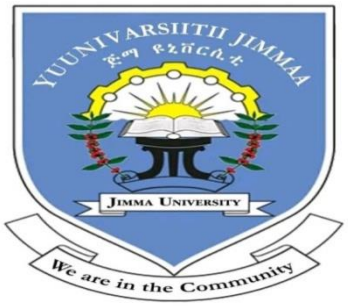

CHALLENGES OF MEDICAL LABORATORIES FOR ISO 15189 ACCREDITATION IN SELECTED PUBLIC HOSPITALS OF JIMMA ZONE, SOUTH WEST ETHIOPIA

BY: ABDULHAK ABAJEBEL (BSc)

ADVISORs: GEMEDA ABEBE (Professor, PhD)

MEKIDIM MOKENNEN (MSc)

ABEBAW TIRUNEH (MSc)

A THESIS SUBMITTED TO SCHOOL OF MEDICAL LABORATORY SCIENCE, FACULTY OF HEALTH SCIENCES, INSTITUTE OF HEALTH, JIMMA UNIVERSITY, IN PARTIAL FULFILLMENT OF THE DEGREE OF MASTER OF SCIENCE IN CLINICAL LABORATORY SCIENCE (LABORATORY MANAGEMENT SPECIALTY)

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Abbreviations and Acronoms

CDC	Centres for Disease Control
EAS	Ethiopian Accreditation Service
EPHI	Ethiopian Public Health Institute
EPSA	Ethiopian Pharmaceuticals Supply Agency
EQA	External Quality Assessment
IQC	Internal Quality Control
ISO	International Organization for Standardization
JCI	Joint Commission International
LQMS	Laboratory Quality Management System
MDG	Millennium Development Goals
NTBRL	National TB Reference Laboratories
PT	Proficiency Testing
QI	Quality Improvement
QMS	Quality Management System
QSE	Quality System Essentials
SLIPTA	Stepwise Laboratory Quality Improvement Process towards Accreditation
SLMTA	Strengthening Laboratory Management towards Accreditation
SSA	Sub-Saharan Africa
TQMS	Total Quality Management System
WHO	World Health Organization
WHO-AFRO	World Health Organization Regional Office for Africa

Abstract

Background: Inadequate quality of medical laboratory services is one of the challenging factors in health care delivery particularly in sub-Saharan Africa. Similarly, in Ethiopia getting consistent laboratory services and quality test results remains a critical challenge. Though laboratory accreditation is important to improve the quality of laboratory service, in Ethiopia, from 2012 up to 2020, only 53 medical laboratories were accredited by Ethiopian Accreditation Service in 74 scopes. Hence, it is important to identify the challenges that hinder public hospital laboratories from ISO 15189 accreditation.

Objective: To assess challenges of medical laboratories for ISO 15189 accreditation in selected public hospitals of Jimma Zone, Oromia Regional State, Ethiopia, 2022.

Method: The study was conducted at five Public Hospitals found in Jimma Zone, those were selected based on their enrolment in SLIPTA/ISO accreditation program. A cross-sectional study design was employed using quantitative and qualitative data collection approaches. The data was collected from October 20, 2021, to January 10, 2022,using a structured questionnaire and in-depth interviews. The data were entered and cleaned using EPI-Data version 4.6 and exported to statistical package software for social sciences (SPSS version 25.0) for further processing and analysis and it was presented using simple descriptive statistics like percentages and frequency.

Result: From the five public hospital laboratories selected, 102 laboratory professionals and 19 key informants participated in this study. Of 102, respondents 75% of them had awareness about SLIPTA/ISO accreditation, of which 60% of them were involved in SLIPTA/ISO implementation. Only around, 39% of the respondents have training related to LQMS. High routine workload by 70%, irregular mentorship by 67%, and low staff participation by 55% of participants was perceived as major challenges encounter during SLIPTA/ISO implementation.

Conclusion: Though their current initiation intended to have an accredited laboratory was appreciated, achieving accreditation was still challenging for almost all of the laboratories under this study because of insufficient training, high routine workload, irregular mentorship, inadequate awareness about SLIPTA/ISO accreditation, and low staff participation among of the identified factors. Based on these facts this study stresses the necessity of awareness, allocating adequate human resources, training, active participation, staff motivation, regular mentorship, and support of all responsible bodies to achieve and sustain the laboratory accreditation system.

Keywords: Accreditation, challenge, ISO 15189, SLIPTA star rating level, Jimma Zone.

Chapter One

Introduction

1.1. Background

Since, the ancient time beginning of tasting urine by mouth towards microscopy and up to the current level of molecular testing, the complexity of diagnostic methods of laboratory sciences continued to progress at a rapid speed. The 20th-century symbols as the start of a quality invention in hospitals and laboratories that began with physicians and healthcare employees. Professional organizations arose as self-regulating groups that aided to confirm the abilities and awareness of laboratory professionals would permit the assessment of the hospitals that employed them. The American College of Surgeons conducted the first assessments of hospitals in 1918, the assessments were based on a single page of standards (1,2).

International Organization for Standardization (ISO) is one of the known international bodies carried out in developing uniform standards for quality in the industrial and provision sectors. Around 157 countries are involved with one member per country and the standards are prepared by ISO technical committees and approved by at least 75% of the member (3).

The ISO 9000 sequences developed standards for quality systems and were used to evaluate particular types of health services. Selected ISO documents that are essential to laboratories are; ISO /IEC 17025 1999; general requirements for the competence of testing and calibration laboratories, ISO guide 43; Proficiency testing by inter-laboratory comparisons, ISO 19011; guidelines for quality and environmental management system auditing and ISO 15189; medical laboratories particular requirements for quality and competence(4).

ISO 15189 standard is medical laboratories requirements for quality and competence. It was for first time published in 2003, revised in 2007 and 2012, again revised recently in 2022. It encourages full involvement and operation of the abilities of all employees at all levels to improve the organization, its goal is to achieve constant progress. By 2015, around 60 countries had made ISO 15189 part of their mandatory medical laboratory accreditation requirements. Management requirements part 4 consists of 15 sub-clauses and Technical requirements part 5 which consists of 10 sub-clauses are the two parts of ISO 15189 standard **(Table 1)** (5,6)

Table 1 ISO 15189 standards, management and technical requirements: General Laboratory Medicine, Geneva, Switzerland: International Organization for Standardization; 15189,2012.

Management requirements Part 4	**Technical requirements Part 5**
4.1 Organization and management responsibility	5.1 Personnel
4.2 Quality management system	5.2 Accommodation and environmental conditions,
4.3 Document control	5.3 Laboratory equipment, reagents, and consumables,
4.4 Service agreements	5.4 Pre examination processes
4.5 Examination by referral laboratories	5.5 Examination processes
4.6 External services and supplies	5.6 Ensuring quality of examination results
4.7 Advisory services	5.7 Post examination processes
4.8 Resolution of complaints	5.8 Reporting of results
4.9 Identification and control of nonconformities	5.9 Release of results
4.10 Corrective action	5.10 Laboratory Information management
4.11 Preventive action management	
4.12 Continual improvement	
4.13 Control of records	
4.14 Evaluation and audits	
4.15 Management review	

Accreditation of medical laboratories is the process by which an autonomous and official institution approves the quality system and capability of a laboratory-based on assured predefined standards. Accreditation officially started in the United States with the formulation of the Joint Commission on Accreditation of Healthcare Organizations in 1951. The accreditation procedure needs the identification of an authoritative body, adoption of standards, and implementation mechanism. It is conducted at consistent intervals to ensure the maintenance of standards and dependability of results made. It provides sureness to workers in offered services and certainty to the laboratory results and offers national/international recognition (7,8).

In low and middle-income countries despite o serious resource limitations, the accreditation process requires many resources and there is a growing trust that strengthening health care quality, they pursue health care reforms to achieve universal health coverage, development of national accreditation systems, in developing and implementing a sustainable and successful national accreditation program (9).

In Lyon, France in April 2008 WHO and the US Centers for Disease Control and Prevention (CDC), held a joint meeting on Laboratory Quality Management systems (LQMSs). They delivered reports on the establishment of a stepwise, standards-based process toward internationally-recognized accreditation. They recommended that countries with insufficient resources consider taking a step method using the national laboratory standards as a minimum requirement (10) .

The criteria settled to participate in Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) program were; a SLIPTA self-assessment score of 55% or higher, involvement in proficiency testing or other methods in the previous 6 months, internal audits and management review in the previous 12 months. After enrollment, a laboratory is evaluated to determine its initial star rating and laboratories that attain a five-star rating are fortified to apply for ISO15189 accreditation (11).

Table 2 SLIPTA Checklist compliance levels, Score points vs. star ratings: WHO, Guide for the SLIPTA in the African Region, 2015.

SLIPTA checklist compliance	< 55%	55-64%	65-74%	75-84%	85-94%	>95%
Score points from total 275	0-150	151-177	178-205	206-232	233-260	261-275
level Star rating	No star	1 star	2 star	3 star	4 star	5 star

Ethiopia conducted laboratory evaluations on a national scale to reveal particular deficiencies and developed a strategic plan. The first laboratory strategic plan 2005 to 2008, empowered the Ethiopian Public Health Institute (EPHI) to lead laboratory programs nationwide. The second strategic plan 2009 to 2013, was established and involved integrated laboratory services and was reviewed from 2010 to 2015, to stress three aims; establishment and strengthening of laboratory quality systems, laboratory capacity building, and laboratory accreditation(12).

ISO 15189 accredited laboratories in Africa up to 2010 were only 340, the majority of them found in South Africa. Only 28 were found in Sub-Saharan African countries (13). In Ethiopia with many obstacles to accreditation from 2012 up to 2020, only 53 medical laboratories were accredited by the Ethiopian Accreditation Service (EAS) in 74 scopes (14). Even though there is significant progress in public hospital laboratories regarding the provision of quality services after the initiative of the strategic plan to strengthen laboratory quality and accreditation system, the number of accredited laboratories were still very few. So, it is important assessing and identify, the challenges of medical laboratories for ISO accreditation in public hospital laboratories, that were impeding them from achieving ISO 15189 accreditation.

1.2. Statement of the Problem

The quality system in medical laboratory diagnosis in developing countries has been mostly ignored and has become a severe disablement to effective healthcare provision and disease surveillance. Most of the physicians are grounded on history taking and symptoms for patient management because they have little sureness in laboratory examination outcomes. Hence, the decisions made based on symptoms are often possibly leading to improper treatment; which resulted in prolonged hospital stays, needless admissions, poor quality of life, deaths, irrational use of antimicrobial drugs, and financial problems for families (15,16).

About 70%, of clinical decisions, are influenced by data produced from a medical laboratory in developed countries. While in developing countries like Africa approximately 50% of medical decision-making is influenced by laboratory testing. However, diagnostic systems have often been ignored in the work to support global health systems. For instance, out of 49 countries evaluated in sub-Saharan Africa in 2013, 37 of them did not have medical laboratories that met international quality standards (17).

The major challenges encountered during the process of accreditation were a shortage of Internal Quality Control (IQC), supplies and reagents, interruption of electric power, low number of skilled laboratory personnel, and absence of equipment service and calibration that lead to service interruptions. Service interruptions and delays in service delivery also caused increased complaints from clinicians and customers(18).

