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ISO 15189 Laboratory Accreditation Utilization Rate and challenges among Accredited Laboratories in Ethiopia, 2021

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This is to certify that the thesis prepared by Zewdu Ayele, entitled: **ISO 15189 laboratory accreditation utilization and challenges among accredited laboratories in Ethiopia, 2021** and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (laboratory management and quality assurance) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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V. Acronyms and Abbreviation

AB	Accreditation Body
AAU	Addis Ababa University
AFRAC	African Accreditation Cooperation
A2LA	American Association Of Laboratory Accreditation
APAC	Asian Pacific Accreditation Cooperation Incorporated
ARAC	Arab Accreditation Cooperation
CAB	Conformity Assessment Body
CDC	Centers For Diseases Control And Prevention
EA	European Cooperation For Accreditation
ENAO	Ethiopian National Accreditation Office
EQA	External Quality Assessment
IAAC	Inter-American Accreditation Cooperation
IAF	International Accreditation Forum
ILAC MRA	International Laboratory Accreditation Cooperation Mutual Recognition Arrangement
ISO	International Organization For Standardization
KENAS	Kenya's National Accreditation Service
MOH	Ministry Of Health
MoTI	Ministry Of Trade And Industry
PT	Proficiency Testing
QMS	Quality Management System
SANAS	South Africa National Accreditation Service
SPSS	Statistical Package For The Social Sciences
SLMTA	Strengthening Laboratory Management Towards Accreditation
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation
TC212	Technical Committee 212
WHO	World Health Organization

VI. Abstract

Background: Accreditation is a procedure by which a third party gives witness for a conformity assessment body conveying formal demonstration of its competence to carry out specific tasks. It is very important for the maintenance of quality; and most accredited laboratories have to be utilizing their quality performance throughout accreditation cycle as long as they are in the service. In this regard, there is limited documented evidence in Ethiopia. Thus, this study aimed to assess the ISO 15189 laboratory accreditation utilization rate and to identify hindering factors among accredited laboratories in Ethiopia, 2021.

Methods: A cross sectional study design was employed in 46 government and private accredited health facility laboratories from January 2021 to June 2021 in Ethiopia by comprising quantitative and qualitative data types. Data was entered and analyzed using SPSS version 20 software. P-value <0.05 was considered as statistically significant. Qualitative data were categorized and described thematically.

Result: There were 276 respondents from 46 accredited conformity assessment bodies (CABs) were participated in this study. Among the current accredited laboratories, 82.6 % were utilized accreditation. Personnel incompetence (0.4, CI [0.003-0.560]) with p-value 0.041, no appointment of quality manager (0.13, CI [0.3-0.595]) with p-value 0.008, and inadequate regulatory follow up (0.014, CI [0.00-0.47]) with p-value 0.017 were found to be major hindering factors for accreditation and had significant association with accreditation utilization. Non-commitment and low attention from top management, inadequate training, inconsistent mentorship and work load were also among the identified factors.

Conclusion: In Ethiopia, even though efforts are there to implement medical laboratory accreditation, we learnt that there is an irregular substantial utilization rate, mainly due to lack of special dealing among the accredited and non-accredited laboratory by regulatory body. Hence, we strongly recommend the need for better engagement, commitment and advocacy with all stakeholders to harmonize and lead accreditation utilization service for the stupendous quality performance that can benefit the community at most.

Keywords: Accreditation, accreditations utilization, accreditation standards, Ethiopia.

1. Introduction

1.1. Backgrounds

Quality management is an essential component for health care laboratories to achieve their goals and to deliver quality results for their customers. Currently health care laboratory managers and owners are bothering with quality issue. There are several uncertainties with regard to market competitive in private and public sectors that challenge their management. Due to these challenges health care laboratory needs to improve their quality and cost effectiveness of the organization(1). So as to be competitive and to implement quality accreditation is essential(2).

Accreditation is the third party attention related to conformity assessment body conveying formal demonstration of its competence to carry out specific tasks. It is a bench mark for performance that assures high standards like ISO15189, in organizational system by conformity assessment body(3).

Accreditation bodies assessing and accrediting conformity assessment bodies and specifies requirements for the competence, consistent operation and impartiality of accreditation bodies as a sole implementer of ISO 17011 standard (4).

Each accreditation bodies are under the umbrella of international laboratory accreditation cooperation (ILAC) which is the international authority on laboratory, inspection body, reference laboratory producer and proficiency testing provider accreditation with a membership consisting of stake holders organizations through the world (5).

The ILAC mutual recognition arrangement (MRA) is an arrangement signed by the signatory accreditation bodies to recognize the equivalence of the accreditation schemes operated within the scope of their signatory status. The ILAC MRA provides assurance that CABs in different economies are operating to the same international standards (6).

ISO 15189 is standard established by TC212 in 2003 as first edition and in 2007 as the second edition for quality and competence of medical laboratories (7). It is extracted from ISO 17025, general requirement for testing and calibration. Currently ISO 15189 is used as standard for medical laboratory quality management system by declaring quality and competence (8).

The accreditation of health care programs were began 1980s globally (9) and Around 1990s in Europe during quality of health care improvement. The pioneer accreditation programs were the North American models for the joint commission on hospital accreditation and then expanded to include health care organizations and the Canadian council on hospital accreditation (10). Most experts who love their profession need technical solutions to make accreditation credible, impartial, robust and consistent throughout the globe. Most research attention has more based on impact on safety and quality in health care provider than including the whole health system (11).

There were around six meetings to strength and standardize medical laboratory in Africa includes January 2008 (Maputo, Mozambique), April 2008 (Lyon, France): September 2008 (Yaoundé, Cameroon), September 2008 (Dakar, Senegal), July 2009 (Kigali, Rwanda) and September 2009 (Kigali, Rwanda). In each meeting WHO and CDC were involved and they set WHO AFRO checklist. Laboratories that demonstrate outstanding performance in the WHO-AFRO process encouraged to apply ISO 15189 accreditation (12).

Few developing country laboratories were established the international ISO 15189 standard as easy and affordable by designing to implement by customized standard. Likewise world health organization regional office for Africa created a step wise approach to laboratories for the fulfillment of ISO 15189 requirements gradually called Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA), through Strengthening Laboratory Management Toward Accreditation (SLMTA) program due to financial limitation for accreditation. It uses stars 0 to 5 for grading and acknowledges only where the laboratory is now but not brings radical change with respect to competence, and to give consecutive technical support and to recognize their progress using scale method (13).

Quality laboratory services are depend on trained and competent laboratory professionals who gain knowledge and skill through continuous professional education. But in sub Saharan countries most health care organizations ignore it. Quality provided by individual laboratories is questioned, and not all facilities are enrolled in proficiency testing program (13).

In Ethiopian accreditation was began in 2010 after the Ethiopian National Accreditation Office establishment by the council of ministers with regulation number 195/2010 and re-established

with regulation number 279/2012 as the sole national accreditation body to give accreditation services (15).

In collaboration with GIZ and SANAS, ENAO trained competent assessors on medical laboratory and other schemes who undertaken assessment on behalf of ENAO. Assessor calibration held regularly in order to address how it can continuously enhance service delivery, which enables that all assessors have access to the same information (16).

PT provider in the country the CABs were enforced to participate EQA outside the country that incurs high cost. Major equipment calibrator materials also cost very high and not access in the country (17). However, there are limited documented information, rather considering as these might be challenges for proper accreditation utilization; and hence this study will assess the current accreditation utilization rate and try to figure out the major hindering factors for ISO 15189 laboratory accreditation utilization among accredited laboratories in Ethiopia.

1.2. Statement of the problem

ISO 15189 laboratory accreditation has benefit to improve testing results, internal efficiency and quality management system for patient safety. It also declares the competence of laboratory personnel, method, equipment and environment of the laboratory (18).

However accreditation utilization is difficult around the globe due to different factors including organizational resistance to change, increased staff workload, lack of awareness about continuous quality improvement, insufficient staff training and support for continuous quality improvement and lack of performance outcome measures (19).

Resources and physical involvement in the accreditation process is essential for proper accreditation utilization. Only 2.5% laboratories without physician and resource can achieve and utilize accreditation as the study shows done in Colombia (20).

There are many identified hindering factors among these coherence, organizational buy in, collective quality improvement action, individual characteristics and influence on organizations experience of accreditation can affect fore mostly the accreditation process utilization(21).

Most African laboratories are implementing quality management system with SLIPTA program by WHO afro checklist. This is due to limitation of financial resources (like for PT and calibration issue) for accreditation. It doesn't give confidence for the ISO 15189 utilization of the quality or accreditation (13). The health care organizations look only for grades from 0-5 stars through year to year. They are not recognized as accredited, and the result of such laboratory will not accept globally. Due to this reason most laboratories ceased from quality. Accreditation declares the acceptance of the result; because in accredited laboratory the laboratory personnel, the environment, the equipment, and the methods competence are declared. but accredited laboratories are not maintain their good performance through in each accreditation cycle (12).

Enthusiasts of medical laboratory professions needs accreditation to solve technical work that brings credible, robust and quality through the globe irrespective of management resistance, limitation of resource and limitation of PT provider (11).

The laboratory that wants to be accredited with ISO 15189 shall first; insure availability of competent laboratory personnel, committed management, efficiency resource and equipped infrastructure; but this are still in limited access (12).

In sub Saharan Africa the issue of quality is under question. The coverage of health facility, human resource, sustainability of quality after implementation of QMS are very limited or no at all (13).

Even if accreditation services are implemented in Ethiopia in a good manner, most accredited laboratories cannot sustain their quality services. There are many challenges that deviate from the standard as ENAO intervention in 2017. These challenges may be regulatory failure, lack of PT provider, lack of calibration material and calibrator, lack of awareness (17).

As of the study in Addis Ababa, accreditation utilization is still challenging for many facilities due to; trained staff turnover, training and mentorship inadequacy, low staff satisfaction, low quality and quantity of equipment's, low management support, and poor quality laboratory infrastructure (22).

Even though there is an effort to fulfill accreditation requirements, there is no study which shows the sustaining and utilizing accreditation throughout the country. There is also no data that shows hindering factors of accreditation utilization in Ethiopia. Thus this research project was therefore tried to identify the hindering factors of accreditation process which are potential challenges for unsustainability of accreditation service among the Ethiopia medical laboratories.

1.3. Significance of the study

This research project tried to identify the challenges of accreditation process which are potential factors for sustainability of accreditation service. Moreover it will be used to policy maker that, how regulatory bodies enforce the conformity assessment body to be accredited and maintain their quality service. Accreditation bodies, conformity assessment bodies and patients also will be used it for their specific purpose. It also used to establish more accredited laboratories which are used for quality of test result deliverance.

This also helps for the researcher and technical supporter/mentor to solve their problem; and to admit their mistakes with regard to accreditation.

More over the finding of this study could be a baseline data for further large scale similar study.

2. Literature review

2.1. ISO 15189 Laboratory accreditation

Accreditation is very important tool to implement quality management system and to deliver quality service with limited resources. Even though few medical laboratories' accredited now a days, accreditation reduce errors early and helps patients not to take unnecessary treatment. Most accredited laboratories are confident for their results and they didn't need third bodies support(23).

The need for accreditation may result committed laboratory management, competent laboratory staff through training and facilitate the improvement of purchasing and supply chain, training, calibration and maintenance of the instrument. Accreditation is thus very important for the sustainable implementation of quality service in health care service intervention(24). There are only 380 internationally accredited medical laboratories in Africa. The majority of them are in south Africa; only 35 medical laboratories are in sub Saharan Africa(25). Those accredited medical laboratories address the criteria required to receive recognition include TAT (> 80% test result within stated TAT), PT (>80% scored by two consecutive PT panel), IQC performance (all IQC result should pass) and test method verification (12).

