory is monitoring environmental conditions regularly as per the standard (room temperature and humidity is monitored)	0	1	2	3	4	5
312. The laboratory has system to selection, purchase and manage laboratory supplies and equipment per ISO standard.	0	1	2	3	4	5
313. The laboratory performs independent equipment verification practice before using for routine patient test reporting	0	1	2	3	4	5

314. The laboratory establishes a system to inspect and verify all laboratory supplies before using for patient testing	0	1	2	3	4	5
315. The laboratory verify new methods before introducing in to routine uses	0	1	2	3	4	5
316. The laboratory performs internal quality control for all tests	0	1	2	3	4	5
317. Laboratory tests reviewed and released by authorized personnel	0	1	2	3	4	5
318. The laboratory evaluate and verify electronic LIS before using it(if LIS is available)	0	1	2	3	4	5

SECTION D: FACTORS AFFECTING ACCREDITATION PROCESS

(a) Please indicate by **encircling** in the appropriate column (with the guidance of the key below) the extent to which accreditation process has been affected by the following: -

0 = Don't Know **1** = Not at all. **2**=Very small degree **3** = Moderate degree **4** = Large degree **5** = Very large degree

Description	**Extent of effect**					
501. High cost in implementing Laboratory Quality Management System	0	1	2	3	4	5
502. Organizational Culture	0	1	2	3	4	5
503. Staff resisting change	0	1	2	3	4	5
504. Lack of staff participation	0	1	2	3	4	5
505. Lack of support from top management	0	1	2	3	4	5
506. Lack of continuous training on LQMS and other pertinent trainings (continuous professional development)	0	1	2	3	4	5
507. Lack of understanding of the LQMS and ISO requirements by the staff	0	1	2	3	4	5
508. Lack of required standards and reference documents to customize polices and manuals	0	1	2	3	4	5
509. Lack of awareness on the benefits of LQMS and accreditation	0	1	2	3	4	5
510. Lack of proper planning in the implementation of LQMS	0	1	2	3	4	5
511. Turnover of trained staff	0	1	2	3	4	5
512. Organizational structure(difficulty in communication and decision making process)	0	1	2	3	4	5
513. Complexity of the processes within the organization	0	1	2	3	4	5
514. Lack of qualified personnel to lead the accreditation process	0	1	2	3	4	5
515. Lack of management reviews to the accreditation process	0	1	2	3	4	5
516. Lack of sensitization on the accreditation process	0	1	2	3	4	5

517. Unavailability of funds to implement the accreditation process	0	1	2	3	4	5
518. Lack of adequate infrastructure e.g. workspace, storage space etc.	0	1	2	3	4	5
519. Massive documentation requirements by the standard	0	1	2	3	4	5
520. Lack of regular mentorship and technical assistance from upper tier levels	0	1	2	3	4	5
521. Lack of adequate equipment and supplies to provide uninterrupted lab tests	0	1	2	3	4	5
522. Routine work load	0	1	2	3	4	5

(b) What other critical challenges are facing medical laboratory's accreditation?

(c) In your view, kindly state measures the management or other concerning body would have taken to reduce the severity of the challenges encountered during the ISO 15189 accreditation process.

(d) In your view please mention if there is any opportunity to implement LQMS and comply all ISO standards?

---------- **Thank you for your time!!!**

Interview questions Guide

1. What is your position in the organization?

3. Could you, please tell me briefly your role in the organization

4. When did the organization initiate for SLMTA/SLIPTA participation or ISO 15189 accreditation process?

5. What is the purpose of SLMTA/SLIPTA participation or ISO 15189 accreditation in your organization?

7. Were the staffs adequately sensitized about the accreditation process?

8. What training /support have you and other employees received in regard to the accreditation?

9. In your view, what was the reaction of the staff to the initiation of the ISO accreditation?

10. Did the staff adopt the accreditation process without difficulty?

11. What has been the extent of support by LQMS consultants/mentors?

13. Has the management been supportive to the process?

14. Have the concerned bodies been in a position to provide all the required support?

15. What other challenges has the laboratory facing in view of this process?

16. In your view, what will be the possible solutions for those challenges?

16. Do you have any other comments or suggestions?

Declaration

This is to certify that the thesis prepared by Mekonnen Girma which is entitled with “Major Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Government Hospitals of Addis Ababa, Debrebrhan, Bishoftu, Ethiopia” and submitted in partial fulfillment of the requirements for the degree of Master of Clinical Laboratory Sciences (Laboratory Management and Quality Assurance Specialty Track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Principal investigator

Mekonnen Girma (BSc) _____ _____

Signature Date

I recommend it to be submitted as fulfilling the thesis requirement.

Advisors

Adinew Desale (Bsc, Msc.) _____ _____

Signature Date

Dr. Aster Tsegaye (Msc, PhD) _____ _____

Signature Date

Fatuma Hassen (BSc, BA, MPH, PHD fellow) _____ _____

Signature Date