Though quality laboratory service is vital for a wide range of diagnosis, treatment, and monitoring in health care delivery but due to the lack of consciousness of the laboratory service implication in many developing countries, laboratory facilities are exposed to many challenges such as scarcity of resources, poor management system, absence of quality assurance program, lack of equipment, lack of training and poor staff motivation system among of stated. Similarly, in sub-Saharan Africa lack of dependability of medical laboratory services was the main challenge encountered in providing quality health delivery(19).

Ethiopia is one of the lowliest health statuses as could be verified by accepted health indicators such as inadequate use of the obtainability of human considerable resources, health service management, patient waiting for service, customer satisfaction, and clients preferred for laboratory services. Because of this, the convenience of quality laboratory test results and the quality of present services remain a critical challenge(20).

According to the study done in Ethiopia on the effective way to improve laboratory quality towards WHO-AFRO Stepwise Laboratory Accreditation in 2015, stated as, most Ethiopian public health laboratories until recently not fully providing the service and they were not in a status of affording quality health care service. Many of them performed below standard, were delayed by decrepit infrastructure, and had poor progress and implementation of laboratory QMS(21).

The other study was conducted in Ethiopia on the status of medical laboratories in of AFRO-WHO accreditation process by 2015. Less than 50% of laboratories scored the laboratory quality essential system elements. The study also indicated that internal audit, corrective action, occurrence management, document and records, management review, organization and personnel, and client management were the areas where the poorest points were scored. Absence of laboratory policy, poor management commitment, poor resource allocation, poor laboratory designing, lack of knowledge, and shortage of supplies to be as the possible reasons the study was specified for scoring the poorest points (22). Still now in Ethiopia, there are only a few studies was conducted so far on SLIPTA/ISO implementation and its challenges on public hospital laboratories found in Addis Abeba and around it. Therefore, this study tried to address the existing challenges that inhibit them to achieve ISO accreditation, the other public hospital laboratories that were enrolled in the SLIPTA/ISO accreditation program out of Addis Ababa or away from Addis Ababa.

1.3. Significance of the Study

Most of the public hospitals found in the Jimma zone were enrolled in AFRO-SLIPTA and started implementation more than nine years since 2013. But still now according to the Jimma zone health office 2020 annual report showed that there is only one public hospital laboratory that was accredited by EAS in single TB Gene x-pert test. Hence, this study tried to identify the challenges that were hindering them from achieving ISO15189 accreditation. Based on the findings the strategies to address the gap and challenges have been recommended for policy makers to solve the problems and improve LQMS implementation to meet the ISO-15189 accreditation requirements. Furthermore, this study will be used by the health sector in building awaerness of the challenges of medical laboratories for ISO15189 accreditation in government hospitals and as an evidence base for the planning and designing strategies to overcome the identified challenges.

Chapter Two

Literature Review

The development and status of medical laboratory accreditation in the world vary from country to country and region to region. A survey was conducted in 2014 among delegates of 39 European Federation of Clinical Chemistry and Laboratory Medicine scientific societies in European countries. Of these, 29(74%) were registered for response and all of these countries started the accreditations process in various ways(23). Whereas, countries of the South-East Asia Region are in flexible stages of progress although, India, Indonesia, and Thailand have established accreditation systems, other countries are still in the preparation stage. In Africa up to 2010, only 340, medical laboratories were internationally accredited. The majority of the accredited laboratories 312 are found in South Africa; only 28 are found in sub-Saharan Africa(8,24).

The case study conducted in Cambodia at 12 tertiary level hospital laboratories in-service training and mentoring program to strengthen improvements in LQMS toward ISO15189 accreditation stated as, regular laboratory mentoring, supported by needs-based training and inter-laboratory collaboration enhances laboratory quality improvement. High levels of staff turnover for more well-paid jobs in the private sector and a shortage of qualified mentors are described as continuing challenges (25).

According to the study conducted in Jamaica on how prepared medical and nonmedical laboratories in Jamaica for accreditation, the participants specified several barriers to accreditation; accreditation procedure was costly, lack of staff motivation, indistinct requirements, and challenges with the understanding and implementation of ISO standards, lack of support from management and lack of a quality manager. The laboratories that performed with quality managers had a good groundwork for accreditation. This study proposed that accreditation needs a cooperative work of management, technical staff, and all stakeholders (26).

The study reviewed in Canada on the value and impact of accreditation in health care, recognized profits of accreditation such as improving patient safety, confirming an acceptable level of quality between health care workers, motivating maintainable quality improvement, and increasing status amongst end consumers. Also, the study specified the accreditation process is stressful, time-consuming, and needs a serious investment of resources (27).

According to the study reviewed on accredited medical laboratories on laboratory professional's attitudes towards ISO 15189:2012 accreditation in three Europe countries; in Croatia in three accredited medical laboratories, of responders considered themselves familiar with ISO 15189:2012, only 14% completely, 32 % very well, 38 % moderately, and 16 % not at all, 68% of responders felt that accreditation increases the usual workload, with extreme paperwork. In Belgium and Netherland; in three laboratories shown as contradictory outcomes in two laboratories, 87% did not thinking that the accreditation process enhanced the quality of the laboratory outcomes yet, they have chosen to work in an accredited laboratory. On other hand in clinical pathology laboratories, 75% of laboratories handled that accreditation influence an enhancement of laboratory services by adapting more documentation and better health and safety training approaches (28,29).

As the study conducted in three Asian countries showed that, in China some staff still did not understand the helpfulness of ISO 15189 requirements and they showed it only as unnecessary additional work required by the accreditation body (30). In Iran laboratories directors and assessors had a progressive outlook toward the standardization process and agreed on it as an instrument for quality improvement. They were well-thought-out main challenges such as excessively bureaucratic, time-consuming, incompetent, increased loads and pressure for laboratory staff, high paper workload, and lack of integration. Lebanon indicated that improvements in quality were revealed by the increase in the clients. As findings showed, accreditation has been related to improved staff satisfaction with quality management and planning. Inadequate resources and staff, irregular laboratory supplies, damaged equipment, high staff turnover and workload, and lack of a referral system were major challenges to implementing the accreditation standards (31,32).

The survey done in Mauritius on the attitude of laboratory personnel towards accreditations, showed that more than 75% of the employees reflected that the workload had increased with accreditation because of rising in documentation and records, consistent monitoring of calibration, and conducting IQC. Though the difficulties that come with accreditation higher workload and more paperwork the majority of staff prefer to work in an accredited laboratory (33). In the qualitative study conducted in South Africa on the need for a quality standard for assurance in medical research laboratories, the participants stated that certain features of the current ISO 15189 standards could be kept in a new standard (34).

According to the study conducted, between 2007 and 2014, in the evaluation of the ISO 15189-based QMS implementation processes at the National TB Reference Laboratories (NTBRLs) of: Benin, Botswana and Uganda using a mixed-methods approach the important perceptions obtained on factors influencing the QMS implementation process were; the unavailability of funding, the role of laboratory management, training, supply chain management, and equipment maintenance capacity, and staff resistance (35).

As the study conducted in three African countries on the implementation of LQMS on attaining ISO15189 accreditation through SLMTA showed that, in Nigeria in six health facilities the staff reluctance to cooperate and follow as they deliberate in LQMS implementation was stated as a challenge. Building capability, improvement plans, follow-up visits, mentorship, and commitment of staff are suggested as important solutions for the improvement of LQMS implementation (36). In Lesotho the study specified some challenges, from the view of the participants to the process as, improvement projects consumed much time and could not be carried out during their regular working day. In Kenya at the baseline audit before SLMTA implementation the laboratory scored 45% conforming to zero stars. Three years after the beginning of SLMTA, the laboratory attained accreditation to ISO 15189. As the author specified the success was due to constructing a team with a shared vision and all struggled to meet ISO 15189 requirements. Mentorship and continuous effort on accreditation after SLMTA was also described as the main factors for attaining greater points. Mentorship and continuous effort on accreditation after SLMTA was also described as the main factors for the laboratory to reach even higher levels. The challenges stated were staff attrition and cost used in pursuit of ISO15189 accreditation(37,38) .

A study conducted in Khartoum Sudan on Assessment Criteria for Accreditation of Government Hospitals' Laboratories according to the international standards showed that 65% of laboratories implement total quality management, 77.5% of laboratories have safe laboratory design and organization, 48.5% have laboratory organization, 45.5% laboratory have well-organized document and management system. The study also specified as, most of the laboratory's lack of establishment the continues quality improvement programs such as quality audits, external quality control, management of reagents, calibration, and quality control material were among the challenges identified (39).

A cross-sectional study conducted in Ethiopia on Perceptions and attitudes of laboratory professionals towards SLMTA showed that 85% observed the SLMTA program as a significant stage in the laboratory QI procedure, and 74% of the respondents stated that they are happy with the SLMTA training set and specified that absence of commitment of laboratory staff and management as challenge, 26% participants had many criticisms with the training approaches (40).

The other study conducted, on Factors Affecting Implementation of LQMS in Addis Ababa Public Health Laboratories, indicated that, from a total of 401 laboratory professionals, 95% of participants in their laboratories had been working on the LQMS implementation, 24.5% of participants did not have LQMS associated training, 46.5% participants were not pleased on LQMS training, 29% participants were identified that their laboratory design and size of the laboratory not suitable, about 3% small use of irregular mentoring and coaching. This study indicated that there is no significant association between workload and laboratory QMS implementation (41).

As the study done, to assess the outcome of Strengthening Laboratory Management Towards Accreditation(SLMTA) on LQMS in Addis Ababa, the study specified that, 76% of the participant's facilities did not have a work plan and budget, 24% absence of resources, 73.4% shortage of enough equipment, 79.9% laboratory equipment did not mend as to the program and 53.9% equipment preventive maintenance was done an in their laboratory, 91.7% their laboratory design and size was not suitable enough for laboratory operation, 18.8% the laboratory did not have frequent communication with top management and 37.5% of the laboratory personnel did not have done their customer satisfaction survey(42).

The survey conducted in Ethiopia, on challenges that faced government hospital laboratories as they applied ISO 15189 accreditation standards, stated that, from 175 respondents, 100% of respondents had awareness about laboratory accreditation and 79% of respondents had been involved in SLIPTA/ISO 15189 accreditation processes. Also, little management support, insufficient training, inadequate infrastructure, need for huge paper works, low mentorship and increased accreditation-linked workload, poor equipment, absence of quality reagents, and highly trained staff turnover were among the challenges identified by this study(43).