The study done in Iran showed that the currently accreditation is most abundantly used health laboratory activity auditing system through the globe. there are major obstacles to sustain accreditation in the hospital; include limitation in quality management system implementation, lack of evaluator and evaluation, content limitation of the standard, psychological readiness of the staff and managerial problems(26).

Training and competence assessment is one of the basic activities to implement quality management system. The training with standard will create competent staff and hence there is no breakdown of quality service in health care laboratory; and accreditation will maintained(27).

As the study done in Denmark, the attitude towards accreditation has different patterns between medical professionals; in which clinical attitudes affect the public decisions on accreditation

usage. The attitude may reflect political agenda than quality service and this may reduce the accreditation usage sustainability(28).

The number and severity of nonconformities found during an assessment of a testing laboratory indicates its level of quality compliance. Quality standards are established and maintained to ensure the reliability of laboratory test reports. Sharing the benefits of laboratory accreditation could help more countries within sub-Saharan Africa overcome existing challenges to achieve accreditation and robust quality systems with ISO 15189 in line with ISO/IEC 17025 accreditation on the performance of sustainability(29).

2.2. Accreditation utilization and its hindering factor

In developing countries quality of health care services are very limited and exposed to different hindering factors. Hence accreditation service should be implemented to declare the associated risks and to deliver quality results. Accreditation makes the conformity assessment body (CABs) to use resources wisely, to establish strong quality management system, to satisfy customers want and to exercise good quality process (30).

The interaction between international and local or/and regulatory body actors are not understand each other for customization and transfer of accreditation policy. Hence low and middle income countries are adopted accreditation standards from developed countries. So the implementation and sustainability of the standard by both CABs and AB (accreditation bodies) are the major obstacles(31).

Accredited health care hospitals make sustainability measurement in its strategies of accreditation through discussion with stake holders or regulatory bodies to improve the level of maturity(32).

Standard agencies have authority to promote, develop and distribute standards. The agencies believe that the standards are effective, efficient as well as appropriate for health care hospitals. But they do not see standards in deep; therefore standards are not develop as familiar as the ground(33).

The main challenges that affect the accreditation utilization of quality medical laboratory service include inadequate resource, lack of management cooperation, inappropriate utilization of equipment and personnel incompetence with regard to knowledge(34).

Accreditation can reduce rates of medical laboratory errors. As the study done on Impact of Laboratory Accreditation on Patient Care and the Health System shows participating PT reduce errors from 26% to 38 % in CD4 (24).

The Weaknesses and the challenges of accreditation utilization includes organizational resistance to change, increased staff workload, lack of awareness about continuous quality improvement, insufficient staff training and support for continuous quality improvement, lack of applicable accreditation standards for local use, and lack of performance outcome measures(35).

There are different hindering factors that are associated with accreditation utilization includes; external quality assessment, root cause analysis, laboratory equipment maintenance, lab personnel competency, measurement uncertainty, evaluation, audit, trained, staff turnover, method validation and verification(36).

According to the study done in health center, Addis Ababa, there are many challenges for the journey of accreditation and for the utilization of accreditation includes; lack of internal quality control materials, limitation of reagents, lack of equipment maintenance, lack of skilled manpower and lack of calibration materials (22).

Moreover, the overall summary of the literature review have been depicted at figure 1.

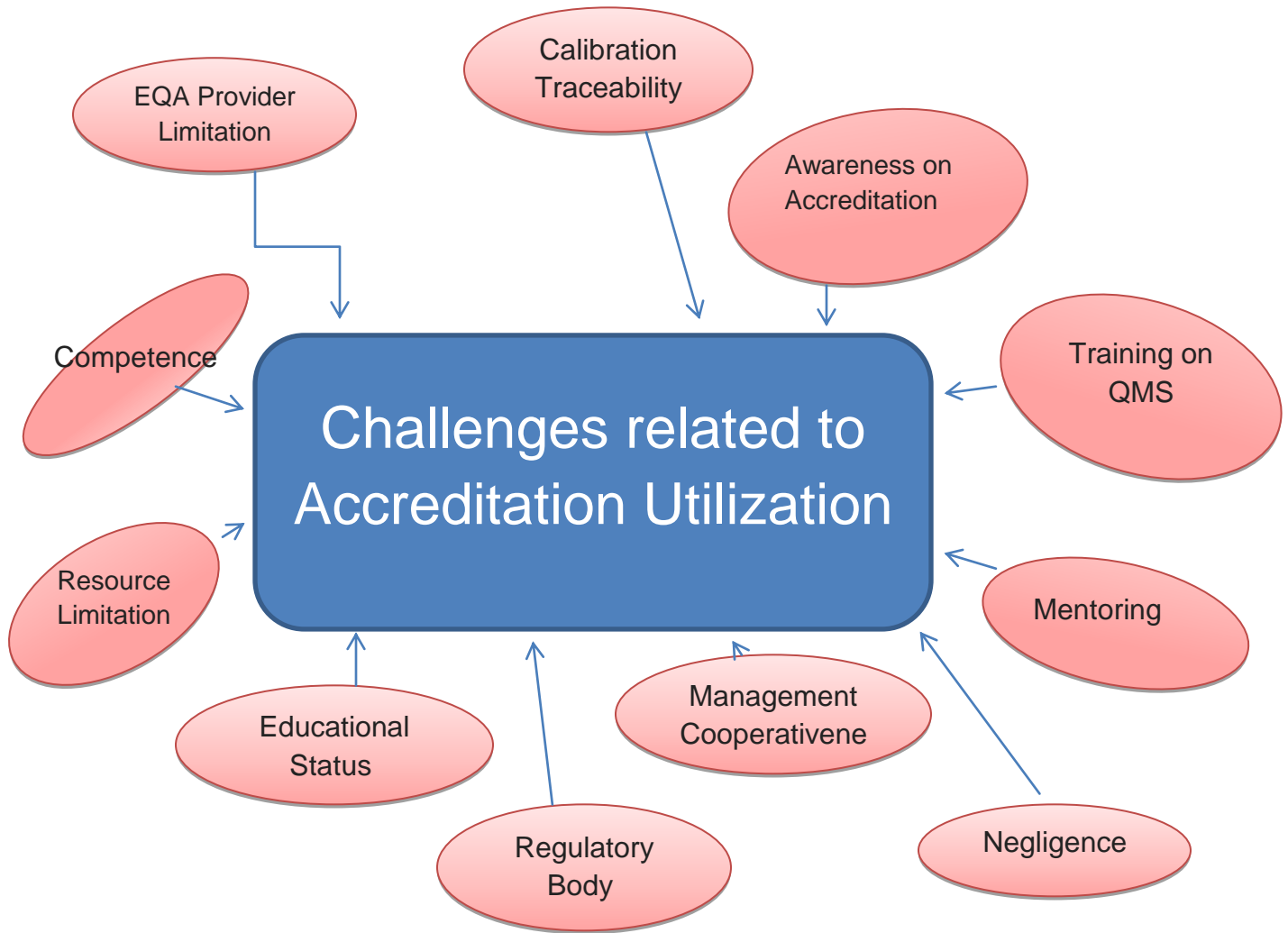


Figure 1: Conceptual framework for ISO 15189 laboratory Accreditation utilization and hindering factors among accredited laboratories in Ethiopia, 2021(26, 34)

3. Objectives

3.1. General objective

The general objective of this study was to assess the ISO 15189 Laboratory Accreditation Utilization rate and to identify challenges among accredited medical laboratories in Ethiopia, 2021

3.2. Specific objectives

1. To assess the accreditation utilization rate among accredited medical laboratories of Ethiopia
2. To identify associated challenges that make conformity assessment body turn aside from accreditation standards in Ethiopia.

4. Hypothesis

HO: There is good accreditation utilization rate among ISO 15189 accredited laboratories in Ethiopia.

5. Materials and methods

5.1. Study area and period

The study was conducted in Ethiopia which is located in the horn of Africa. According to the 2019 revision of the World Population Prospects, the total population of Ethiopia was 109,224,414. The capital city, Addis Ababa, is one of the diplomacy cities in the world in which African union is located. As of 2019 report the health coverage index is still 39% and there is also inadequate quality of care which is only 31% of quality process and output(37). The country is composed with 10 regional state of Federal Democratic arrangement and 68 administrative zones(38).

In Ethiopia, there are 353 functional and 107 under construction hospitals, 3735 functional and 96 under construction health centers with recommended level of diagnostic laboratories: which indicates there is a huge investment by the government. Note that all have a diagnostic laboratories (37). To the contrary, of these, not more than 46 medical laboratories have been accredited by ENAO, of which 36 are government health care facilities and 10 are private hospitals and standalone advanced medical laboratories. From these 22 are in Addis Ababa. The other 24 are in different regions of the country. The study was conducted between January and June 2021. Figure 2 illustrates the location of accredited health care facility in Ethiopia, 2021.

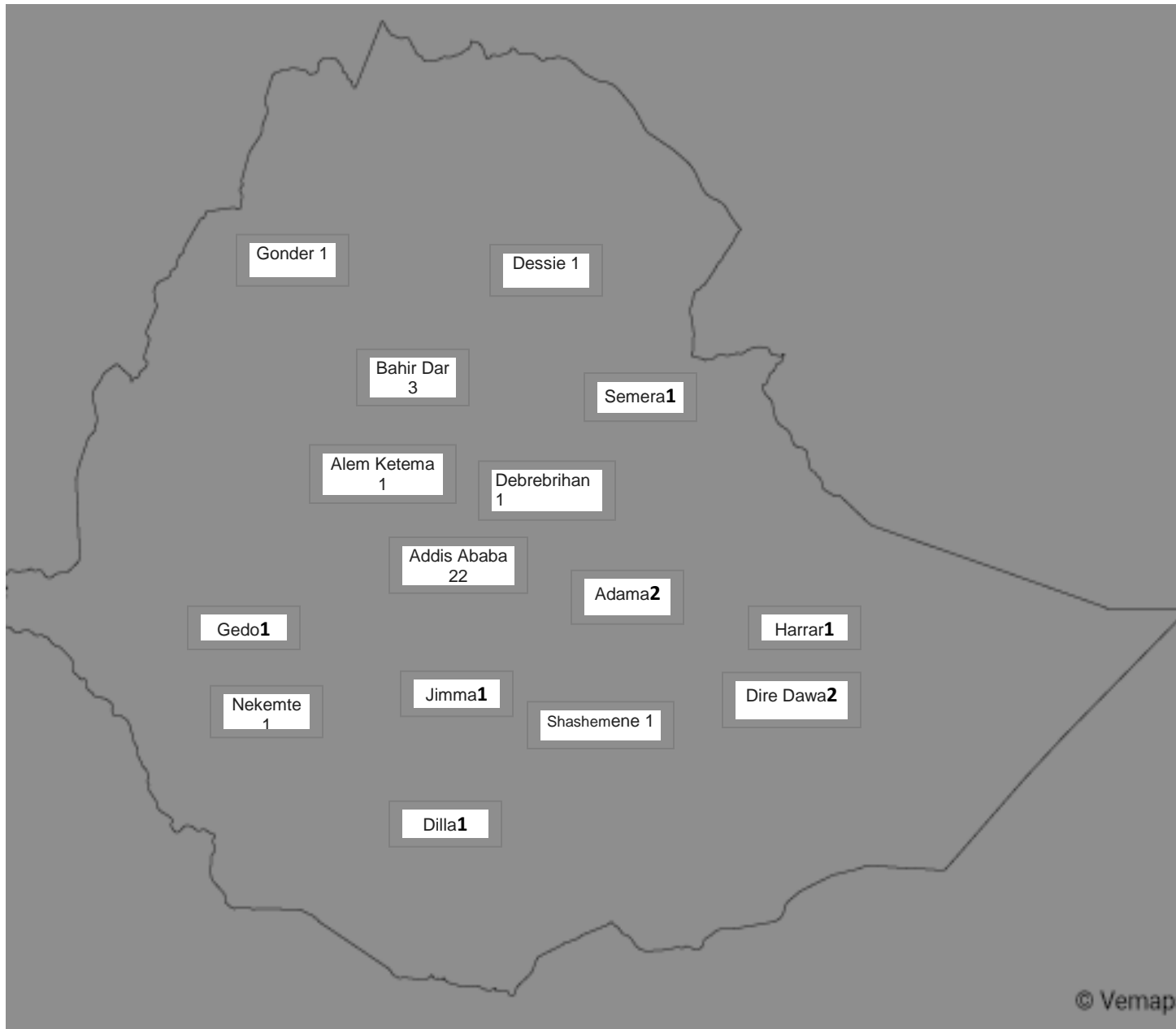


Figure 2: map of Ethiopia with cities where accredited health care facilities found, 2021. The name of each accredited labs are listed in the annex part tigray region accredited labs are not indicated in this map.