2.1. The conceptual frame works on challenges for ISO 15189 accreditation.

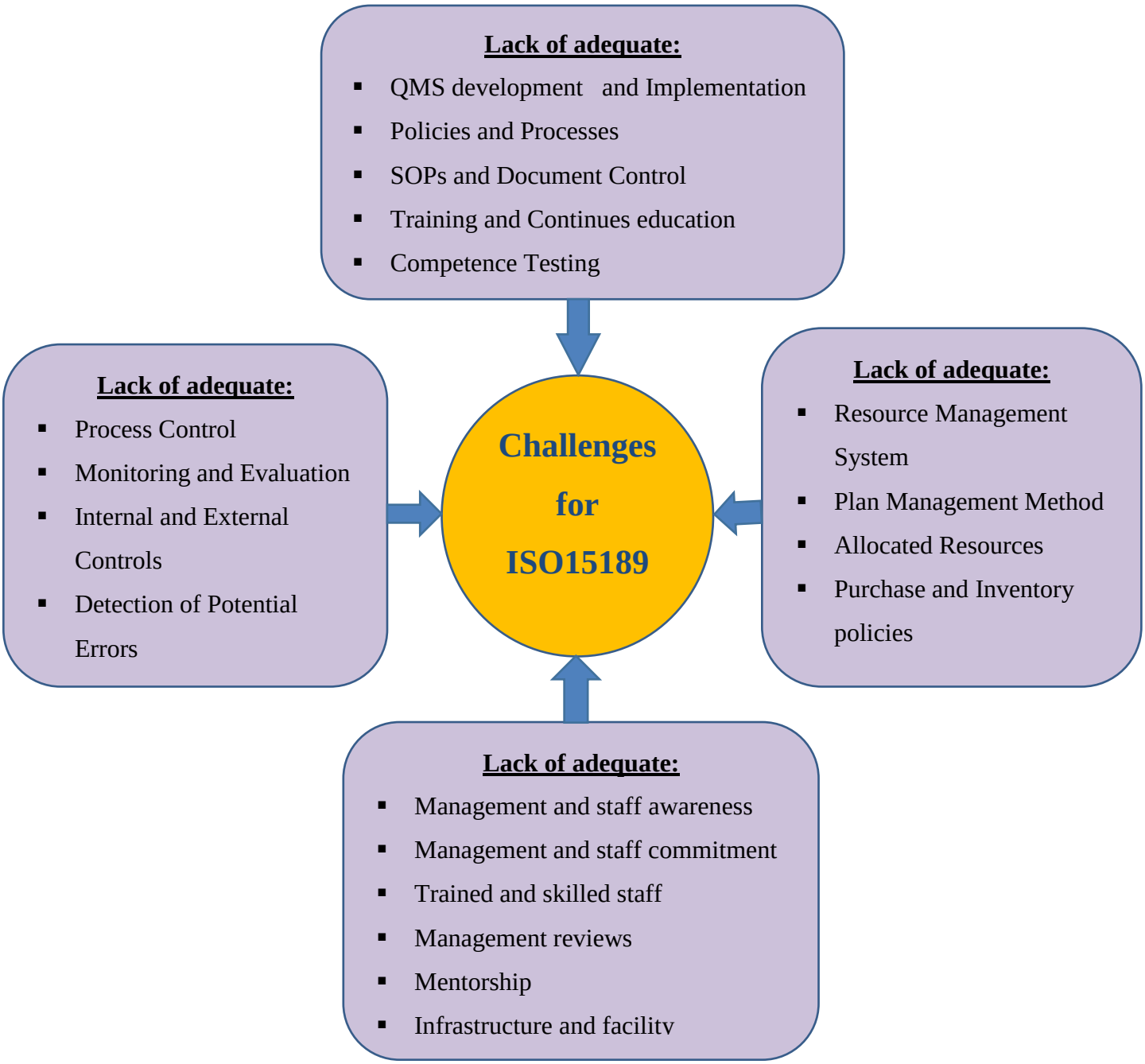

Figure 1 . Conceptual frame work on challenges for ISO 15189 accreditation, Jimma Zone, Oromia Regional State, Ethiopia, 2022.

Chapter Three

Objectives

3.1. General objective

- To assess challenges of medical laboratories for ISO-15189 accreditation in selected Public Hospitals of Jimma Zone, Oromia Regional State, Ethiopia, 2022.

3.2. Specific objectives

- To identify major challenges for the ISO-15189 accreditation across studied laboratories.
- To assess the awareness of laboratory professionals about the degree of LQMS implementation.
- To assess the perception of laboratory professionals on the factors affecting laboratory accreditation.

Chapter Four

Method and Material

4.1. Study Area

This study was conducted in Public Hospitals found in Jimma Zone, Oromia Regional State, Ethiopia. Jimma town is the center of the Zone located at 357 km distance to South West of Addis Ababa. Its temperature range from 11.5 to 27.1^{0}C, annual rainfall is 1200 to 2000mm and its altitude is about 1760 meter above sea level. The total population of 2,486,155, according to the 2007 census conducted by the Central Statistics Agency of Ethiopia. Up to the second-quarter year report of 2021, there were a total of Nine functional Public hospitals found in Jimma Zone form those one referral Hospital (Jimma University Medical Center), Three general hospitals (Limmu Genet General hospital, Shanan Gibe General hospital and Agaro General hospital) and five primary hospitals (Seka Primary Hospitals, Nada primary hospitals, Dedo primary hospital, Santema primary hospital and Dimtu primary hospital), 122 Health Centers, and 486 Health Posts. Five out of nine hospitals were enrolled in LQMS/SLIPTA program and implementing LQMS with different degrees of achievement and status. The enrolled hospitals were Jimma University Medical Center, Limmu Genet General Hospital, Shanan Gibe General Hospital, Agaro General Hospital, and Seka Primary Hospitals. This study focused on those enrolled hospitals in LQMS/SLIPTA program and tried to identify what challenges impeded them from achieving accreditation and fully implementing a quality management system.

4.2. Study Design and Period

4.2.1.Study Design

A cross-sectional study design was employed using quantitative and qualitative data collection approaches.

4.2.2. Study Period

This study was conducted from October 20, 2021, to January 10, 2022.

4.3. Population

4.3.1. Source Population

- Public hospital laboratories that were found in Jimma Zone and all laboratory professionals working in those hospitals were used as a source population for this study.

4.3.2. Study Population

- All laboratory professionals with more than six months of work experience and working in Public hospital laboratories participating in the SLIPTA program or applied for ISO-15189 accreditation.

4.4. Sample Size and Sampling Technique

The hospitals involved in this study were purposely selected based on their enrolment in SLIPTA/ISO accreditation program implementation. Laboratory professionals involved in this study were also selected based on those enrolled hospitals. The total number of laboratory professionals working in those enrolled hospitals was 110 (68 in Jimma University Medical Center, 13 in Agaro General Hospital, 7 in Limmu Genet General Hospital, 9 in Seka Primary Hospital, and 13 in Shanan Gibe General Hospital). Since the expected total number of laboratory professionals working in those hospitals enrolled in the LQMS/SLIPTA program is minimal all laboratory professionals were included exhaustively in this study. Key informants such as Laboratory Head, Quality Officer, Hospital CEO/Medical Director, Human Resource Head, and Finance Head were purposively selected according to their participation in the implementation of the SLIPTA/ISO accreditation process.

4.5. Data Collection Procedures

4.5.1. Data Collection Tool

The questionnaires was prepared based on a review of the literature on the implementation of LQMS and it was used for the quantitative data collection from technical laboratory professionals. An open-ended question was used for the qualitative data collection to assess more information from technical laboratory professionals that were written by them. Face-to-face interview using interview guide used for the qualitative data collection from key informants.

4.5.2. Data Collection

Quantitative data were collected using structured questionnaires from technical laboratory professionals by laboratory profession that have training on LQMS after he had short orientation. Qualitative data were collected through face-to-face interviews with key informants by the principal investigator. The opinion of the key informants was recorded using a handphone, and the recorded opinion of the interviewee was transcribed to a written form by listening from the phone record.

4.6. Study Variables

4.6.1. Dependent Variable

- ISO 15189 accreditation process.

4.6.2. Independent Variable

- Mentorship
- Staff participation
- Routine workload
- Staff training in LQMS
- Trained staff turn-over
- Cost in implementing LQMS
- Staff awareness and commitment
- Budget for LQMS implementation
- Laboratory equipment and supplies
- Infrastructure; workspace, storage space
- Management support, commitment and awareness on SLIPTA/ISO accreditation.

4.7. Data Analysis and Interpretation

Collected quantitative data were entered and cleaned using EPI-Data version 4.6 and exported to statistical package software for social sciences (SPSS version 25.0) for further processing and analysis. Simple descriptive statistics like percentages and frequency were used. The qualitative data from in-depth interviews were organized, categorized, summarized, and finally discussed by describing the findings.

4.8. Data Quality Assurance

To ensure the validity of the data collection tool, 5% of pre-study test was done in Bedele General Hospital before the study period, which was not included in the main study. Appropriate correction of the data collection tool was made accordingly before the actual data collection. During data collection, the completeness of data was checked by the principal investigator. To protect data from abuse the data were stored in a password-protected computer and backup was saved by CD and personal email.

4.9. Ethical Consideration

Ethical clearance was obtained from the Institutional Review Board of the Institute of Health, Jimma University reference number, **IHRPGn/568/.** Official letters of cooperation were also written to the study sites, Jimma University Medical Center, and Jimma Zone Health Office, and permission were obtained. Jimma Zone Health Office also wrote letters of cooperation for the respective hospitals to get permission. The information collected was kept in a file without stating the name of the organization rather by a code assigned from 01 to 05, to assure confidentiality of the hospitals, laboratories, and respondents.

4.10. Dissemination Plan

The result of this study will be submitted to Jimma University School of Medical Laboratory Sciences and Jimma University Research Directorate, Jimma University Medical Center, Jimma Zone Health Office, Hospital Managements, and Laboratory Departments under this study. Efforts will be made to present at scientific conferences and to publish in any Medical Reputable Journal to make it more available to be used by any stakeholders and other researchers for further investigation.

4.11. Opertional definition

- **Laboratory accreditation**: laboratory that implements ISO 15189 and its competency is declared by EAS or accreditation body.
- **Challenge:** different obstacles that medical laboratories face to achieve ISO 15189 accreditation.
- **Trained staff turnover:** the rate of laboratory professional that had training and experience on LQMS/ISO accreditation left that laboratory.

- **Staff Awareness:** perception, mindfulness and understanding of laboratory professionals, about the LQMS implementation in their facililities.
- **Mentorship:** the support that was given for participated laboratory by external consultant to assist the implementation of SLIPTA/ISO accreditation from regional or national.
- **Budget:** the financial plan that was allocated for implementation of LQMS or SLIPTA/ISO accreditation.
- **Work load:** the routine laboratory work that makes the professionals full of activities and prevents them from accomplishing tasks that SLIPTA/ISO accreditation requires.

Chapter Five

Result

5.1. Background of the study sites

This study was conducted in five selected public hospital laboratories found in Jimma Zone, based on their participation in SLIPTA/ISO accreditation process. The selected public hospitals were; one general hospital and one teaching referral hospital found in Jimma town, while the rest of two general and one primary hospital were found in the Jimma Zone. According to the recent national and regional SLIPTA assessment results of each hospital laboratory, their star levels were from 1-star to 3-stars. One laboratory had a 1-star level, two laboratories had a star level of 2 and the other two laboratories had a 3-star level. From the five laboratories involved in this study, only one laboratory was accredited by EAS in the TB Gene x-pert test.

5.2. Demographic characteristics of the study participants

The participants in this study had varying background characteristics including sex, age, educational level, length of service, position, and distribution by the department. Of a total of 110 laboratory professionals expected to participate in this study, 102 laboratory professionals completed the questionnaire and submitted it back to the data collectors giving a response rate of 93 %. For qualitative data collection, 19 informants were included; 5 laboratory heads, 5 quality officers, 3 medical directors, 2 hospital CEOs, 2 finance heads, and 2 human resource management heads were interviewed and forwarded their opinion regarding the challenges of medical laboratories for ISO 15189 accreditation.

Of, the 102 total respondents, 64(62.7 %) were males. The age of respondents ranged from 22 to 43 of which were 50(49.0%) respondents who belonged to the age group of 26 to 30 followed, by 27(26.5%) respondents from 31 to 35. The majority of the respondents 77(76.5%) were BSc degree holders followed by diploma holders 15(14.7%) and the rest, 10(9.8%) were MSc and above. The working experience of the study participants in those given organizations ranged from 8 months to 13 years and the majority of the respondents 59(57.8%) had 1 to 5 years of work experience. Regarding the position of respondents in the organization, 79 (77.5 %) were technical staff followed by section heads 9(8.8 %)(**Table 3)**.