5.2. Study design

A cross sectional study design for quantitative and grounding study design for qualitative data types were employed among accredited laboratories that have been providing laboratory service in Ethiopia.

5.3. Populations

5.3.1 Source population

All government health care facility laboratories, private hospital's and advanced medical laboratory service provider health facilities in Ethiopia.

5.3.2 Study population

Key personnel from Government and private laboratories in Ethiopia that submitted a request for accreditation to ENAO and accredited against ISO 15189 standards were the study population for this particular study

5.4. Inclusion and exclusion criteria

5.4.1 Inclusion criteria

Medical laboratories which were applied for accreditation and accredited irrespective of their utilization status; and those which are applied and not grant accreditation certificate.

5.5. Study variables

5.5.1 Dependent variable

- Accreditation utilization rate

5.5.2 Independent variable

- Training and personnel competence
- Management support and resource allocation
- Proficiency testing and calibration access
- Awareness on accreditation and quality management system
- Mentoring follow up and regulatory activities
- Management commitment

5.6. Measurement and data collection

5.6.1 Sample size determination

All key personnel in 46 accredited laboratory of the country were accommodated. 276 personnel were included in this study for both quantitative and qualitative data. The key personnel's were medical director/CEO, laboratory head, quality officer, equipment officer, and two other laboratory personnel's.

5.6.2 Sampling method

Purposive sampling technique was applied to select health care accreditation key personnel's: CEO/ medical director, laboratory head, quality manager, purchase personnel, equipment focal personnel considering they have good engagement with the requirements of accreditation, which will help to generate objective evidence for the assessment of accreditation utilization and the associated factors.

5.6.3 Data collection procedure

The data collection instrument interviewing by data collectors with anonymously likert scale questionnaire was prepared by reviewing different standards, guideline and documents. To know the utilization rate of accreditation and to identify the hindering factors of accreditation utilization, the questionnaire were incorporate different questions: laboratory profile, the laboratory current status, key personnel's education background, characteristics of laboratory QMS implementation, work experience of the personnel's, stake holders of the laboratory, PT issues, calibration issues and regarding knowledge and attitude of laboratory accreditation. Two senior laboratory technologists were trained using questionnaire for data collection. The principal investigators was involved in overall controlling activities of data collections and assists the data collectors during the process of data collection and collect the filled questionnaires regularly and check for their consistencies. Questionnaire comprising likert scale was administered to each accredited laboratories making an allowance for to get a reputable research finding. The questionnaire was prepared by English language and no need of translating to local language as of the selected key personnel do can understand English language.

5.7. Data quality assurance

To assure data quality, two data collectors was trained and the questionnaire was pre-test before the actual data collection at Addis Ababa in EPHI bacteriology reference laboratory as pre analytical phase. In analytical phase; Completeness, accuracy and consistency of the collected data was checked on daily bases during data collection by the principal investigator.

From post analytical phase principal investigator review overall data consistency, where those questionnaires found incomplete, inaccurate and inconsistent the investigator was return back for data collectors to be filled again.

Moreover the data was cleaned, edited and coded after data entry.

5.8. Data analysis and interpretation

Data was entered, cleaned and analyzed using SPSS version 20.0 software for quantitative data and for qualitative data from in-depth interviews and open-ended questions were organized, categorized, summarized, and finally discussed by narrating the findings in a thematically manner. Descriptive statistics was computed for most of the study variables for quantitative data. Frequency distribution, tables and graphs were used to describe the findings. P-value less than 0.05 were taken as statistically significant when looking for associations between accreditation utilization and its hindering factors.

For the purpose of this study, accredited medical laboratories are classified as laboratories that were accredited and withdraw, those which are accredited and sustain their performance and reapply for the second round of accreditation according to accreditation cycle, those which are apply for accreditation and terminated/ not apply for reapplication, and those which are accredited and suspend for some defined period.

5.9. Ethical considerations

Ethical clearance and permission was obtain from department research ad ethics committee (DREC) of department of clinical laboratory sciences, Addis Abba University with a protocol number MLS/037/20 and from the respective accredited health institutions before the data collection process. The study participants was informed about the purpose of the study and the importance of their participation in the study by contributing information that may help in assessing the sustainability, factors and Practices of accreditation. The study participants was also inform that they can skip a question or questions that they do not want to answer fully or partly and also to stop the interviewing process at any time if they want to do so. Then after assuring the confidential nature of responses and obtaining informed consent from the study participants interviewing was proceed with strict privacy.

Moreover, confidentiality of the data was maintained throughout the study by keeping hard copies in lockers and electronic files by password protection.

5.10. Dissemination of results

The results will be presented to users of accreditation and policy makers including AAU, Ethiopian national accreditation office, ministry of trade and industry, and ministry of health through presentation. The investigator with stakeholders will discuss about findings in results and their implications in quality implementation process. The investigator will explore how research findings fit with current practice and policy, in what ways they could inform improvements to practice at all levels, and how best to translate this research findings into usable and effective outputs. From these meetings and discussion the investigator and the stakeholders will generate actionable messages and recommendations for wider dissemination, including via traditional and novel methods. Finally the result will be disseminated through a multi-faceted approach including: a major media campaign including articles in professional journals and Website that acts as a repository for all reports and other outputs such as the digital stories

5.11. Operational definitions

Accreditation Body: (single or multi economy AB): an organization that operates an accreditation system for one or more types of conformity assessment bodies(14).

Accreditation cycle: the time table that covers 4 and ½ years for initial assessment and follow up assessments in between(15).

Accredited laboratory: laboratory that implements ISO 15189 and its competence is declared by ENAO/AB.

Accreditation utilization: well exercising and implementation of the accreditation process as per the ISO 15189 standard specifically quality and competence.

CAB: - it stands for conformity assessment body in which different scheme of conformity body includes like medical laboratory, inspection body and so on.

Peer Evaluation: A structured process of evaluation of a Regional Group or accreditation body by representatives of accreditation bodies(14).

Reapplication: applying for accreditation after the full cycle of accreditation is finished.

Signatory: A Member of IAF and/or ILAC who has signed one or more of the Arrangements of a Regional Group or has signed the IAF and/or ILAC Arrangement.

Terminated: ceased from accreditation process due to different reasons.

Withdrawal: resignation from accreditation due to non-comply of ISO 15189 standard.(3)

6. Result

6.1. Background Information of the study area

The data was collected from 46 government and private health facility laboratories; of these 22 laboratories were found in Addis Ababa while the rest 24 were at different towns of the region. According to the study, Ethiopian national accreditation office (ENAO) categorizes those laboratories as well utilized, terminated, and suspended or withdrawal accordingly; 38 laboratories had been well utilized the accreditation, 1 laboratory had been terminated, 3 laboratories had been suspended and 4 laboratories had been withdrawal. Of 46 laboratories visited by this study, most of them were accredited in the scope of gene Xpert. From the total accredited health facility included in this study, 36 (78.3%) were government and 10 (21.7%) were private owned. The service year of the health facilities after establishment ranged from 5 to 10 was 12; and 11 health facilities belong to the service year group of 11 to 15 followed by 23 health facility greater than 15 years' service.

Majority of the health facility 17, (37.0%) were general hospitals followed by public health institutes 12, (26.1%). The other organizational levels were 6 comprehensive hospital, 4 primary hospital, 3 specialized hospitals, 3 diagnostic laboratories and 1 health center. The numbers of the employees in that given organization ranged from 4 to 10 were 4, from 11 to 20 were 12, from 21 to 30 were 11 and above 30 employees were 19. Regarding responsibility of health facility in hierarchy, 26 (56.5%) were responsible to ministry of health followed by 19(41.3%) were responsible to regional health bureau and the remaining 1 (2.2%) health facility is responsible to zonal health bureau, as the detailed depicted at table 1.

Table1 Demographic characteristics of the study area of Public and private health facilities (n=46), Ethiopia, 2021

Variables	Demographic Item	Freq uen cy	Percent
Type of organization	Public	36	78.3
	Private	10	21.7
	Total	46	100
Service year of the organization since established	5-10	12	26.1
	11-15	11	23.9
	>15	23	50.0
	Total	46	100
Facility type	Health center	1	2.2
	Primary hospital	4	8.7
	General hospital	17	37.0
	Comprehensive hospital	6	13.0
	Specialized hospital	3	6.5
	Public health	12	26.1
	Diagnostic lab	3	6.7
	Total	46	100
No. of laboratory employee	4-10	4	8.7
	11-20	12	26.1
	21-30	11	23.9
	>30	19	41.3
	Total	46	100
Responsible to	Ministry of health	26	56.5
	R. health bureau	19	41.3
	Zonal health office	1	2.2
	Total	46	100

6.2. Background characteristics of the respondents

The population under study had varying demographic and background characteristics including sex, age, educational level, length of service and position. 254 laboratory professionals and 22 other health professionals (medical directors/chief executive's officers/director generals/MD/CEO/DG) a total 276 participants were accommodated in this study. Out of 282 questionnaires distributed, 276 were completed and submitted back to the principal investigator with a response rate of 97.8 percent. The distribution of the respondent regarding to position were; 40 laboratory head, 44 quality officers, 36 store man, 22 medical directors/CEOs/DGs and 134 operational workers who were interviewed to forward their opinion regarding utilization of accreditation and challenges of medical laboratories for ISO 15189 accreditation utilization. From the total respondents, 214 (77.5%) were males and 62 (22.5%) were females. Majority, 147(53.3%) respondents belong to the age group of 26 to 35 followed by 70 (25.4%) respondents from 36 to 45. Majority of the respondents 120 (43.5%) were masters holders followed by BSc holders 108 (39.1%). Working experience of the study participants in the given organization ranged from 5 to 10 years were from the majority [152, (55.1%)] of participants as the detail illustrated in Table 2.

Table 2 Demographic characteristics of respondents of Public and private health facilities participated in this study (n= 276), Ethiopia, 2021.

Variables	Demographic Item	Frequency	Percent
Sex	Female	62	22.5
	Male	214	77.5
	Total	276	100
Age Group	20-25	28	10.1
	26-35	147	53.3
	36-45	70	25.4
	46-55	31	11.2
	Total	276	100
Educational level	College Diploma	28	10.1
	Bachelor degree	108	39.1
	Master's Degree	120	43.5
	PhD	20	7.3
	Total	276	100
Work Experience	6-10	152	55.1
	11-15	76	27.5
	>15	48	17.4
	Total	276	100
Management level	Laboratory heads	40	14.5
	Quality manager	44	15.9
	Store man	36	13.0
	Operational	134	46.8
	MD/CEO/DG	22	5.8
	Total	276	100

6.3. Accreditation utilization rate

The result showed that, in Ethiopia there were 38 (83% n=46) accredited health facilities utilized accreditation practice in accordance with ISO 15189 standard and had competent laboratory personnel and committed management for well utilization. On the other hand 8 (17% n=46) accredited health care facility laboratories found to be not utilizing the accreditation due to many challenges. After getting accredited, there are 3 (6% n=46) health facility laboratories have been suspended for some specific defined period. The respondent from these laboratories gave their reasons for suspension as: due to calibration failure of major equipment's on accreditation scope; until the laboratory calibrate the equipment, ENAO wrote a suspension letter. As the suspended laboratory responded explanation during interviewing, the laboratory never uses any ENAO/ILACC symbol during suspension time.

The other reason for suspension of accreditation is due to cost of accreditation. The respondents assure that the accreditation fee and related costs like PT and calibration was extra expenditure. Some of the respondents believe that accreditation adds nothing for the business on their laboratory. Those cost related accreditation suspension and withdrawal reasons are mainly proven from private health care facility laboratories.

1 (1%) of the study facility was terminated from accreditation due to incompetent staff and uncommitted management to proceed the accreditation process. The terminated event happened during document completeness by ENAO. After the laboratory submits its available documents and necessary requirements, ENAO asked to submit all requirements that are required with ISO 15189. If at that specified time those documents did not submitted by CABs, there is a rule that the accredited laboratory terminated from accreditation, because of not complying those competence. Accordingly, 4 health care facility laboratories were not included in this study, which is found in Tigray region in which there were unsuitable situation during data collection time. Accreditation utilization status is illustrated in fig. 3. Each hindering factors are expressed in category next to this.

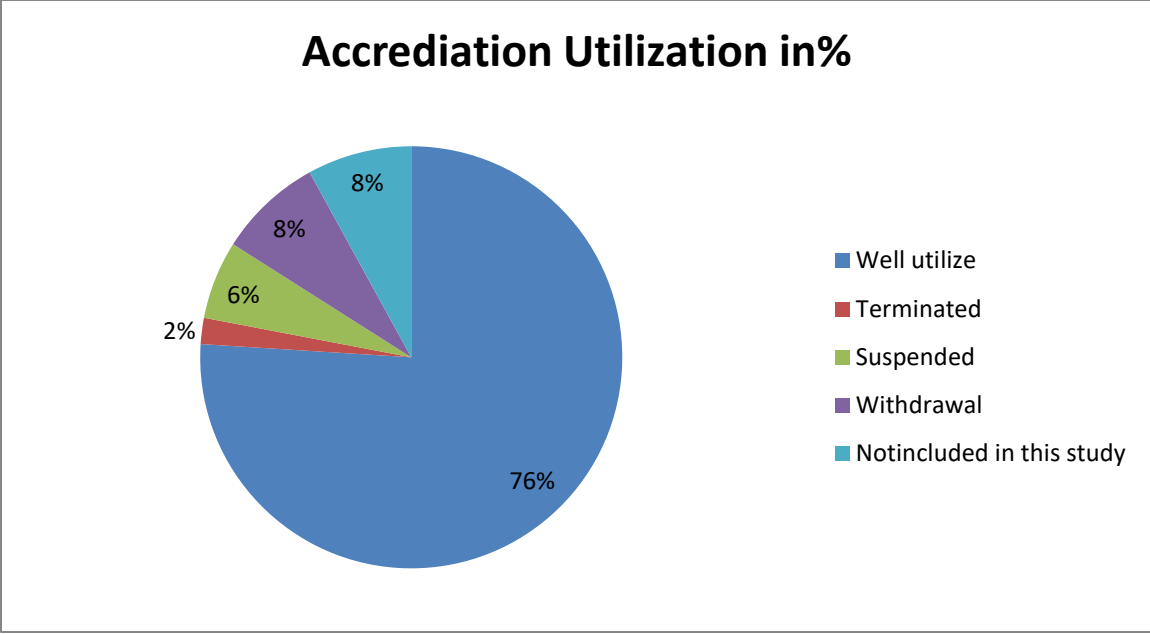


Figure 3 accreditation utilization statuses in Ethiopia, 2021.

6.4.Hindering factors for utilization of accreditation

Based on this study 8 (17%) accredited health care facility laboratories found to be not utilize the accreditation. As the result showed that, 4 (9% n=46) health care facilities found to be, they were withdrawal from accreditation; this is due to high staff turnover, management negligence, lack of appropriate training and incompetent staff. We learnt from the respondent during the focused group discussion, they explained that accredited and non-accredited laboratories are treated the same by regulatory bodies; and they think that accreditation is exited for their laboratory. Most respondents believe that, this was the main reason for improper accreditation utilization and the labs lead to withdraw. consistent regulatory follow up (0.014, CI [0.00-0.47]) with p value 0.017), appointment of quality manager (0.13, CI [0.3-0.595]) with p value 0.008) and personnel competence (0.4, CI [0.003-0.56]) with p value 0.04) are found to have significant association with accreditation utilization (table 9). Inadequate training of the personnel, limitation of Upper management commitment, limitation of resource allocation, limitation of Incentive for accreditation award, in adequate awareness on ISO 15189 and QMS of the personnel, improper mentoring of the mentor and improper follow up of the regulatory bodies are found to be the hindering factors of accreditation utilization. The result showed that almost all accredited health

care facility laboratories didn't give any incentive for their employees to their effort in accreditation award. Among 276 participants in this study 26 (9%) respondent want to leave their institution due to lack of encouragement for their reward and effort for accreditation. Around 109 (39.5%) of the participant complain that the management is not committed for the implementation of quality management system/ accreditation. Greater than half participant states their opinion from "very small extent" to "moderate extent" on the resource allocation for accreditation purpose. The budget for accreditation is not allocated by upper management instead it is done unintentionally from other budget line.

Regarding equipment calibration: 166 (60.1%) of the respondent said that some of their equipment are not calibrated and the calibrator is not accessible and affordable; the calibrator institution also not decentralized. But for assay calibration the company calibrates the machine and most calibrators are traceable and affordable in cost. Almost all laboratories are not plan to cease from accreditation due to calibration inaccessibility and unaffordability issue.

Around 112 (40.5%) participant did not know about ISO 15189. 30 (10.9%) participant complained that the standard (ISO 15189) is very complicated to understand. 77 (27.9%) participant believe that accreditation is not important rather it give the laboratory personnel another burden. The other 199 (72.1% n=276) participant gave their answer to "moderate extent", which means the accreditation have little advantage to the customer. 6 (13% n=46) laboratories did not have mentor, the rest 40 (87% n=46) health care facility laboratories had mentor. Only 44 (15.9% n=276) participant said that mentors are used in "moderate extent". The other 232 (84.1% n=276) participant said as "very small extent" to "small extent". They explained that the mentors were not show how quality management system implemented and how to be accredited. Nearly all laboratories assured that they can sustain their accreditation status without mentor and had no any plan to cease if mentor stops to mentoring. Almost half of the accredited laboratories are evaluated by regulatory bodies. Almost all accredited laboratories are not supported by regulatory body to be accredited. The regulatory bodies are not separate accredited and non-accredited laboratories and they are not encouraging the accredited laboratories. The respondents assure that there is no incentive by regulatory bodies for accredited lab employees.

6.4.1 Effect of COVID-19 pandemic on the utilization of Accreditation

This study was conducted during the current pandemic and we have a chance to see its effect on the accreditation system in Ethiopia. Note that, this is not a detailed one rather to give a highlight and an overview for the readers.

COVID -19 is an ongoing public health pandemic globally that affects many services including accreditation process. There is no specially excuse in the Ethiopian accreditation system and it was the main challenge for accreditation process. 1 from 3 suspended accredited health care laboratories was suspended due to COVID -19 pandemic. Based on the study finding : COVID -19 pandemic enforce the CAB to focus on the prevention of the pandemic. The laboratory personnel who are the signatory to ENAO also assigned to the pandemic prevention. The study shows that COVID-19 pandemics have dramatic influence on accreditation utilization processes, which may lead to change or adjust the time line rules and the requirements of the Ethiopian national accreditation body due to changes in the fulfillment of the accreditation by the conformity assessment body during this period. Health care facility laboratory accreditation is an essential measurement for any conformity assessment body performance, since accreditation is a significant means of assuring quality of service. Thus accreditation utilization works as one of the cornerstones toward health care facility laboratories. Some CABs were assessed offsite by sending all requirements to ENAO. The respondents from this study affiliated that the sudden change from onsite assessment to offsite and desk review assessment process did not give CABs the time to adjust the necessary requirements or did not give the ENAO assessors the time to review the needed documents toward the accreditation. This situation creates a dilemma for all conformity assessment bodies involved in the accreditation process.

6.4.2 Trend of accreditation

Even if Ethiopian national accreditation office established in 2010 with ministry of council by proclamation number 195/2010 as the sole accreditation body in Ethiopian, it starts accreditation service in 2013 for three CABs after it recognized as affiliated member by ILAC in 2012. In 2017 ENAO was become full member of ILAC MRA and that fiscal year it gave accreditation service for 7 health care laboratories; it was made the total accredited CABs 17 with other 4 back fiscal years. By the year 2019 the tendency of health care facility laboratory accreditation rate had been increased by 10. Currently there are around 46 accredited CABs irrespective of their utilization status; and there were also 4 accredited laboratories not included in this study as illustrated Table 3.

Table 3- Accreditation trend in Ethiopian from the beginning to now, 2021.

Year	Frequency	Percent
2013	2	4.0
2014	4	8.0
2015	3	6.0
2016	1	2.0
2017	7	14.0
2018	2	4.0
2019	12	24.0
2020	13	26.0
2021	6	12.0
Total	50	100.0

6.4.3 Training and personnel competence

Based on the result found in this study 88 (31.9%) of the participant respond at least at “moderate extent”, 57 (20.7%) “Large extent” and only 17 (6.2%) personnel are responding at most at “very large extent” on the basic/ comprehensive training. The rest 144 (52.4%) were at “very small” and “small extent” indicates majority of the laboratory staff didn’t get basic laboratory trainings. Majority of the respondent didn’t get the incentive for their accreditation award 130 (47.1%) at least at “Very small extent” and 118 (42.8%) at most at “Small extent”. Most respondents take the assigned work process, ethics and confidentiality. 105 (38.0%) said that “moderate extent” on competence assessment is performed based on established criteria; the rest 114 (41.3%) are at “very small extent” and at “small extent”. most respondents were competent on equipment maintenance, direct observation on records, reporting and reviewing, review of records, problem solving. The challenges for accreditation utilization identified during focus group discussion here were inadequate training of the on basic laboratory procedure, no reward for accreditation award, incompetent of the lab personnel. Table 4; summarizes training and personnel competence.