Table 3. Demographic characteristics of public hospital laboratory staffs, Jimma zone, Oromia Regional State, Ethiopia, 2022(n=102).

Variables		Number of respondents (%)
Sex	Male	64 (62.7)
	Female	38(37.3)
Age	21-25	19(18.6)
	26-30	50(49.0)
	31-35	27(26.5)
	36-40	4(3.9)
	41-45	2(2.0)
Educational level	MSc and above	10(9.8)
	BSc	77(75.5)
	Diploma	15(14.7)
Experience in current organization, in years	<1	11(10.8)
	1-5	59(57.8)
	6-10	29(28.5)
	11-15	3(2.9)
Working section or unit /department	Hematology and Molecular	21(20.6)
	Clinical chemistry and Serology	30(29.4)
	Microbiology	12(11.8)
	Parasitology and Urinalysis	16(15.7)
	Emergency and Centeral Processing Unit (CPU)	13(12.7)
	All department/unit	6(5.9)
	Others	4(3.9)
Work position	Technical Staff	79(77.5)
	Section Head	9(8.8)
	Lab Manager	5(4.9)
	Quality Manager	5(4.9)
	Safety Officer	4(3.9)

5.3. Awareness, participation, mentorship and training related to SLIPTA/ISO accreditation.

The outcomes of this study showed that of 102 laboratory professionals who participated in this study, 76(74.5%) of them responded that they have awareness about laboratory SLIPTA/ISO 15189 accreditation. Of 76 respondents who had awareness, only 46(60.5%) of them replied that they have been involved in the SLIPTA/ISO implementation.

Of 46 participants involved in the SLIPTA/ISO implementation, the majority 39(84.5%) of them had been involved for 1-5 years, 13% of them had for less than a year, while 2.2% of tem are had more than six years. They participated in different activities of SLIPTA/ISO implementation, 20(43.5%) of 46 were involved in document preparation, 15.2% in auditing and coordination, in addressing non conformities 8.7%, in sensitization or awareness creation, while others 6.5% in more than one activities and 4.4% decision making or management.

Only about 4(39%) of the respondents said they have training related to LQMS. Regarding the degree of mentor support, 23(22.6%) responded mentors' support was, “not at all and very small degree’’, while 38(37.2%) were responded mentors support their facilities “moderately’’ and 20(19.6%) responded that their support was at “large and very large degree’’.

Of 23 who responded that mentors' support was, “not at all and very small degree’’, the majority 15(65.2%) of them believed that, “it was due to lack of adequate budget for external consultants’’, followed by 6(26.1%) respondents’ who responded that “it was due to lack of management support’’. From 20 study participants, who responded that mentors support was, at “large degree and very large degree’’, 15(75%) of them said the support was, “as good as expected’’ and the rest 5(25%) said, “as not expected’’(**Table 4**).

Table 4 : Awareness, participation, mentorship, and training related to SLIPTA/ISO accreditation at public hospitals in Jimma Zone, Oromia Regional State, Ethiopia, 2022(n=102).

Variables		Number (%)
Awareness about SLIPTA/ISO accreditation (n=102)	Yes	76(74.5)
	No	26(25.5)
Involvement in the SLIPTA/ISO implementation (n=76)	Yes	46(60.5)
	No	30(39.5)
Length of the year in the SLIPTA/ISO implementation (n=46)	<1	6(13.0)
	1-5	39(84.8)
	6-10	1(2.2)
Ways of participation in the SLIPTA/ISO implementation (n=46).	Decision making/management	2(4.4)
	Sensitization/awareness	3(6.5)
	document preparation	20(43.5)
	Auditing	7(15.2)
	Coordination	7(15.2)
	Addressing non conformities	4(8.7)
	In more than one activities	3(6.5)
Training experience related to LQMS(n=102)	Yes	40(39.2)
	No	62(60.8)
The degree of mentors support laboratory (n=102)	I do not know	21(20.6)
	Not at all	17(16.7)
	Very small extent	6(5.9)
	Moderate extent	38(37.3)
	Large extent	17(16.17)
	Very large extent	3(2.9)
Reason for not at all and very small degree(n=23)	Lack of competent consultants.	2(8.7)
	Lack of adequate budget	15(65.2)
	Lack of management support	6(26.1)
Expected quality assistance for large and very large extent(n=20)	Yes	15(75.0)
	No	5(25.0)

5.4. Awareness of laboratory professionals on degree of LQMS implementation.

From a total of 102 participants in the study, 25(24.5%) of the respondents indicated that awareness creation and sensitization of staff on the benefits of accreditation was implemented in their facilities, to a "large and very large degree'', while 39(38.2%) of them said, at "moderately'' and 32(31.4%) responded, at "not at all and very small degree''.

Regarding quality manual with the clear quality policy statement and objectives development and communication, 49(48%) of the participants responded, to at "large and very large degree'' it was developed and communicated in their facilities, while 35(34.3%) at "moderate degree'' and 16(15.7%) responded as it was, "not at all and very small degree''.

The support and commitment of hospital top management to fulfill all ISO standards were responded by 30(29.4%) of participants, at "large and very large degree'', while 43(42.2%) of them stated, "moderately'' and 25(24.5%) of the respondents stated as it was "not at all and very small degree''. About, 47% of participants responded that the establishment of laboratory logistic systems to avoid understock and overstock was implemented in their facilities, at "large and very large degree'', while 31 (30.4%) of them said, at "moderate degree'' and around 20% were responded that it was "not at all and very small degree''.

Regarding conducting of internal audit at planned time intervals 47(46.1%) of participants that it was conducted at a "large and very large degree'', while 37(36.3%) of them responded that it was at a "moderate degree'' and 20(19.6%) of participants, as it was, "not at all and very small degree''. Developing action plan based on internal audit findings was assumed, by 33(32.3%) respondents as it was conducted, at "large and very large degree'', while 34(33.3%) were responded as, "moderately'' and 29(28.4%) responded, as it was, "not at all and very small degree''.

Concerning the effective implementation of training and continuing education for all managerial, technical, and supporting staff, 26(25.5%) of the respondents, at "large and very large degree'', while 35(34.3%) at "moderate degree'' and 41(40.2%) of them as it was, "not at all and very small degree'' **(Table 5).**

Table 5: Awareness of laboratory professionals on degree of LQMS implementation at public hospitals of Jimma Zone, Oromia Regional State, Ethiopia,2022 (n=102)

Requested questions	Don't Know	Not at all	Very small degree	Moderate degree	large degree	Very large degree
Awareness creation and sensitization of staff on benefits of SLIPTA/ISO accreditation conducted	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
	6(5.9)	7(6.9)	25(24.5)	39(38.2)	19(18.6)	6(5.9)
Commitment of top management was evident to fulfill all ISO standards	4(3.9)	5(4.9)	20(19.6)	43(42.2)	23(22.5)	7(6.9)
Quality manual developed and communicated	2(2.0)	2(2.0)	14(13.7)	35(34.3)	36(35.3)	13(12.7)
Laboratory logistics system was established	3(2.9)	5(4.9)	15(14.7)	31(30.4)	35(34.3)	13(12.7)
Internal audits were conducted as planned	2(2.0)	2(2.0)	14(13.7)	37(36.3)	35(34.3)	12(11.8)
Action plan was developed based on internal audit findings	6(5.9)	5(4.9)	24(23.5)	34(33.3)	20(19.6)	13(12.7)
Training and continual education were implemented effectively at all level	0(0)	16(15.7)	25(24.5)	35(34.3)	20(19.6)	6(5.9)
Adequate space allocated for the performance of its quality work	0(0)	3(2.9)	16(15.7)	33(32.4)	37(36.3)	13(12.7)
Laboratory has adequate storage space for laboratory supplies	0(0)	1(1.0)	15(14.7)	30(29.4)	38(37.3)	18(17.6)
Laboratory has wash rooms and latrines for staffs	7(6.9)	7(6.9)	8(7.8)	14(13.7)	41(40.2)	25(24.5)
Laboratory has adequate latrine for clients as per standard	3(2.9)	8(7.8)	15(14.7)	21(20.6)	36(35.3)	19(18.6)
Laboratory has adequate sample collection space for clients	0(0)	1(1.0)	22(21.6)	24(23.5)	30(29.4)	25(24.5)
Laboratory monitored regularly environment condition	3(2.9)	3(2.9)	15(14.70	41(40.2)	33(32.4)	7(6.9)
Laboratory has system for; selection, purchase and manage supplies and equipment	9(8.8)	7(6.9)	13(12.7)	38(37.3)	28(27.5)	7(6.9)
Laboratory performs independent equipment verification practice	4(3.9)	1(1.0)	23(22.5)	39(38.2)	26(25.5)	9(8.8)
Laboratory has established a system to inspect and verify all supplies	1(1.0)	4(3.9)	17(16.7)	42(41.2)	30(29.4)	8(7.8)
Laboratory verifies new methods before uses	2(2.0)	6(5.9)	18(17.6)	28(27.5)	36(35.3)	12(11.8)
Laboratory performs internal quality control for all tests	1(1.0)	1(1.0)	7(6.9)	34(33.3)	38(37.3)	21(20.6)
Tests reviewed and released by authorized personnel	1(1.0)	5(4.9)	12(11.8)	35(34.3)	39(38.2)	10(9.8)
Laboratory evaluates and verifies electronic LIS before using it	18(17.6)	16(15.7)	14(13.7)	25(24.5)	22(21.6)	7(6.9)

5.5. Perception of staffs on factors affecting medical laboratory SLIPTA/ISO accreditation process.

The current study showed that out of 102 respondents, 55% stated that low staff participation in LQMS implementation affected SLIPTA/ISO accreditation process at "large and very large degree'', 20(19.6%) said at "moderately'', and 25% were assumed as it was "not at all and very small degree".

Inadequate support of top management was supposed by 54(53%) of participants, at "large and very large degree'', affected SLIPTA/ISO accreditation process, while 38(37.3%) of participants supposed, at "moderately'' and 10(9.8%) of participants, at "not at all and very small degree''.

Concerning trained staff turnover, 57(55.8 %) of participants supposed it was at a "large and very large degree'' affected SLIPTA/ISO accreditation process, while 36(35.3%) were assumed, at a "moderate degree'' and 8(7.8%) were assumed, at "not at all and very small degree''. About 67% of the study participants responded that inadequate mentorship affected SLIPTA/ISO accreditation process, at "large and very large degree'', whereas 21(20.6%) were supposed, at "moderately'' and around 11% were supposed, at "not at all and very small degree''.

Around 70% of respondents believe that the high burden of routine workload affected SLIPTA/ISO accreditation process, at "large and very large degree'', while 24(23.5%) said, at "moderately'' and about 6% of respondents were supposed, at "not at all and very small degree'' **(Table 6).**

Table 6: Perception of staffs on factors affecting medical laboratory SLIPTA/ISO accreditation process in public hospitals of Jimma Zone, Oromia Regional State, Ethiopia, 2022 (n=102).