Table 4: Perception of staffs on extent of training and personnel competence at public and private health facilities Ethiopia, from March to May 2021 (n=276)

Variables	No. of responses (n=276) indicating respective extent Of Training and competence				
	Very small extent	Small extent	Moderate extent	Large extent	Very large extent
	n(%)	n(%)	n(%)	n(%)	n(%)
Training on comprehensive lab tests	57(20.7)	57(20.7)	88(31.9)	57(20.7)	17(6.2)
Trainings on the assigned work process	31(11.2)	120(43.5)	118(42.8)	7(2.5)	0(0)
Training on the applicability of ethics and confidentiality	34(12.3)	114(41.3)	101(36.6)	27(9.8)	0(0)
Incentive as scholarship offer accreditation	130(47.1)	118(42.8)	28(10.1)	0(0)	0(0)
Recognition and/or any promised					
Leave the institution due to conflict of interest	186(67.4)	64(23.2)	26(9.4)	0(0)	0(0)
Competence of each personnel	56(20.3)	58(21.0)	105(38.0)	57(20.7)	0(0)
Competence on direct observation of each equipment maintenance	31(11.2)	118(42.8)	120(43.5)	7(2.5)	0(0)
Competence on the monitoring and Reporting of each examination	33(12.0)	115(41.7)	101(36.6)	27(9.8)	0(0)
Competence on the reviewing of records	186(67.4)	64(23.2)	26(9.4)	0(0)	0(0)
Competence on problem Solving skills	131(47.5)	118(42.8)	27(9.8)	0(0)	0(0)

6.4.4 Management support and resource allocation

About 17 (6.2%) of the respondents agreed that top management commitment of the health care facility laboratory for implementation of ISO 15189 was evident at least at “very small extent”, while 92 (33.3%) of them affirmed at “small extent” and the rest perceived that top managements’ commitment and support was evident to be at most at “moderate, large and very large extent” are 161 (58.3%). As most of the respondent 37 (13.4%) responded that management establish quality policy at most at “very small extent” and 56 (10.3%) “Small extent”). The other respondent 90 (32.6%) says as “moderate extent”, 56 (20.3%) “Large extent” and 37 (13.4%) “very large extent”. About 37 (13.4%) of the respondents agreed that top management existence on establishment quality objective of the health care facility laboratory was evident at least at “very small extent”, while 54 (19.6%) of them affirmed at “small extent” and the rest perceived that top managements’ existence on establishment quality objective was evident to be at most at “moderate, large and very large extent” are 184 (66.6%). The challenges for accreditation utilization identified during focus group discussion here were the upper management didn’t allocate budget for accreditation, for training, for PT, for calibration, for better infrastructure purpose instead the accreditation held with other budget line of the institution. On the discussion the respondents affirmed that, the upper management does not involve the quality objective plan and establishment of communication process as illustrated in Table 5.

Table 5: Perception of staffs on extent of management support and resource allocation at accredited public and private health facilities Ethiopia, from March to May 2021 (n=276)

Variables	No. of responses (n=276) indicating respective extent of Management and resource allocation				
	Very small extent	Small extent	Moderate extent	Large extent	Very large extent
	n(%)	n(%)	n(%)	n(%)	n(%)
Management committed to implement QMS	17(6.2)	92(33.3)	74(26.8)	75(27.2)	18(6.5)
Management establish quality policy	37(13.4)	56(20.3)	90(32.6)	56(20.3)	37(13.4)
Management ensuring that quality objective and planning	37(13.4)	54(19.6)	76(27.5)	91(33.0)	18(6.5)
Defining authority, responsibility and interrelationship	18(6.5)	54(19.6)	113(40.0)	74(26.8)	17(6.2)
Establish communication process	18(6.5)	74(26.8)	93(33.7)	74(26.8)	17(6.2)
Appointing quality manager	0(0)	0(0)	0(0)	153(55.4)	123(44.6)
Conduct management review	18(6.5)	18(6.5)	92(33.3)	111(40.2)	37(13.4)
Availability of adequate resource	18(6.5)	37(13.4)	93(33.7)	91(33.4)	37(13.4)
Adequate human resource to	38(13.8)	18(6.5)	89(32.2)	93(33.7)	38(13.8)
Adequate budget for accreditation	50(18.1)	53(19.2)	100(36.2)	73(26.4)	0(0)
Adequate infrastructure	56(20.3)	42(15.2)	104(37.7)	74(26.8)	0(0)
Adequate budget for Trainings	36(13.0)	36(13.0)	130(47.1)	74(26.8)	0(0)
Adequate budget for PT and calibration	92(33.3)	18(6.5)	91(33.0)	75(27.2)	0(0)

6.4.5 PT and calibration access

Around 100 of the respondents (36.2%) respondent affirmed at “large extent” and 176 (63.8%) at “very large extent” on their laboratory participation on PT program i.e. all 46 accredited healthcare facility laboratories participate to PT provider. All 276 (100%) agreed at “very large extent” that, the PT provider in which all accredited laboratories participated is traceable to the high order reference material. The PT provider is easily accessible and it is also affordable. But the PT sample cost is covered by CDC through EPHI as the respondent gives their reason for accessibility and affordability issue. About 166 (60.1%) of the participant responded as “very small extent” i.e. the calibration institute is not decentralized for equipment calibration. But for assay calibration the calibrator material is purchased upon the reagent purchasing and machine installation. The other 90 (32.6%) “Very large extent” and 20 (7.2%) “Moderate extent” respondent said that the calibration material/ institutes are easily accessible and affordable in cost. The hindering factor found here during discussion were; there is no metrological calibrator and no traceability for some machines; for instance there is no calibrator organization for microscope and there is no traceability for hygrometer. The existed calibrator institution, national metrology institution, was not decentralized. Table 6; summarizes proficiency testing and calibration.

Table 6: Perception of staffs on extent of PT and calibration accessibility at accredited public and private health facilities Ethiopia, from March to May 2021 (n=276)

Variables	No. of responses (n=276) indicating respective extent of PT and calibration access				
	Very small extent	Small extent	Moderate extent	Large extent	Very large extent
	n(%)	n(%)	n(%)	n(%)	n(%)
Participate to any PT Provider	0(0.0)	0(0.0)	0(0.0)	100(36.2)	176(63.8)
PT provider accessibility	0(0.0)	6(2.2)	60(21.7)	210(76.1)	0(0.0)
PT provider affordability	160(58.0)	28(10.1)	30(10.9)	58(21.0)	0(0.0)
Traceable to high order Reference cease due to PT inaccessibility and Unaffordability	0(0.0)	0(0.0)	0(0.0)	0(0.0)	276(100)
Calibrate its equipment Calibrator material/calibration institute Accessible	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Calibration Affordability	0(0.0)	0(0.0)	0(0.0)	0(0.0)	276(100)
Traceable to high order reference Cease due to calibration Inaccessibility and Unaffordability	166(60.1)	0(0.0)	20(7.2)	0(0.0)	90(32.6)
	100(36.2)	101(36.6)	19(6.9)	56(20.3)	0(0.0)
	9(3.3)	0(0.0)	0(0)	0(0)	297(96.7)
	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)

6.4.6 Awareness on accreditation and quality management system

Almost 100% of the respondents affirmed that awareness on accreditation and quality management system was at “moderate extent”, “large extent” and “very large extent”. 190 (68.8%) of the respondent were understand the standard very well or it is not complicated to them while 50(18.1%) of them at in “small extent” it is difficult; and around 6 (2.2%) responded at “moderate extent”. There are 30 (10.9%) respondent who said “large extent” i.e. they faced difficulty to understand the ISO 15189 standard. Over half of study participants (199 (72.1%)) responded, they are agreed accreditation is important at most at “moderate extent” while 71 (25.7%) of them said it was at “small extent” and 6 (2.2%) responded, it was at least “very small extent”. Almost 116 (42.0%) of respondents perceived, accreditation adds value for the customer was at most at “very large extent” while the other 39 (14.1%) of them responded it was at “large extent” and the rest 101 (36.6%), 20 (7.2%) responded the accreditation adds value to the customer at “moderate extent” and “small extent” respectively. Almost all 100% respondent agree that quality management system knowledge is important for the implementation of accreditation which was at “very large extent”. The challenges for accreditation utilization proven here were; the difficulty of the standard to understand, the wrong perception on the importance of accreditation for customer, improper implementation of ISO15189. Table 7; summarizes awareness on accreditation and quality management system.

Table 7: Perception of staffs on extent of awareness on accreditation and quality management system allocation at accredited public and private health facilities Ethiopia, from March to May 2021 (n=276)

Variables	No. of responses (n=276) indicating respective extent of Awareness on accreditation and QMS				
	Very small extent n(%)	Small extent n(%)	Moderate extent n(%)	Large extent n(%)	Very large extent n(%)
Awareness training on standard	0(0.0)	0(0.0)	92(33.3)	92(33.3)	92(33.3)
Knowledge about ISO 15189	92(33.3)	20(7.2)	19(6.9)	100(36.2)	45(16.3)
Standard complication	190(68.8)	50(18.1)	6(2.2)	30(10.9)	0(0.0)
Accreditation importance	6(2.2)	71(25.7)	199(72.1)	0(0.0)	0(0.0)
Accreditation adds value to the customer	0(0.0)	20(7.2)	101(36.6)	39(14.1)	116(42.0)
Provide training on the QMS	36(13.0)	55(19.9)	74(26.8)	92(33.3)	19(6.9)
Know all quality Essentials	0(0.0)	0(0.0)	84(30.4)	192(69.6)	0(0.0)
QMS knowledge importance	0(0.0)	0(0.0)	0(0.0)	0(0.0)	276(100)
QMS adds value to the customer	0(0.0)	0(0.0)	144(52.2)	132(47.8)	0(0.0)

6.4.7 Mentoring follow up and regulatory activities

Majority, 246 (89.1%) of the respondents affirmed that they have mentor which was at “very large extent”. 30 (10.9%) of the respondent didn’t have the mentor at all. 15.9% of the respondent affirmed that the mentor add value to the laboratory to be accredited in “moderate extent”. The rest 75 (27.2%) and 157 (56.9%) said that the mentor adds value to the laboratory in “small extent” and “very small extent” respectively. around 20 (7.2%) of the respondent said that the mentor didn’t show how the lab personnel implement ISO 15189 instead they cook the document and gave us as responded at “large extent”. While 23 (8.3%) were at “moderate extent” whereas the rest 77 (27.9%) and 156 (56.5%) were at “small extent” and “very small extent”. Nearly all 276 (100 %) respondent affirmed that they can sustain the accreditation usage and they never plan to cease the accreditation even if the mentor stops mentoring. There are 92 (33.3%) respondent who said “very large extent” on “does the laboratory evaluated by regulatory body?”. The other respondents were at “large extent”, “moderate extent” and “small extent” with corresponding amount of 92 (33.3%), 37 (13.4%), 55 (19.9%) respectively. Almost all respondent affirmed that regulatory body didn’t support the CABs to be accredited; they also didn’t give any incentive for accredited laboratories for encouragement as the respondent response at “very small extent”. Nearly all respondent said that the regulatory body didn’t do anything to separate accredited and non-accredited laboratories affirmed at “very large extent”. Only 2 (0.7%) respondents said that the regulatory body gives acknowledgment which affirmed at “small extent”. The rest 274 were at “very small extent”. The respondent assured that the challenges for proper accreditation concerning to mentoring follow up and regulatory activities were inconsistent and inadequate mentoring, non-separation of accredited and non-accredited CABs by regulatory bodies and lack of incentive and acknowledge by regulatory body. Table 8; summarizes mentoring follow up and regulatory body activities.