Requested questions	Don't Know	Not at all	Very small degree	Moderate degree	Large degree	Very large degree
High cost in implementing LQMS	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
	9(8.8)	6(5.9)	15(14.7)	19(18.6)	21(20.6)	32(31.4)
Working environment	7(6.9)	3(2.9)	17(16.7)	21(20.6)	33(32.4)	21(20.6)
Inadequate staff participation	1(1.0)	8(7.8)	17(16.7)	20(19.6)	28(27.5)	28927.5)
Staff resisting change	2(2.0)	6(5.9)	16(15.7)	30(29.4)	27(26.5)	21(20.6)
Inadequate support from top management	0(0)	2(2.0)	8(7.8)	38(37.3)	33(32.4)	21(20.6)
Inadequate training on LQMS	4(3.9)	4(3.9)	9(8.8)	28(27.5)	29(28.4)	30(29.4)
Inadequate understanding of LQMS/ISO requirments	0(0)	5(4.9)	12(11.8)	32(31.4)	33(32.4)	20(19.6)
Inadequate required standards/reference	1(1.0)	8(7.8)	26(25.5)	33(32.4)	27(26.5)	7(6.9)
Inadequate awareness on benefit of LQMS & accreditation	2(2.0)	6(5.9)	18(17.6)	29(28.4)	31(30.4)	16(15.7)
Inadequate proper planning on the implementation of LQMS	0(0)	12(11.8)	10(9.8)	22(21.6)	33(32.4)	25(24.5)
Turnover of trained staff	1(1.0)	0(0)	8(7.8)	36(35.3)	34(33.3)	23(22.5)
Difficulty in communication and decision	2(2.0)	6(5.9)	9(8.8)	26(25.5)	36(35.3)	23(22.5)
Complexity of the processes	1(1.0)	5(4.9)	15(14.7)	37(36.3)	28(27.5)	16(15.7)
Inadequate qualified personnel	2(2.0)	7(6.9)	15(14.7)	31(30.4)	36(35.3)	11(10.8)
Inadequate management reviews to the accreditation program	2(2.0)	7(6.9)	13(12.7)	26(25.5)	39(38.2)	15(14.7)
Inadequate sensitization	2(2.0)	3(2.9)	13(12.7)	34(33.3)	34(33.3)	16(15.7)
Inadequate funds to implement the accreditation process	5(4.9)	2(2.0)	9(8.8)	31(30.4)	37(36.3)	18(17.6)
Inadequate infrastructure	1(1.0)	7(6.9)	12(11.8)	27(26.5)	33(32.4)	22(21.6)
Massive documentation requirement	1(1.0)	4(3.9)	7(6.9)	31(30.4)	23(22.5)	36(35.3)
Inadequate regular mentorship	2(2.0)	5(4.9)	6(5.9)	21(20.6)	37(36.3)	31(30.4)
Inadequate equipment/supplies to provide uniterrupted lab tests.	1(1.0)	2(2.0)	8(7.8)	37(36.3)	39(38.2)	15(14.7)
High routine work load	1(1.0)	0(0)	6(5.9)	24(23.5)	35(34.3)	36(35.3)
Electric power interruption	2(2.0)	10(9.8)	12(11.8)	30(29.4)	28(27.5)	20(19.6)

5.5. In-depth interview outcomes

The total key informants who participated in this study were nineteen (19); 5 Laboratory heads,5 Quality officers, 3 Medical directors, 2 Hospital CEOs, 2 Finance heads, and 2 Human resource heads were included. Their opinions were organized, categorized, summarized, and finally discussed by describing the findings. For confidentiality instead of stating the name of the facilities involved in this study the codes from 01 to 05 were given to them.

5.5.1. Laboratory heads and Quality officers opinion regarding challenges of medical laboratory encounter during the SLIPTA/ISO accreditation process.

Laboratory heads and Quality officers forwarded their opinions, about the challenges their facilities encountered during SLIPTA/ISO implementation and the factors that were supposed to, hinder their laboratories from achieving SLIPTA/ISO accreditation as follows:

Low top management awareness and commitment: two laboratory heads and one of the quality officer said, their facility's top management were well aware and committed to supporting the implementation of SLIPTA/ISO accreditation program but the majority of the rest laboratory heads and quality officers consider, as it was one of the responsible factors adversely affecting their facilities from achieving the SLIPTA or ISO accreditation.

Laboratory head of hospital 02, explains his view regarding the negative impact of low top management awareness and commitment on SLIPTA/ISO accreditation as, *"in our facility top management support and their commitment for LQMS/SLIPTA implementation was very limited, due to their inadequate awareness of laboratory accreditation''*. He also suggested as, *"for the successful implementation of SLIPTA/ISO accreditation, all technical and non-technical staffs of the hospital need to be aware of laboratory accreditat*

ion". The other laboratory head of hospital 03 added his opinion for low implementation of SLIPTA/ISO accreditation in their facilities, "*Yet the effort of laboratory staffs were very good, where the hospital managements had inadequate awareness and low commitment to support SLIPTA/ISO implementation, achieving laboratory accreditation was too difficult"*.

The laboratory quality officer of hospital 04 said, one of the reasons for the low implementation of SLIPTA/ISO accreditation in their hospital, was "*due to frequent medical directors and hospital CEOs, were changed supports of top management for SLIPTA/ISO implementation were fluctuating"*.

Low staff commitment and awareness: majority of laboratory heads and quality officers raised their opinion as, even though many of the staff were aware of SLIPTA/ISO accreditation and committed to implementing the program, rarely same of the staff have low commitment to participate actively in SLIPTA/ISO implementation considering as additional work.

Laboratory head of hospital 01, forwarded his opinion for low implementation of LQMS in their facility as *"during the starting of the LQMS /SLIPTA implementation many of the staffs were resisting to participate actively in the program due to lack of adequate awareness. Slowly after getting adequate awareness and training most of them were willing to participate in the SLIPTA/ISO implementation".*

The other laboratory head of hospital 05 added his opinion for the reason of low SLIPTA/ISO implementation as, *"even if some of the staffs getting adequate awareness about SLIPTA/ISO accreditation in our facility, still they were not committed to participate in LQMS /SLIPTA implementation".* Laboratory head of hospital 04 also described his opinion for the low achievement of SLIPTA/ISO accreditation as, *"most of the time during the period of preparation for an external assessment, many of the staffs were committed and actively participating in SLIPTA/ISO implementation, after an assessment process their commitment was decreased".*

High staff turnover: most of the laboratory heads and quality officers shared the same opinion, as there is high staff turnover in their facilities especially trained and experienced staff for the need of high payment and better facilities, which is mainly affecting their facilities from fully implementing SLIPTA/ISO accreditation.

Laboratory head of hospital 04 clarified his view of about slow achievement of SLIPTA/ISO accreditation as, *"in our laboratory, because of there is no a culture of experience sharing, when qualified and trained laboratory professional shift the laboratory, mostly laboratory performance was declined"*. Laboratory head of hospital 03 supported his reason for low SLIPTA/ISO implementation in their facilities as, "*there was highly trained and experienced staff turnover, due to low level of their satisfaction, which is resulted from lack of a chance for upgrading their educational level, lack of incentive for laboratory risk they were faced during their routine work, poor infrastructure and absence of motivation from upper management".*

Inadequecy of training related to LQMS and regular mentor: majority of laboratory heads and quality officers agreed on the significant role of training related to LQMS and support by mentors was played to achieve SLIPTA/ISO accreditation. They also indicated that inadequate

training related to LQMS and irregular mentors were as main challenging factors that impeded their facilities from fully implementing SLIPTA/ISO accreditation.

The laboratory head of hospital 01, raised his opinion for low SLIPTA/ISO implementation as, "*though many of new employees committed to participate actively in LQMS/SLIPTA implementation, due to inadequacy of training related to the LQMS, they couldn't fully participate in SLIPTA/ISO implementation".* The other laboratory head of hospital 02, forwarded his opinion, one of the factor that was contributed for low implementation LQMS in their facilities as, *"during regular mentors support the staffs were very committed and struggle to implement all the gaps the mentors identified, by feeling as we were under supervision. But when there is no regular mentorship our commitment was declined"*.

Quality officer of hospital 05, gave his view for unsuccessful LQMS/SLIPTA implementation as, "*most of the time since training and mentorship were conducted based on the program of the donors, without identifying which facilities need training and the kind of training needed, and also areas where need more strong external consultant or support, were not identified early, so the targeted aim was not achieved".* The other quality officer hospital 02 also added his opinion for low LQMS/SLIPTA implementation as "*because of most of the training gives more times for theoretical part, it was difficult for staffs during the real LQMS implementation".*

High routine workload: majority of laboratory heads and quality officers shared the same idea as it was hindering their facilities from achieving SLIPTA/ISO accreditation.

Laboratory head of hospital 04 gives his view about the unsuccessful implementation of SLIPTA/ISO accreditation as, *" since the high number of clients coming for daily laboratory services and the number of laboratories staffs were unbalanced, the staffs were faced for high routine workload, which has limited their participation in SLIPTA/ISO implementation''.* Laboratory head of hospital 05 gives his opinion regarding the slow achievement of SLIPTA/ISO accreditation as, *"for successful SLIPTA/ISO implementation staffs delegation for additional work and offering time was needed, but as a result of high routine workload, the delegated staff has no enough time, that required for fully implementing the program".* The other laboratory head of hospital 03 also added his opinion for low SLIPTA/ISO implementation as, "*since the SLIPTA/ISO implementation is a continuous process that needs more efforts for documentation, daily follow up and monitoring the quality of the tests done, with relating to the standard requirements, it was too difficult to achieve by a small number of staffs".*

Poor laboratory infrastructure: of five facilities that participated in this study three of the facility's laboratory heads and quality officers were raised with the same ideas because their laboratory design was not built according to the ISO requirements, their room was small in size, not separated, and also not well ventilated. Generally, they said, it was not convenient for SLIPTA /ISO implementation as per standards. Two of the other facilities' laboratory heads and quality officers suggested, that as their current laboratories were built recently their design was somewhat better, but still, it needs some renovation to fulfill the ISO requirements.

Laboratory head of hospital 04 assumed his view relating to low SLIPTA/ISO implementation and poor laboratory design as, "*lack of laboratory expert participation as a consultant during the laboratory designing and constructing, were resulted for many laboratories design defect, which is uncomfortable for laboratory work".* The quality officer of hospital 03 raised his view, "*because our laboratory design and set up was not built as per ISO requirements, achieving the requirements indicated by ISO was difficult to us most of the time".*

Poor laboratory equipment and supplies: according to the majority of Laboratory heads and Quality officers' opinions, the most commonly raised complaint from patients and clinicians about the quality of laboratory services in their facilities were, mostly happened due to poor laboratory equipment and supplies, which leads to low client satisfaction with laboratory services.

The laboratory head and quality officer of hospital 02 indicated their views for low SLIPTA/ISO implementation as, the quality of tests the laboratory provide was highly affected, due to the poor quality of reagents that were sometimes supplied by the same vendors. Also, they added their ideas, to their facilities due to a lack of equipment service maintenance, for several months' hematology, clinical chemistry, and gene Xpert tests were interrupted at different times. The other laboratory head of hospital 05 added his opinion as, "*lack of equipment calibrator, controls and reagents''* were the most difficulty their laboratory was faced during LQMS implementation.

The procurement and purchasing process: many of the Quality officers and Laboratory heads forwarded similar ideas, since the time required from ordering up to purchasing, and receiving the purchased items was too long, same time their facilities encountered stock out of laboratory reagents and supplies, which was resulted in laboratory service interruption in their facilities.