Table 8: Perception of staffs on extent of mentoring follow up and regulatory activities at accredited public and private health facilities Ethiopia, from March to May 2021 (n=276)

Variables	No. of responses (n=276) indicating respective extent Of Mentoring regulatory activities				
	Very small extent	Small extent	Moderate extent	Large extent	Very large extent
	n(%)	n(%)	n(%)	n(%)	n(%)
Has mentor	30(10.9)	0(0.0)	0(0.0)	0(0.0)	246(89.1)
The mentor adds value	157(56.9)	75(27.2)	44(15.9)	0(0.0)	0(0.0)
The mentor show how Implement ISO 15189	156(56.5)	77(27.9)	23(8.3)	20(7.2)	0(0.0)
Sustain accreditation if the mentor stop mentoring	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Cease if the mentor stop mentoring	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Evaluated by regulatory body	0(0.0)	55(19.9)	37(13.4)	92(33.3)	92(33.3)
They support to be accredited	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
They give incentive	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Separate accredited and non-accredited	276(100)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Give acknowledgment for the accreditation	274(99.3)	2(0.7)	0(0.0)	0(0.0)	0(0.0)

6.5. Summary of associated factors for accreditation utilization in Ethiopia

A binary logistic regression analysis was performed to determine whether there is an association between accreditation utilization and independent factors. No appointment of quality manager was 0.13 times less likely to utilize accreditation than appointing (0.13, CI [0.3-0.595]). The health care facility laboratory which had no committed upper management were utilizes accreditation 0.2 times less likely than that had committed management (0.22, CI [0.01-3.85]). the result showed that those laboratories' respondent responded on accreditation budget allocation affirmed at "large extent" were 1.5 times more likely utilize accreditation than affirmed at "moderate extent" and at "small extent" (1.52, CI [0.7-3.3]). the result showed that those laboratories' respondent responded on competency declaration affirmed at "very small extent" were 0.4 times less likely utilize accreditation than affirmed at "small extent" and at "moderate extent" (0.4, CI [0.003-0.56]). The health care facility laboratory supported by regulatory body responded at least at "moderate extent" were 0.014 times less likely utilize accreditation than responded at "large extent" and at most at "very large extent" (0.014, CI [0.0-0.47]). So based on the result found, the null hypothesis for competency assessment (P value=0.04), budget for accreditation (P value= 0.03) and regulatory follow up (P value= 0.017) were rejected as it had a significant statistical difference in the utilization of accreditation services.

The regression analysis also showed that provision of comprehensive basic laboratory test training, management commitment, availability of mentor and awareness on ISO 15189 had no a significant association with health care facility laboratory accreditation utilization. Table 9 Summarizes crudes odd ratio, adjusted odd ratio and p value on the Impact of laboratory personnel competency, accreditation budget allocation, appointment of quality manager, training on QMS and regulatory follow up practices.

Table 9: Impact of laboratory personnel, management, competency, training and regulatory follow up practices on accreditation utilization in accredited health care laboratories, Addis Ababa, Ethiopia, 2021.

Independent Variables		Accreditation utilization		95% CI	P Value	95% CI	P Value
		Utilize	not utilize	COR		AOR	
Competency Assessment	V.S.E	52	4	0.26(0.08-0.86)	0.03*	0.4(0.003-0.56)	(0.041)*
	S.E	43	15	1.18(0.5-2.78)	0.70	4.2(0.64-26.5)	0.133
	M.E	89	16	0.6(0.27-1.38)	0.233	0.78(0.13-4.5)	0.78
	L.E	4	13	√			
Management Commitment	V.S.E	15	2	0.38(0.08-2.1)	0.25	0.03(0.001-1.2)	0.06
	S.E	76	16	0.55(0.58-1.75)	0.31	0.23(0.001-1.2)	0.230
	M.E	62	12	0.5(0.15-1.67)	0.26	0.22(0.01-3.85)	0.302
	L.E	62	13	0.55(0.17-1.8)	0.32	0.07(0.6-1.1)	0.059
QM appointment	V.L.E	13	5	√			
	L.E	138	15	0.3(0.12-0.57)	0.000*	0.13(0.3-0.595)	0.008*
	V.L.E	90	33	√			
Budget for Accreditation	V.S.E	49	1	√			
	S.E	41	12	0.10(0.013-0.8)	0.03*	0.336(0.01-8.7)	0.51
	M.E	77	23	1.49(0.61-3.6)	0.383	2.52(0.33-19.1)	0.37
	L.E	61	12	1.52(0.7-3.3)	0.29	1.02(0.176-5.97)	0.797
Evaluated by	S.E	53	2	√			
Regulatory body	M.E	27	10	0.14(0.03-0.61)	(0.036) *	0.014(0.0-0.47)	0.017*
	L.E	76	16	1.33(0.55-3.2)	0.521	2.6(0.35-19.6)	0.349
	V.L.E	72	20	0.76(0.36-1.58)	0.458	0.412(0.08-2.1)	0.282

Key; * shows Significant association at $\alpha=0.05$ √ shows reference category, V.S.E=very small extent, S.E=small extent, M.E= moderate extent, L.E=Large extent, V.L.E=very large extent

7. Discussion

This research aimed to assess the utilization of accreditation rate and to figure out the factors that influence accredited healthcare facility laboratory. In this study almost half of the respondents had taken basic trainings which are helpful for ISO 15189 accreditation and utilization. In 2019 the health facility laboratory accreditation utilization rate had been increased by 10 (24%) and currently there are around 38 accredited CABs with good accreditation utilization status, 4 withdrawal and 3 suspended. As of the majority (26 [9.4%]) respondent's explanation, the management does not facilitate the accreditation process through giving of training, giving of incentive for accreditation award which could be the reason for seeking to run off from the institution, which is in line with a study done by Ng G, Leung et al., in Xiangtan yi xue za zhi and by El-Jardali, F., et al. suggested that the challenges of accreditation utilization includes top management resistance, lack of awareness on QMS, inadequate training and inadequate support for quality improvement process (19, 39). It was believed by majority laboratory professionals that; for successful accreditation utilization, awareness and commitment of top management was a key factor. Even if upper management support was evidenced in some of the laboratories visited by this particular study, still it was believed to lack full participation and commitment.

It was suggested that, the health care facility staffs had no adequate knowledge regarding the importance of having accredited laboratory apart from only little support for their clinical management which discourages laboratory professionals to strive for better quality and accreditation utilization, which was a similar study done in Addis Ababa Public Health Laboratories, Addis Ababa, Ethiopia 2019 by Misganaw A. et al., (40).

From this study we understand that, those people who took quality management system awareness training were 24.6 times more likely utilize accreditation than those who didn't took the training. Low incentive level of the lab personnel highly contributed for high turnover of laboratory professionals. As the respondents' opinion, there are high turnover laboratory professionals; especially those experienced professionals always plan how to join high paid organization for better life style and experience, which is supported by a research done in Caribbean Region s 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 (41).

Inadequate upper management commitment, laboratory personnel incompetence and considering accreditation as a one-time achievement that ends after assessment cycle 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 recognize the importance of accreditation and consider it as only useless extra work required by Ethiopian national accreditation body (42).

Managements are concerned not only with the level of resources allocation and how they are distributed across each activity but also with how these resources translate into improved quality management system of the laboratory. In this study as most of the respondent (50(18.1%) which affirmed at "Very small extent" and 53 (19.2%) "Small extent"), the upper management didn't allocate budget for accreditation purpose instead the accreditation held with other budget line of the institution. The result showed that those laboratories' respondent responded on accreditation budget allocation affirmed at "large extent" were 1.5 times more likely utilize accreditation than affirmed at "moderate extent" and at "small extent" (1.52, CI [0.7-3.3]). According to the result, almost all accredited health care facilities have been participated proficiency testing because it's mandatory to be accredited. However, they get it and accessed through EPHI and mainly from one world accuracy. The budget is allocated centrally by CDC through EPHI and hence the accredited laboratory didn't have any question with regard to affordability. Those accredited health care laboratories which implement accreditation in a good manner were not plan to cease due to PT inaccessibility and unaffordability issue, because successful PT participation is one of the mandatory requirements by accreditation body of Ethiopia (ENAO).

In adequate budget allocation for PT and calibration only are also big challenges for proper accreditation utilization as 110 (39.9%) respondent complain that there is no adequate budget for PT and calibration at "very small" and "small extent" respectively. But still the budget was covered by CDC trough EPHI. The study conducted at WHO by kopllan JP and the study done at Addis Ababa governmental hospital laboratories by Gurmessa A. and A. Misganaw, supported

this study as there is limitation of financial resources for PT and calibration issue for accreditation in sub-Saharan countries(13, 43).

Laboratory facility and infrastructure highly contributes for low accreditation utilization practice and retarded accreditation progress. As observed in some laboratories, there was lack of adequate room for testing and different laboratory machines were located in a single room. The result showed that 98 (35.5%) respondent said that there is no adequate infrastructure at “small and very small extent”. Similar study done before by Abay S. also reported that laboratory design and quality of floor contributed for low success in accreditation implementation (44). Majority of the respondents said that facility or infrastructures of their laboratories are much more bellow the standard that tends the laboratories to fail before assessment process. This situation tends to the laboratory to be terminated and withdrawal from accreditation. This is also supported by the study done in Addis Ababa by Sisay A., achieving and maintaining accreditation status requires a significant investment of resources and Factors Affecting Implementation of Laboratory Quality Management System in Addis Ababa Public Health Laboratories respectively (36).

As remarked by some respondents, unless laboratories are calibrated their equipment and traceable to higher reference material, it is so challenging to participate in the accreditation process. ENAO was present its report in 2017 stating the advantages and disadvantages of decentralization in calibration institute, improved calibration efficiency in the provision of quality of calibration services, stimulation of local private participation in their own calibration. Among the disadvantages were issue of traceable for meeting national policies and international requirement (17). In the current study, respondents criticize the centralized system from the point of view of improving their provision of calibration service in particular and their journey at large. Reagent and quality control material stock outs followed by test interruption were another challenging part in most of the accredited laboratories visited by this study and explained by the respondents. These challenges contribute for the gaps they faced in the different assessment experiences they had and remained still unsolved problem. It was agreed by majority of the respondents, that good quality of equipment was due to for calibration of all necessary equipment and in turn helps for accreditation process. It was specifically explained that, some of the equipment were difficult for calibration because of absence of calibrator in the country (e.g.

microscope), some are calibrated without traceable evidence (e.g. hygrometer). more than half 166 (60.1%) of the respondent claim that; it is difficult to get calibration service with affordable cost and 20(7.2%) respondents affirmed that the calibration institute is decentralized at “moderate extent”. This is a big challenge for well accreditation utilization. But no one respond that their lab didn’t plan to cease from accreditation due to calibration unaffordability and inaccessibility (17).

Of 46 laboratories visited by this study, most of them were accredited in the scope of gene Xpert and most of the respondent (60.1%) assured that they can’t afford PT for all scopes and that is why most of the accredited laboratories accredited with limited scope which is gene Xpert. Most CABs accredited with gene Xpert not only for the sake of PT unaffordability but also due to method verification for gene Xpert is easy. On the contemporary of this there were some CABs which were accredited with full scope. Some of the respondent assured that they received PT sample from the Ethiopian public health institute without any expenditure which helps them to be accredited. However, the Ethiopian public health institute got the PT sample from CDC. The study done by Greenfield D, Braithwaite J. on Health sector accreditation research: a systematic review assures the PT costliness (11). Due to these challenges, it was noted that the government should not necessarily force the laboratories to establish PT provider in the country.

Around 77 (27.9%) of the respondent claim that; accreditation is not important. They said that accreditation bring nothing advantages for them, rather than an extra work load as they affirmed at “very small extent” and “small extent”. In the current study, awareness on ISO 15189 and quality management system and initiation of laboratory staffs regarding accreditation utilization varies from institution to institution. More than half of the respondents agreed, they are aware of ISO 15189 and quality management system. Around 20 (7.2%) respondents agreed that accreditation adds nothing to the user’s result rather they consider accreditation as an extra burden for the lab personnel, which is concordance with a study done by Alkhenizan A, Shaw C. on the attitude of health care professionals towards accreditation(45). This situation after then created disagreements and conflicts between the lab personnel and the management which is a barrier for success in accreditation utilization.