The quality officer of hospital 03 gave his opinion, *"most of the time shortage and lack of preference equipment and supplies happened, in Ethiopian Pharmaceuticals Supply Agency (EPSA), since it was the only monopolized vendor supplied for public health facilities without procurement process".*

Lack of independent budget for the implementation of LQMS: most of the Laboratory heads and Quality officers agreed on, the unavailability of an independent budget for the implementation of LQMS in their facilities. They indicated that it was one of the challenging factors that contribute to low SLIPTA/ISO implementation. Also, they indicated that, since there is no allocated budget for LQMS implementation in their facilities, their laboratory couldn't perform equipment calibration, training, equipment service maintenance, and repair at the time it was needed.

The assessment process: some laboratory heads and quality officers forwarded similar ideas, about the current assessment process, as it focuses more on the documentation part rather than the real situation of the laboratory, which may lead to the assessors' bias.

The laboratory head of hospital 03 raised his view about the current assessment process as, *"some of its requirements do not consider the capacity of facilities being assessed and all laboratory categories assessed by the same checklist, that may be difficult for some of the facilities to achieve fully the indicated requirements".* The other hospital 05 quality officer raised his ideas regarding the current assessment system as, "*the assessment system by itself made laboratory staffs too busy, on the preparation of paper-based documentation".*

5.5.4. Hospital CEO and Medical director's opinion regarding challenges of medical laboratory encounter during SLIPTA/ISO accreditation process.

Two hospital CEOs and three Medical directors forwarded their views on the challenges encountered in their laboratory during SLIPTA/ISO implementation. Almost all of the participated hospital CEOs and Medical directors had better awareness of laboratory accreditation. All of them agreed on the importance of laboratory accreditation.

Of the two hospital CEOs, hospital 03 CEO stated his opinion of low implementation of SLIPTA/ISO accreditation as, *"even though laboratory accreditation is very expensive and needs many efforts to achieve, it is one of the very important systems to provide reliable, accurate and timely results for clients. So that, it is required to have accredited laboratory to provide high-quality laboratory service".*

Also hospital CEO of hospital 05 added his idea, "*lack of the hospital managements detailed awareness about ISO accreditation and low commitment of some of the laboratory staffs"* were as the possible causes for the slow achievement of laboratory accreditation.

The medical director of hospital 01 also added his opinion, "*weak linkage between laboratory and upper management, was one of the possible reasons for poor implementation of SLIPTA/ISO accreditation''.* He suggested, *"strengthening the linkage between laboratory and upper management, was a key for better implementation of SLIPTA/ISO accreditation".*

Two of the medical directors of hospitals 02 and 04, were forwarded similar ideas for the unsuccessful implementation of SLIPTA/ISO accreditation since most health professionals who graduate from different universities and colleges at the undergraduate level didn't have enough awareness about LQMS and SLIPTA/ISO accreditation. They were incapable to implement LQMS effectively unless additional supporting training was given to them, which required more resources and time. They suggested that including issues related to laboratory, accreditation was better in teaching curriculum as one subject at universities and colleges level for all undergraduates health professionals to pre-informed them.

5.5.5. Human resource heads and Finance heads opinions regarding challenges of medical laboratory encounter during SLIPTA/ISO accreditation process.

Two Human resource heads and two Finance heads participated in this study and they forwarded their views about the challenges of SLIPTA/ISO accreditation. Though the participating human resource heads and finance heads had limited awareness of SLIPTA/ISO accreditation, all of them recognized the laboratory accreditation, as an important tool used to improve the quality of laboratory service.

The finance head of hospital 02 forwarded his opinion for poor laboratory quality services implementation as, "*inconsistency of laboratory supplies often occurred in our facility, due to the complexity of purchasing process, lack of the required amount items, lack of ordered item type from EPSA and delayed order report from the facility, was the most responsible factors for laboratory service interruption".*

The finance head of hospital 04 added his idea for under implementation of LQMS as, *" lack of adequate budget"* as one of challenging factor that was contributed for the shortage of important medical equipment, laboratory supplies, reagents, and other medicinal drugs, and as a main limiting factor for the services required from the facility.

Human resource head of hospital 02 supposed his view for the slow achievement of laboratory accreditation as, *"lack of clear job description for staffs, absence of clarity during hiring the employee and staff transferring were among of the challenging factors affecting the performance of the staffs".*

The human resource head of hospital 03 also added his ideas for low LQMS implementation, *"there is low staff satisfaction in our facility, which is resulted, from the remoteness of our facility from the center of the zone, poor infrastructure and lack of staff motivation".*

5.5.3. Opinion of Laboratory technical staffs' about challenges of medical laboratory encounter during SLIPTA/ISO accreditation process.

Additional views of technical laboratory professionals were collected using open-ended questions, which are written by them. Most of the technical laboratory professionals pointed out the following points, as challenges that contributed to delaying their laboratories from achieving the SLIPTA/ISO accreditation.

Among the factors, the technical staff' were pointed out, as responsible factors for the low implementation of LQMS, absence or rare chance of getting education for further upgrading their knowledge and educational level, as suggested by many technical staffs, as one of the responsible factor reducing their motivation that leads to low staff participation of LQMS implementation.

The other factor many technical laboratory professionals stated inadequate training and awareness related to LQMS /SLIPTA, were raised as the challenging factors that encounter their facilities during the LQMS /SLIPTA implementation. Also, many other technical staffs supposed, irregular mentor support, and supervision from higher hierarchy, as the factors that contributed to the slow achievement of SLIPTA/ISO accreditation.

The majority of technical staff' also listed he high routine workload, as the most challenging factor hindering them from active participation in LQMS/SLIPTA implementation. The absence of a staff motivation mechanism, for the good performance they achieved, lack of risk allowance, for risks they faced during conducting their routine work, and low salary payment, was written by many of the technical staff as a factor that demotivated them from the active participation in LQMS/SLIPTA implementation.

The investigator observation

The workload is the quantity of the work accomplished gained by multiplying the total of all individual procedures by the unit value expressed. While discussing workload, the amount of laboratory work, the staffing level, equipment, and efficiency of the laboratory must be considered. Precise evidence of workload is important to calculate productivity and the ratio of outputs to inputs (44).

The investigator tried to ensure the existence of a high routine workload in facilities under this study. Currently, there is no precise and accurate evidence available that is required to calculate the workload correctly. The investigator used the method, which helps to estimate laboratory workload that mainly depends on the total number of tests accomplished per laboratory staff, which doesn't consider the complexity of different tests. Based on this the investigator used the annual total number of laboratory tests performed per total number of laboratory staff.

The average annual number of tests per staff of laboratory 01 was 3,561, which is the lowest number relatively to others and 70% of human power, participated in routine activities against the required number of human power for the laboratory unit. The average annual number of tests per staff of laboratory 03 was 11034, which is the highest number relative to others. Only about 44% of the human power participated in the routine activities as compared to the required number of human power for the laboratory unit, which is about 66% of the routine workload shared by an inadequate staff.

Currently, due to the unavailability of the standards that state the optimum number of tests per laboratory staff, it is difficult to determine the degree of the facility's workload based on the results obtained by the above method only. Generally, the investigator observed that the average annual number of tests per staff of the five selected laboratories was 5,299, and the average percent of human power for the five selected laboratories against the required number of human power for laboratory units was 71%, which is about 29 % of routine workload were shared among inadequate staffs (Oromia Health Bureau; General and Primary Hospital up to date career scale structure, 2019 and Jimma University Medical Center; Information of Health Professionals, 2022.) **(Table 7).**

Table 7: Annual number of tests per laboratory staff and human power of selected public hospital laboratories of Jimma Zone, Oromia Regional State, Ethiopia, 2022(n=05).

Variables	Name of participated facilities					
	JUMCL	**Shenan Gibe GHL**	**Limmu Genet GHL**	**Agaro GHL**	**Seka PHL**	**Total**
Total number of tests	242,143	107052	77238	91966	64526	582,925
Number of staff	68	13	7	13	9	110
Number of required staff	97	16	16	16	11	156
Tests/ Staff	3,561	8,235	11034	7,074	7169	5,299
$\frac{\text{Number of staff}}{\text{Number of required staff}} * 100$	70%	81%	44%	81%	82%	71%

NB: JUMC Jimma University Medical Center
GHL General Hospital Laboratory
PHL Primary Hospital Laboratory

Chapter Six

Discussion

This study aimed to identify the challenges that hinder medical laboratories from achieving SLIPTA/ ISO 15189 accreditation. Of twenty-three factors listed in the table (**Table 6**), sixtee0n factors were rated by more than, 50% of 102 laboratory professionals who participated in this study, as major challenges affecting the SLIPTA/ISO accreditation process, at "large and very large degree''. High routine workload by 70%, inadequate training, difficulty in communication and decision making, and massive documentation of the standards by 58%, irregular mentorship, and poor planning by 57%, highly trained staff turnover by 56%, low staff participation by 55%, inadequate funds, and poor infrastructure by 54%, organizational culture, inadequate management reviews, low top management support, and poor equipment/supplies by 53%, high cost in implementing LQMS, and inadequate understanding of LQMS/ISO were rated by 52% laboratory professionals.

The staff's awareness of SLIPTA/ ISO 15189 accreditation was one of the important factors for the successful implementation of laboratory accreditation. In this study, from the total of 102 respondents, about 75% of the respondents had better awareness about SLIPTA/ ISO 15189 accreditation, from the 75%, those had already aware, only 46(60.5%) have been involved in SLIPTA/ ISO implementation. This report was lower than the study conducted before in Ethiopia in which 100% of respondents had awareness about laboratory accreditation, and 79% of them had been involved in the accreditation process(43). The other study conducted in Addis Ababa indicated that 95% of participants had been working on the LQMS implementation, which was also a higher number relative to the current study finding (41). In the study reviewed in Croatia, about 84% of respondents considered themselves familiar with ISO accreditation at different degrees, and only 16 % did not at all, which is more than the current study this may be due to all of the respondents were working in the accredited laboratory(28).

The result of the current study showed that about 70% of laboratory professionals indicated the SLIPTA/ISO implementation was affected, to a "large and very large degree'' by high routine workload. It was also thought by the majority of the key informants, as a major challenging factor, preventing the staff from active participation in SLIPTA/ISO implementation.

This fact was supported by a study conducted in Lebanon stating, that routine workload, is a major challenge encountered in the laboratory during the implementation of the accreditation standards(32). The study conducted in Addis Ababa, however, was contradicting the current study findings which stated that workload does not affect the LQMS implementation. This is mainly due to the current study human power of laboratory were 71% as compared to the declared number of human power for laboratory units, this indicated that 29% of routine workload was shared among inadequate staff (41).

About, 67% of laboratory professionals who participated in this study indicated that inadequate regular mentorship affects the implementation of SLIPTA/ISO accreditation, to a "large and very large degree''. This evidence was supported by a study conducted in Cambodia where a shortage of qualified mentors was described as a persistent challenge for laboratory accreditation(25). This report is also supported by a study conducted in Ethiopia which stated that irregular mentoring and coaching programs were negatively affecting the LQMS implementation(41).

In this study, 58% of laboratory professionals agreed that inadequate training related to LQMS was one of the challenging factors that contribute to the low implementation of SLIPTA/ISO accreditation. The key informants reported that since many of the training gave more coverage on the theoretical part, it was difficult for staff during the real implementation. This study was supported by research conducted, at NTBRL of Benin, Botswana, and Uganda which stated that the absence of training related to LQMS is a challenging factor to implement LQMS(35). This report was also supported by studies conducted in Ethiopia that indicated that the existing training approaches have many criticisms(40). The other study conducted in Ethiopia stated, as there was a shortage of LQMS related to training(41).

The current study indicated that most laboratory professionals recognized that, massive documentation requirements during the implementation of laboratory accreditation, was one of the challenging factor affecting the implementation of laboratory accreditation. This study result was supported by a study done in Croatia, accreditation increases the usual workload with extreme paperwork (28). The study done in Iran stated as accreditation increases high paper workload and pressure on laboratory staff (31). In the study done in Mauritius, higher workload and more paperwork were the difficulties that come with laboratory accreditation(33).

This study finding specified that low staff commitment was one of the factors that contributed to the low achievement of laboratory accreditation. The evidence was supported by a study done in Jamaica in which lack of staff motivation was one of the obstacles to achieving laboratory accreditation (26). It was also supported by a study conducted in Ethiopia where the absence of commitment of laboratory staff was one of a factor affecting LQMS implementation (40).

According to our current study result, during the starting of the LQMS /SLIPTA implementation program, most of the staff were resisting to participate effectively in the program by considering it as an additional job. Even though some of the staff were getting adequate awareness, still they were not committed to participating actively in LQMS /SLIPTA implementation. This report was supported by the studies conducted in China where some staff still did not understand the helpfulness of ISO 15189 requirements(30). The study conducted at the NTBRL of Benin, Botswana, and Uganda also reported staff resistance as one of the significant factors influencing the LQMS implementation. In the study conducted in Nigeria, the staff's reluctance to cooperate and follow as they deliberate in LQMS implementation was stated as a challenge to LQMS implementation (35, 36).

This study identified that, yet the successful implementation of SLIPTA/ISO accreditation, needs top management awareness and commitment, as most of the respondents recognized, due to low awareness and commitment of top management, the implementation of laboratory accreditation was negatively affected. This study was supported by research conducted in Jamaica which stated that lack of support from upper management was one of the barriers to laboratory accreditation (26). A study conducted in Ethiopia also supported the current finding that the absence of top management commitment was the main challenging factor encountered in medical laboratories during LQMS implementation(40).

Many of the respondents indicated that trained and skilled staff turnover is the main challenging factor affecting the SLIPTA/ISO implementation. Mostly trained and experienced laboratory professionals left the laboratory for better salaries, further learning, and lack of job satisfaction. This report was supported by a study conducted in Cambodia where well-qualified staff turnover for more well-paid jobs was described as continuing challenge for laboratory accreditation(25). Studies were done in Lebanon and Kenya specified that high staff turnover a major challenge to implement laboratory accreditation(32, 38).

The outcome of this study showed that many of the respondents accepted poor laboratory infrastructure as one of the challenging factors encountered during the implementation of LQMS. This evidence was supported by studies done in Addis Ababa where most laboratory designs and sizes were not suitable enough for the implementation of laboratory QMS (41, 42).

This study indicated that lack of equipment calibration and maintenance, and poor equipment and supplies were supposed, as the major challenge encounter during the implementation of LQMS. The report was supported by studies conducted in Lebanon in which irregular laboratory supplies and damaged equipment were indicated as major challenges to implementing the accreditation standards(32). A study was done at NTBRL Benin, Botswana, and Uganda specified that supply chain management and equipment maintenance capacity were the reported factors affecting the ISO15189 implementation(33). In a study done in Khartoum Sudan, poor reagent management, lack of calibration, and quality control were identified as challenges that delay laboratory accreditation(39). Similarly, in a study done at Addis Ababa, shortage of enough equipment, lack of equipment maintenance, and preventive maintenance were specified as major challenges that were encountered during the LQMS implementation(39).

The respondents of this study stated that the assessment process by itself is one of the challenging factors in the accreditation process. All laboratory categories were assessed by the same checklist, and it also made laboratory staff busy with paper-based document preparation. This study was supported by a study conducted in South Africa, certain features of the current ISO 15189 standards could be kept in a new standard (34).

The finding of this study indicated that an inadequate budget for LQMS implementation is one of the challenging factors that contribute to the low achievement of LQMS implementation. It was supported by studies conducted in Lebanon, inadequate resource was a major challenge to implement the accreditation standards(32). Studies conducted, in Benin, Botswana, and Uganda at NTBRL stated that lack of funding is the significant factor influencing the QMS implementation(35).

The report of this study showed that the high cost of implementing LQMS and poor planning affected the implementation of SLIPTA/ISO accreditation. This report was supported by studies conducted in Kenya where the cost used in pursuit of ISO 15189 accreditation was stated as the challenge and by a study conducted in Ethiopia that most of the facilities did not have a work plan and budget for their laboratory particularly purpose (38, 42).

6.1. Strength and Limitation of the study

6.1.1. Strength of the study

- This study tried to address challenges encounter public hospital laboratories far from Adis Abeba during the SLIPTA/ISO implementation.
- This study also included the views and recommendations of key informants about the challenges that medical laboratories encounter during the accreditation process.

6.1.2. Limitation of the study

- Because of some inquiries and administrative concerns, it was difficult to collect full information from key informants.
- Since data was only collected in public hospital laboratories found in Jimma Zone, the outcome of this study would be difficult to generalize for all laboratories found outside in Jimma Zone.

Chapter Seven

Conclusion and Recommendations

7.1. Conclusion

This study identified the major challenges hindering medical laboratories from achieving ISO 15189 accreditation. Among the major challenges high routine workload was perceived by 70% of technical staff as it was affecting the implementation of SLIPTA/ISO accreditation, to a "large and very large degree''. Also, most of the key informants indicated as it was preventing the staff from actively participating in the implementation of SLIPTA/ISO accreditation. This is mainly due to laboratory routine activities being covered by about 71% of the human power, as compared to the number of human power required for laboratory units. Inadequate training related to LQMS, low staff participation, inadequate awareness about SLIPTA/ISO accreditation, low support of top management, highly trained staff turnover, and irregular mentorship were also perceived by majority of the participants, as the major challenging factors affecting SLIPTA/ISO accreditation process.

So, this study emphasizes mainly the necessity of allocating adequate human power for facilities to share the burden of workload, awareness, training, active participation, regular mentorship, commitment, and support of all responsible bodies to achieve and sustain the laboratory accreditation system.

7.2. Recommendation

The investigator recommended the following suggestion based on the outcome of this study.

- The Federal Ministry of Health and Regional Health Bureaus should allocate adequate human power required for each facility.
- The Federal Ministry of Health, Regional Health Bureaus, and other Stakeholders should more to work on laboratory accreditation programs, to have more accredited laboratories in the country.
- National and Regional laboratories should implement regular laboratory mentorships for continuous laboratory quality improvement.
- National and Regional laboratories, and other Stakeholders that have a responsibility to provide training have better exert more efforts on the availability of training related to LQMS that focuses more on the practical aspect.
- Zone and Woreda health offices should work cooperatively with the facilities under their catchments to strengthen the health care service and laboratory accreditation system.
- The Hospital Management should support and facilitate the implementation of SLIPTA/ISO accreditation in their facility.
- The Hospital Management should build and implement the mechanism used for staff motivation that is further used for staff responsibilities and laboratory accreditation.
- The Hospital Management should be holding regular meetings and discussions with laboratory staff to address early the obstacles encountered during the implementation of SLIPTA/ISO accreditation.
- The Laboratory Staff should give awareness to hospital management and other staff about laboratory accreditation.
- All Laboratory Staff should actively participate in SLIPTA/ISO implementation.
- Laboratory Experts should participate in the laboratory design preparation as a consultant to build the laboratory as per ISO standards.
- The Laboratory Reagents and Supplies should be certified before introducing to the market by a responsible body.
- The Procurement and Purchasing System of the country has to be updated for a better supply system that considers SLIPTA/ISO accreditation process.

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Annexes

Annex 1. Participant Information Sheet

Jimma University, Institute of Health, Faculty of Health Sciences, School of Medical Laboratory Science, In track of Laboratory Management, Jimma, Ethiopia.

Background: My name is **Abdulhak Abajebel,** I am going to do research in partial fulfillment of the requirement of a master's degree in laboratory management at Jimma University School of Medical Laboratory Sciences. In the title; **"Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Public Hospitals of Jimma Zone South West, Ethiopia".**

Laboratory accreditation is a commonly known method of assessment of a laboratory's quality, performance, reliability, and efficiency, where a considerable autonomous body gives official acknowledgment that the laboratory is capable to perform particular tasks. It is used to support and apply improved quality in laboratory testing and eventually reduce testing errors. The value of accreditation lies in promoting the delivery of reliable results for patient management and the generation of reliable data for critical public health interventions.

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

Aim of the study

The purpose of this study is to assess the challenges of medical laboratories for ISO 15189 accreditation and identify the possible future solutions for the identified challenges. So, the information you will provide can help to find out the level of participation of staff and management in the accreditation process, challenges, and possible solutions.

Benefits for participants

The findings of this study will have many benefits to your organization and for staff working in the organization regarding identifying the challenges that hindering your organization from accreditation, commenting on the possible solution, increasing awareness of upper management, and motivating the staff for more working to achieve accreditation. But there are no financial incentives or other inducements for participants from participating in this study.

.

Risks for participant

This study will not have any known harm, social discrimination, physiological trauma, and economical loss to study participants.

Confidentiality

All the information you provide during the interview and data collection process will be kept private by using codes instead of names. Your participation in this research is fully voluntary.

Assurance of Principal Investigator

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

Abdulhak Abajebel (PI): Signature: _____ Date: _____

Note: If you have any questions about this study, feel free to ask now or anytime throughout data collection and the study period by contacting me at Mobile Number**: +25191716158** or Email: **abdulhakabajebel@gmail.com**

Annex 2: Consent Forms

I have been informed about the study which ideas for the **"Assessment of challenges of medical laboratories for ISO15189 accreditation in selected public hospitals of Jimma Zone South West, Ethiopia, 2021."** The objective and the use of the study are briefly described to me. I am also informed that all information contained within the questionnaire is to be kept confidential. Furthermore, I have been well informed of my right to refuse information, decline to cooperate, and drop out of the study if I want. It is, therefore, with a full understanding of the situation that I agreed to give the informed consent voluntarily to the researcher to give my idea/ knowledge for the mentioned study. I give my consent to giving the requested information for this stud.

Signature: _____ **Date: _____**

Annex 3: English Version Data Collection Tool

My name is Abdulhak Abajebel I am a post-graduate student at, Jimma University following a Master of Laboratory Management. I am working on a study under the title of **"Assessment of Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Public Hospitals of Jimma Zone South West, Ethiopia, 2021"** for my final thesis. I hope the outcomes of this study will have many benefits for your laboratory and other organizations. If you decide to participate in this study, please answer all questions as honestly as possible. Participation is strictly voluntary and you may refuse to participate at any time. There is no incentive for responding or any known risk. The data collected will be for research purposes only.

Thank you for your collaboration!!!

Abdulhak Abajebel

The Questionnaire has four separated parts:

Part I. Socio-demographic Information

Part II. Awareness, Participation, support by mentors, and training experience of study participants related to SLIPTA/ISO implementation.

Part III. Awareness lab proffessionals about degree of LQMS Implementation.

Part IV. Factors affect the SLIPTA/ISO implementation**.**

Part I. <u>Socio-Demographic Information</u>

Hospital code (completed by the investigator) _____

Please, kindly encircle that best describes your answer.