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. Even if a little more than half of the respondents had awareness and training related to either QMS or accreditation process or both, 36 (13%) responded had faced difficulty to understand the standard (ISO15189) at “large extent” and “moderate extent”. Quality management system training was believed to be the key for successful accreditation utilization process which uses all staffs to be trained. But 114 (41.4%) respondents believe, trainings were inadequate in terms of quality and quantity for successful accreditation utilization. From our analyzed data, we understand that laboratory that has at most at “large extent” QMS trainer were more likely utilize accreditation than at “very small extent”, “small extent”, and “moderate extent” (24.6, CI (1.3-5.10) p value=0.08). However, most of the trainings in our country were unplanned which was not based on the actual gaps that the accreditation requires as a system. Similarly, researches done here in Ethiopia by Tilahun M. *et al.* 2013 and Abay S. *et al.* 2015 reported that training inadequacy and inconsistency were a challenge for laboratories participating in accreditation process (44, 46).

Still lack of adequate training regarding QMS and accreditation remain a challenge in the current research evidenced with 112 (40.5%) respondents were do not know about ISO 15189 standard.

Around 246 (89.1%) respondent agreed that their institution had mentor. In most of the study sites, the quality and adequacy of mentorship was questioned as being not up to standard and in some of the laboratories was not believed to be a special support because of the mentors had the same training experience and knowledge with the mentee lab personnel. All of the respondents do not believe in getting the expected support from external mentors. It was confirmed that some of the mentors do not show the mentee how they implement ISO15189 and rather the mentor produce the document centrally and distribute it for each CAB (mentee), this is a quite identified problem, that can lead those can sustain accreditation status and didn't plan to cease from accreditation weather the mentor stops mentoring or not, which is concordance with findings of researchers reported by in the Caribbean Region and Kenya, supported the current study in that low adequacy and quality of mentorship contributed for slow accreditation utilization (23, 28).

As majority of the respondents 221 (80.1%) confirmation, their laboratory were wrongly evaluated by respective regulatory body for their own interest only and were not believed to be supportive and helpful for accreditation. According to this study the health care facility laboratory supported by regulatory body responded at least at “moderate extent” were 0.014

times less likely utilize accreditation than responded at “large extent” and at most at “very large extent” (0.014, CI [0.0-0.47]).

There is no clear difference between accredited and non-accredited laboratories which was mentioned as a major challenge for accreditation process. As it was confirmed by all 276 (100%) respondents in this particular study, the regulatory body did not support the health care facility through giving financial support or by giving incentive/acknowledgment the CABs to be accredited. As all areas responders in the study, the regulatory bodies do not consider the actual situation and capacity of the country’s accreditation body (ENAO), it was suggested that any concerned body is better to think over it and modify its assumption and consider the applicability of accreditation. As all respondents opinion non separate between accredited and non-accredited laboratory leads them improper accreditation utilization and then for suspension and withdrawal from accreditation. Regulatory bodies should be considered the issue of separation between accredited and non-accredited labs for quality laboratory service as well as better accreditation status.

8. Strength and limitation of the study

8.1 Strength of the study

- ✓ The opinions of respondents to give their perception on accreditation utilization and to suggest the major challenges facing health care facility laboratories' accreditation utilization were extensively taken and analyzed in this study.
- ✓ This study was conducted during the current COVID 19 pandemic and we have a chance to see its effect on the accreditation system in Ethiopia. Even though it's not a detailed one, this can give a clue and highlight and an overview for the readers how to manage its effect and a way forward.

8.2 Limitation of the study

- ✓ Due to nationwide research inclusiveness of higher official it was difficult to access the opinion of all medical directors/ CEOs/ DGs.
- ✓ Due to uncomfortable chaos in the region, Tigray region accredited laboratories were not accommodating in this study.

9. Conclusion and recommendation

9.1 Conclusions

In Ethiopia there were 38 (83% n=46) accredited health facilities utilized accreditation practice in accordance with ISO 15189 standard and had competent laboratory personnel and committed management for well utilization. On the other hand 8 (17% n=46) accredited health care facility laboratories found to be not utilize the accreditation due to many hindering factors

Even though there were an existing effort to implement accreditation utilizations very wells, maintaining accreditation in a good manner 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. Accordingly, of 276 respondents about 187 (67.8%) of them had training experience related to QMS whereas all 276 respondents had awareness on ISO 15189. It was also evidenced 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 utilization and the regulatory body is not yet fully ready to support/facilitate the accreditation utilization.

High turnover of trained and experienced laboratory professionals due to inadequate incentive majorly affected accreditation utilization. Staff competence and management commitment and budget for accreditation were explained as the main factors for successful accreditation utilization. Even if the commitment of the management and the competence of the lab personnel was said to be improved in small extent, still some management members and some laboratory personnel consider accreditation as an extra burden and some consider it as a one-time achievement that ends after assessment cycle.

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 health care facility laboratories, the awareness and support of the upper management for accreditation utilization was not as expected by the laboratory personnel.

Laboratory equipment's calibration and traceability issue were among the challenges for accreditation utilization and found unavoidable challenge for some health care facility

laboratories in some equipment. The laboratory infrastructure, non-separation of accredited and non-accredited laboratory by regulatory body; and reagent stock out were not concise with ISO 15189 standard which is so challenging to resolve it in a short period of time

9.2 Recommendations

Based on the findings from the current study, the following points should be considered and any concerned body should give a due attention for the improvement of the accreditation utilization in Ethiopia.

- The health care facility management is better to understand the importance of having accredited laboratory in their health care facility laboratory and support it for better health accreditation utilization and better health care delivery.
- Top management and its staffs are better to be proud to their profession and strive to increase the reputation of their profession in accreditation utilization.
- The Ethiopian national metrology institute is better to expand its calibration office to different regions of the country and give special consideration for metrological traceability to its calibration service.
- The mentor from wherever is better to show the mentee rather than cooking the documents centrally distributing it 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.
- Ministry of health and concerning stake holders are better separate accredited and non-accredited considering the importance of having accredited laboratories in the country in its health care plan and should closely follow and support the accreditation utilization.
- 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 QMS and accreditation at undergraduate level
- Further ,detailed and extensive study on the challenge of COVID-19 on accreditation utilization should conducted

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11. Annexes

Annex I; Information sheet in English Version

Title of the Research Project: to assess the ISO 15189 Laboratory Accreditation Utilization and hindering factors among accredited laboratories, Ethiopia.

Principal Investigator: Zewdu Ayele (BSc, MSc candidate)

Name of the Organization: Department of Medical Laboratory Sciences, College of Health Sciences, Addis Ababa University

Introduction

You are invited to participate as a study subject in a research conducted by MSc candidate, from Addis Ababa University. Your participation is voluntarily. The research teams will include one principal investigator, two advisors; who from Addis Ababa University medical laboratory department. Please take as much time as you need to read or listen in the information sheet.

Purpose of the Research Project

We are asking you to take part in this study because we will try to assess the ISO 15189 Laboratory Accreditation Utilization and hindering factors among accredited laboratories, Ethiopia.

Purpose of the research:

The health laboratory plays an indispensable role in the health care system. It supports to show the gaps on quality management implementation, monitoring of response to accreditation, fill competence gaps, monitor management commitment, highlight resource allocation and can guide regulatory bodies. Since accreditation is voluntary activity and hence no regulatory body involvement for the sustainability of accreditation. Therefore, the purpose of this proposed study is to assess the sustainability in ISO 15189 Laboratory Accreditation Utilization and hindering factors among accredited laboratories, Ethiopia. You have been chosen for this study. Therefore, we invite you to take part in this study and contribute to the finding of hindering factors for

unsustainability of accreditation. The values are needed for providing quality laboratory service. Thus, result from this study is anticipated to improve the health status of the population at large in Ethiopia.

Procedures and the expected participation

If you are willing to participate, you need to understand the purpose of the study and give your consent. Not only this but also data collected from you will be used for the research purpose, and the results of your information will be exposed to some concerned professional staffs as it is needed. The required information will be collected by trained data collectors. Then, you are requested to give your consent to the data collector. After consent, information will be taken from asking you. There will be a face-to-face interview for additional questions.

Procedures: After agreeing that you can take part, one or more of our research staff will ask you some questions which will take up to 15 minutes. You will be asked to provide information on accreditation utilization includes educational status and competence, management support and resource allocation, PT and calibration access, awareness on accreditation and quality management system and about mentoring follow up and regulatory activities.

Potential risks and Discomforts

There will be minimal discomfort in giving the current accreditation status of the laboratory. However, the information is never disclosed to somebody else other than the research team. Nevertheless, we will try to minimize the discomfort as much as possible, as the information will be taken by experienced data collector laboratory professionals.

Confidentiality; we respect your privacy and confidentiality. Any information that identifies you will not be shared with anyone else outside the study team. The information we will collect from you as part of the study will be kept in a locked file cabinet, or be protected by a password on the computer only accessible to personnel involved in the study. There is no sensitive issue that you will be asked related with your social desirability but any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Potential benefits to subjects and/or to the society

You will not receive any payment for your participation in this research study as compensation. However, by participating in the study, you will directly benefit by being investigated for finding of hindering factors of accreditation utilization and other quality and accreditation challenges. Identifying the factors of accreditation will be used in the future to improve the general health status of Ethiopians.

Participation and Withdrawal from the Study

The participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind. You may also reject to give any information. You can ask any questions regarding to this study.

Contact information

If you have any questions about this study you can contact the following principal investigators and advisors for further information.

Name **Phone**.....**E-mail:**

Name **Phone**.....**E-mail:**

Annex II; Informed consent form

I had been informed that the objective of this study is ISO 15189 Laboratory Accreditation Utilization and hindering factors among accredited laboratories

The results of this study have an importance to maintain quality of services in the health care institutes, and to be used as an input for the future development of strategies or guidelines for policy making of quality/ accreditation in Ethiopia. I had been also informed about the confidentiality of this study. The principal investigator requested me to participate in the study that would require my willingness to provide the required data and filling questionnaire. Therefore, with full understanding of the importance of the study, I agreed voluntarily to provide the requested information and my benefit will be nothing

I _____ hereby give my consent for providing the requested information.

Signature: _____ Date _____

Annex III; List of CABS accredited by ENAO and included in this study

S.no	Name of accredited CABS	Accredited with	Accreditation No	Remarks
1	National clinical chemistry reference laboratory of Ethiopian public Health institute	Clinical chemistry	M0025	
2	Ethiopian public Health institute national clinical mycology & bacteriology reference laboratory	Microscopy, culture and sensitivity	M0026	
3	Oromia public health research capacity building & quality assurance laboratory	TB gene xpert, hematology, DBS, microscopy and sensitivity	M0027	
4	National TB reference laboratory of Ethiopian public health institute	TB gene xpert	M0028	
5	National HIV reference(EID) laboratory of the Ethiopian public health institute	DBS	M0030	
6	St.Peter TB specialized Hospital	TB gene xpert, microscopy and sensitivity	M0031	
7	Amhara public health institute	TB gene xpert, culture clinical chemistry, hematology, microbiology, leshimania, measles and rebula	M0033	
8	ALERT center Clinical laboratory	Hematology	M0034	
9	Hema Advanced Medical laboratory	Chemistry and hematology	M0035, M0008	
10	South nations nationalities and people's regional health bureau regional public health laboratory	TB gene xpert	M0036	
11	St paul hospital millennium college	TB gene xpert and clinical chemistry	M0037	
12	Nekemte public health research and referral laboratory	DBS	M0039	
13	Gedo hospital	TB gene xpert	M0041	
14	Felegehiwot comprehensive specialized hospital	TB gene xpert	M0043	
15	Hiwot fana university specialized hospital	TB gene xpert	M0048	

16	Gondar university specialized hospital laboratory	TB gene xpert, DBS	M0049	
17	Arsho advanced medical laboratory	Clinical chemistry, hematology and endocrinology	M0051	
18	Debrebirehan referral hospital	TB gene xpert and DBS	M0053	Suspended
19	Armed force comprehensive specialized hospital lab	TB gene xpert	M0056	
20	Shashemene referral hospital	TB gene xpert	M0057	
21	Wolayita sodo university hospital	TB gene xpert	M0055	
22	Butajira general hospital	TB gene xpert	M0054	
23	AHRI	TB culture, microscopy and sensitivity	M0058	
24	Worabe general hospital	TB gene xpert	M0059	
25	Girum Genral Hospital	Chemistry and hematology	M0060	
26	Bethzathaadvanced Medical Laboratory	Chemistry and hematology	M00	
27	Tekilehaimanot General Hospital	Chemistry and hematology	M00	
28	National hematology reference laboratory of the Ethiopian public health institute	Hematology	M00	
29	Hawasa university specialized hospital laboratory	Gene expert	M00	
30	Addis Ababa City Administration Public Health Research And Emergency Management Core Process Laboratory	Genexpert, hematology and DBS	M0005	Suspended
31	Adama General Hospital and Medical college laboratory	Gene xpert, serology and endocrinology	M0014	Withdraw
32	Medical Biotech Diagnostic laboratory	Endocrinology	M0004	Withdraw
33	Santé medical center	Chemistry and hematology	M0011	
34	Lagare General Hospital	Hematology	M0029	Withdrawn
35	Gamby hospital	Gene xpert	M0042	
36	Jimma university medical center	Gene xpert	M0046	
37	Zewiditu memorial hospital	Gene xpert	M0044	

38	Diredewa Regional laboratory	Gene xpert	M0047	Suspended
39	Sabian General Hospital	Gene xpert	-	Terminated
40	Merhabetie enat hospital	Gene xpert		On process
41	Afar public health institute	Gene xpert		On process
42	APHI desie	Gene xpert		On process
43	Police hospital	Gene xpert and DBS		On process
44	Dilla university hospital laboratory	Gene xpert		On process
45	Yirgalem general hospital laboratory	Gene xpert		On process
46	Addis ketema health center	Gene xpert, hematology		Withdrawal

Annex IV; Questionnaire

This questionnaire has been designed for the sole purpose of collecting data in accredited laboratories from Laboratory Heads, Quality Managers, and Logistic Officers, other any two laboratory professionals and medical directors/ CEO/director generals, on the ISO15189 accreditation utilization and hindering factors among accredited laboratories, Ethiopia. The data collected was treating with a very high degree of confidentiality. The questionnaire was anonymous and the results were used for scientific purposes only. Your consent to participate in the study is implied, should you return the completed questionnaire.

Thank you for your contribution!

I. Institution information

	Variables	Response/ coding
1	Institution Name
1.1	Service years of the institutionyears
1.2	Type of ownership	1. Public..... 2. Private
1.3	Facility type (please tick where appropriate)	1 Health center 2 Primary hospital 3 General hospital 4 Comprehensive hospital 5 Specialized hospital 6 Public health institute /regional lab... 7 Others specify
1.4	How many lab employees are there?
1.5	Responsible to	1 Ministry of health 2 Regional Health bureau..... 3 Zonal health office 4 Others specify.....

II. personal information

	Variables	Response/ coding
1	Gender (please tick where appropriate)	Malefemale.....
1.1	Age in yearsyears
1.2	Educational level (please tick where appropriate)	1. College diploma 2. Bachelor's degree..... 3. Master's degree..... 4. PhD Degree.....
1.3	How many years have you been employed?years
1.4	Responsibility in this institution	1. Lab head 2. Quality manager..... 3. CEO/medicaldirector/directorgeneral..... 4. Others specify.....

III. General information

Part A: training and personnel competence

Please rate to what extent the following accreditation requirement implemented in your organization. The scale below will be applicable: 1 = to a very small extent, 2 = Small extent, 3 = moderate extent, 4 = Large extent 5 = very large extent. The following are Personnel management on professional trainings practice

1.0	Personnel management on professional trainings	1	2	3	4	5
1.1	Does the laboratory provide training for all personnel on the comprehensive lab tests?					
1.2	Does the laboratory provide training for all personnel on the assigned work processes and procedures?					
1.3	Does the laboratory provide training for all personnel on the applicability of laboratory ethics and confidentiality?					
1.4	Does the laboratory provide incentive as scholarship after accreditation recognition and/ or any promised?					
1.5	Do you want to leave the institution due to training/scholarship conflict of interest?					
	If your answer is 1 or 2 please indicate the reason.					
2.0	Competence related Management	1	2	3	4	5
2.1	Does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria?					
2.2	Does the laboratory assess the competence of each person on the direct observation of equipment maintenance and function checks?					
2.3	Does the laboratory assess the competence of each person on the monitoring,					

	the recording and reporting of examination results?					
2.4	Does the laboratory assess the competence of each person on the review of work records?					
2.5	Does the laboratory assess the competence of each person on the assessment of problem solving skills?					
2.6	Does the laboratory assess the competence of each person on the examination of specially provided samples, such as previously examined samples, interlaboratory comparison materials, or split samples?					
	If your answer is 1 or 2 please indicate the reason.					

Part B: management support and resource allocation

Please rate to what extent the following accreditation requirement implemented in your organization. The scale below will be applicable: 1 = to a very small extent, 2 = Small extent, 3 = moderate extent, 4 = Large extent 5 = very large extent. The following are management support and resource allocation practices

1.0	management support	1	2	3	4	5
1.1	Do laboratory/institution/ management, committed to the development and implementation of the quality management system and continually improve its effectiveness?					
1.2	Do laboratory/institution/ management establishing the quality policy?					
1.3	Do laboratory/institution/ management ensuring that quality objectives and planning are established?					
1.4	Do laboratory/institution/ management defining responsibilities, authorities and interrelationships of all personnel?					
1.5	Do laboratory/institution/ management establishing communication processes?					
1.6	Do laboratory/institution/ management appointing a quality manager, however named					
1.7	Do laboratory/institution/ management conducting management reviews?					
1.8	Do laboratory/institution/ management ensuring that all personnel are competent to perform their assigned activities?					
1.9	Do laboratory/institution/ management ensuring availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities?					
	If your answer is 1 or 2 please indicate the reason.					
2.0	resource allocation	1	2	3	4	5
2.1	Do the laboratory have adequate human resources to implement ISO 15189 standard for accreditation?					

2.2	Do the laboratory have adequate budget to spend for accreditation?					
2.3	Do the laboratory have adequate infrastructure for implementation of ISO 15189 standard for accreditation?					
2.4	Do the laboratory have adequate budget to spend for trainings?					
2.5	Do the laboratory have adequate budget to spend for PT sample and calibration of major machines?					
	If your answer is 1 or 2 please indicate the reason.					

Part C: PT and calibration access

Please rate to what extent the following accreditation requirement implemented in your organization. The scale below will be applicable: 1 = to a very small extent, 2 = Small extent, 3 = moderate extent, 4 = Large extent 5 = very large extent. The following are PT and calibration access practices

1.0	PT access and traceability	1	2	3	4	5
1.1	Does the lab participate to any PT provider?					
1.2	Is the PT provider is easily accessible?					
1.3	Is the cost of PT provider affordable?					
1.4	Is PT provider traceable to the high order reference material/ accredited with ISO 17043?					
1.5	Does the lab plan to cease to accreditation due to PT inaccessibility and unaffordability?					
	If your answer is 1 or 2 please indicate the reason.					
2.0	Calibration access and traceability	1	2	3	4	5
2.1	Does the lab calibrate its equipment for the better measurement?					
2.2	Is the calibrator material/ calibrator institute is easily accessible?					
2.3	Is the cost of calibrator material/ calibrator institute affordable?					
2.4	Is calibrator material/ calibrator institute traceable to the high order reference material/ accredited with ISO 17025?					
2.5	Does the lab plan to cease to accreditation due to calibration inaccessibility and unaffordability?					
	If your answer is 1 or 2 please indicate the reason.					

Part D: awareness on accreditation and quality management system

Please rate to what extent the following accreditation requirement implemented in your organization. The scale below will be applicable: 1 = to a very small extent, 2 = Small extent, 3 = moderate extent, 4 = Large extent 5 = very large extent. The following are awareness on accreditation and quality management system practices

1.0	awareness on accreditation	1	2	3	4	5
1.1	Does the lab give awareness training on ISO 15189 standards?					
1.2	Do you know all about the requirements of ISO 15189 standards?					
1.3	Is the standard complicated to implement quality and to be accredited?					
1.4	Do you agree that accreditation is important?					
1.5	Do you agree that accreditation adds value to the customers?					
	If your answer is 1 or 2 please indicate the reason.					
2.0	Awareness on quality management system	1	2	3	4	5
2.1	Does the laboratory provide training for all personnel on the quality management system?					
2.2	Do you know all quality essentials?					
2.3	Do you agree that quality management system knowledge is important for accreditation?					
2.4	Do you agree that QMS adds value to the customers?					
	If your answer is 1 or 2 please indicate the reason.					

Part E: mentoring follow up and regulatory activities

Please rate to what extent the following accreditation requirement implemented in your organization. The scale below will be applicable: 1 = to a very small extent, 2 = Small extent, 3 = moderate extent, 4 = Large extent 5 = very large extent. The following are mentoring follow up and regulatory activity practices

1.0	mentoring follow up	1	2	3	4	5
1.1	Does the laboratory have mentor?					
1.2	Does the mentor add values to the lab to be accredited?					
1.3	Does the mentor show the lab personnel how you/they implement the ISO15189?					
1.4	can the lab sustain accreditation, if the mentor stops mentoring?					
1.5	Does the lab cease, if the mentor stops mentoring?					
	If your answer is 1 or 2 please indicate the reason.					
2.0	regulatory activities	1	2	3	4	5
2.1	Does the laboratory evaluated by the regulatory bodies?					
2.2	Do they support to be accredited?					
2.3	Do they give incentives to the lab for the accreditation award?					
2.4	Do they have plan to separate accredited and non-accredited labs?					
2.5	Do they give acknowledgment for the accreditation?					
	If your answer is 1 or 2 please indicate the reason.					

Part F: Key personnel group discussion questions on the utilization of accreditation

(Per institution)

1. What is your laboratory current status regarding to accreditation utilization? From which alternatives lies your lab among the following?
 - 1.1 Well utilizes the accreditation? What are the opportunities that made the lab implemented accreditation utilization well?
 - 1.2 Suspended? Why?
 - 1.3 Withdraw? Why?
2. Do you think that **improper** accreditation utilization is due to;
 - 2.1 The lab personnel's? Why?
 - 2.2 The organization management? Why?
 - 2.3 Resource? Why?
 - 2.4 External factors like regulatory body, mentor, PT, calibration access? Why?
3. What do you think about the major obstacles of accreditation utilization? What are the attrition factors of accreditation in your laboratory? (you can use back side for answering)

Declaration

The undersigned declares that this thesis complies with the regulations of the University and meets the accepted standards with respect to originality and quality. PI also agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports.

M.Sc. candidate: Zewdu Ayele (B.Sc. BA)

Signature: _____

Date of submission: _____

This proposal has been submitted with our approval as advisors.

Advisors: Abay Sisay (MSc, PhD Cand., Assistant Professor)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: Alemayehu Nigatu (MSc, MPH)

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.