1. .Sex 1. Male. 2. Female.
2. Age (in years) _____
3. Educational level 1. MSc and above. 2. BSc 3. Diploma. 4. Certificate
4. How long have you worked at this hospital? specify _____
5. In which unit/department are you working?

   1. Haematology 2. Clinical chemistry 3. Microbiology 4.Serology
   5. Parasitology 6. Urinalysis. 7. Other (specify) _____
6. Which of the following describes your position in your organization?

   1. Lab Manager/head 2. Lab Quality Manager 3. Safty Officer
   4. Section Head 5. Technical staff. 6. Others/specify_____

Part II. Awareness, Participation, support by mentors, and training experience of study participants related to SLIPTA/ISO implementation.

Answer the questions below by relating to your experience, while your hospitals concerning for SLIPTA/ISO 15189 implementation of your laboratory by encircling below the appropriate item.

7. Are you aware of your organization's effort to seek ISO 15189 accreditation recognition?
   1. Yes 2. No
8. If your answer in the question number 7 is **"Yes"** have you been involved in the accreditation process? 1. Yes 2. No
9. If your answer for question number 8 is **"Yes"** how long have you been involved in the process? specify _____
10. If your answer for question 8 is **"Yes"** in which way have you been involved in the accreditation process?
    1. Decision making /Management. 2. Sensitization/Awareness.
    3. Document Preparation. 4. Auditing.
    5. Coordination. 6. Addressing non-conformities.
    7. more than one activities.
11. Have you ever taken training related to ISO15189 accreditation?
    1. Yes 2. No
12. To what extent did your organization use external mentors to assist with quality system implementation?
    1. I don't know 2. Not at all. 3. Very small extent.
    4. Moderate extent 5. Large extent. 6. Very large extent
13. If your answer for question 12 is **"Not" at all** and **very small extent**, what are the reasons?
    1. Lack of competent consultants. 2. Lack of adequate budget for external consultants.
    3. lack of management support 4. Other/specify ----------
14. If your answer for question 12 is **at large extent** and **very large extent**, have you got the expected quality assistance? 1. Yes 2. No

Part III. Awareness laboratory proffessionals about degree of LQMS Implementation.

To what degree was the following items implemented as part of your SLITA/ISO 15189 accreditation effort?							
Please, encircle in column that best defines your implementation experience with the regulation of the key below. 1= Don't Know 4= Moderate degree 2= Not at all 5= Large degree 3= Very small degree 6= Very large degree		Degree of Implementation					
S.no	Item implemented	Don't Know	Not at all	Very small degree	Moderate degree	Large degree	Very large degree
15.	Adequate awareness creation and sensitization of staff on benefits of SLIPTA/ISO accreditation conducted	1	2	3	4	5	6
16.	Commitment of top management was evident to fulfil all SLIPTA/ISO standards	1	2	3	4	5	6
17.	A Quality manual with clear Quality policy statement and objectives was developed and communicated.	1	2	3	4	5	6
18.	Laboratory logistics system is established to manage laboratory supplies to avoid over stock and under stock	1	2	3	4	5	6
19.	The laboratory is conducting internal audits at Planned intervals to check the compliance of all required standard	1	2	3	4	5	6
20.	Action plan is developed based on internal audit findings	1	2	3	4	5	6
21.	Training and continual education is implemented effectively for all managerial, technical and supporting staffs	1	2	3	4	5	6
22.	The laboratory have space allocated for the performance of its work that is designed to ensure the quality of its work	1	2	3	4	5	6
23.	The laboratory has adequate storage space for laboratory supplies which is regularly monitored including refrigerators	1	2	3	4	5	6

Continuity of Part III. Awareness about degree of LQMS Implementation							
24.	The laboratory has wash rooms and latrine for staffs	1	2	3	4	5	6
25.	The laboratory has adequate latrine for clients as per standard	1	2	3	4	5	6
26.	The laboratory has adequate sample collection space for clients	1	2	3	4	5	6
27.	The laboratory is monitoring environmental condition regularly as per the standard	1	2	3	4	5	6
28.	The laboratory has system to; selection, purchase and manage laboratory supplies and equipment per ISO standard	1	2	3	4	5	6
29.	The laboratory performs independent equipment verification practice before using for routine patient test reporting	1	2	3	4	5	6
30.	The laboratory establishes a system to inspect and verify all laboratory supplies before using for patient testing.	1	2	3	4	5	6
31.	The laboratory verifies new methods before introducing in to routine uses	1	2	3	4	5	6
32.	The laboratory performs internal quality control for all tests.	1	2	3	4	5	6
33.	Laboratory tests reviewed and released by authorized personnel	1	2	3	4	5	6
34.	The laboratory evaluates and verifies electronic LIS before using it.	1	2	3	4	5	6

Part IV. Factors Affect the SLIPTA/ISO accreditation process.

The degree to which accreditation process has been affected by the following?							
Please, indicate by encircling in the appropriate column with the guidance of the key below. 1 = Don't Know 4 = Moderate degree 2 = Not at all 5 = Large degree 3= Very small degree 6 = Very large degree		Magnitude of effect					
S. no.	Description	Don't Know	Not at all	Very small degree	Moderate degree	Large degree	Very large degree
35.	High cost in implementing LQMS,	1	2	3	4	5	6
36.	Working environment.	1	2	3	4	5	6
37.	Lack of staff participation	1	2	3	4	5	6
38.	Staff resisting change	1	2	3	4	5	6
39.	Inadequate of support from top management	1	2	3	4	5	6
40.	Inadequate training on LQMS and other pertinent trainings	1	2	3	4	5	6
41.	Inadequate understanding of the LQMS and ISO requirements by the staff	1	2	3	4	5	6
42.	Inadequate required standards and reference documents to customize polices and manuals	1	2	3	4	5	6
43.	Inadequate awareness on the benefits of LQMS and accreditation.	1	2	3	4	5	6
44.	Inadequate proper planning in the implementation of LQMS	1	2	3	4	5	6
45.	High turnover of trained staff.	1	2	3	4	5	6
46.	Organizational structure; difficulty in communication and decision making process.	1	2	3	4	5	6
47.	Complexity of the processes within the organization	1	2	3	4	5	6
48.	Inadequate no of qualified personnel to lead the accreditation process	1	2	3	4	5	6
49.	Inadequate management reviews to the accreditation process	1	2	3	4	5	6
50.	Inadequate sensitization on the accreditation process	1	2	3	4	5	6
51.	Unavailability of funds to implement the accreditation process	1	2	3	4	5	6
52.	Inadequate infrastructure; workspace, storage space etc.	1	2	3	4	5	6

Continuity of Part IV. Factors Affect SLIPTA/ISO accreditation process.							
53.	Massive documentation requirements by the standard	1	2	3	4	5	6
54.	Inadequate regular mentorship and technical assistance from upper tier levels.	1	2	3	4	5	6
55.	Inadequate equipment and supplies to provide uninterrupted lab tests	1	2	3	4	5	6
56.	High routine work load	1	2	3	4	5	6
57.	Electric power interruption	1	2	3	4	5	6

58. What additional serious challenges are for medical laboratory's accreditation?

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59. Please, state the possible solutions you are think that can be the management or other concerning body would have taken to reduce the severity of the challenges encountered during the ISO 15189 accreditation process.

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60. In your view please mention if there is any opportunity to implement LQMS and to complying all ISO standards?

Thank you for your time!!!

Interview guide for key Informants.

1. What is your position in this hospital?
2. Could you, please tell me briefly your role in the hospital.
3. When did this hospital initiate for SLMTA/SLIPTA participation or ISO 15189 accreditation processes?
4. What is the purpose of SLIPTA /ISO 15189 accreditation in your hospital?
5. Were the staffs adequately sensitized about the accreditation process?
6. What training have you and other employees received in regard to the ISO accreditation?
7. In your view, what was the reaction of the staff to the initiation of the ISO accreditation?
8. Did the staff adopt the accreditation process without difficulty?
9. What has been the extent of support by LQMS mentors?
10. Has the management been supportive to the process?
11. Have the concerned bodies been in a position to provide all the required support?
12. What is the benfit and disadvantages of SLIPTA /ISO 15189 accreditation process?
13. What other challenges has the laboratory facing in view of this process?
14. In your view, what will be the possible solutions for those challenges?
15. Do you have any other comments or suggestions?

Annex 4: Amaharic Version of Participant Information Sheet

<u>የተሳታፊ መረጃ ወረቀት</u>

የጅማ ዩኒቨርሲቲ ጤና ኢንስቲትዩት ፣የጤና ሳይንስ ፋኩልቲ ፣የህክምና ላብራቶሪ ሳይንስ ትምህርት ቤት ፣ የላብራቶሪ አስተዳደር ክፍል ጅማ ፣ ኢትዮጵያ

ስሜ አብዱልሃቅ አባጀበል እባላለሁ በጅማ ዩኒቨርስቲ የድህረ ምረቃ የላብራቶሪ ማኔጅመንት ማስተር ተማሪ ነኝ ። ለመመረቂያ ጥናቴ መነሻ በሆነው" **በደቡብ ምዕራብ ኢትዮጵያ፣ በጅማ ዞን ፣ 2021 በተመረጡ የህዝብ ሆስፒታሎች የ ISO 15189 እውቅና ለማግኘት የህክምና ላብራቶሪዎች ተግዳሮቶች ምዘና**" በሚል ርዕስ ጥናት እሰራለሁ ።

የላቦራቶሪ ዕውቅና የላብራቶሪ ጥራት፣ አፈጻጸም እና አስተማማኝነት እና ቅልጥፍና የሚገመገምበት የተለመደ ዘዴ ሲሆን ብዙ ራሱን የቻለ አካል ላብራቶሪው ልዩ ተግባራትን ማከናወን እንደሚችል በይፋ እውቅና ይሰጣል። በላብራቶሪ ምርመራ ውስጥ የተሻሻለ ጥራትን ለመደገፍ እና ተግባራዊ ለማድረግ እና በመጨረሻም የሙከራ ስህተቶችን ይቀንሳል. የእውቅና ማረጋገጫው ዋጋ ለታካሚ አስተዳደር አስተማማኝ ውጤቶችን ማድረስ እና ለወሳኝ የህዝብ ጤና ጣልቃገብነት አስተማማኝ መረጃ ማመንጨት ላይ ነው። የዚህ ጥናት መረጃ የተዋቀረ መጠይቅ እና ጥልቅ ቃለ መጠይቅ በመጠቀም ይሰበሰባል። የሶሺዮ-ስነ-ሕዝብ መረጃዎን፣ በእውቅና አሰጣጥ ሂደት ውስጥ ያሉ ተግዳሮቶች እና ለእነዚያ ተግዳሮቶች ሊሆኑ የሚችሉ መፍትሄዎች ይጠየቃሉ።

<u>የጥናቱ ዓላማ</u>

የዚህ ጥናት አላማ የህክምና ላቦራቶሪዎችን ፈተናዎች ለመገምገም ለ ISO 15189 እውቅና እና ለተለዩት ተግዳሮቶች የወደፊት መፍትሄዎችን መለየት ነው። ስለዚህ እርስዎ የሚያቀርቡት መረጃ የሰራተኞች እና የአመራር አካላት በእውቅና አሰጣጥ ሂደት ውስጥ ያላቸውን ተሳትፎ ደረጃ፣ ተግዳሮቶችን እና መፍትሄዎችን ለማወቅ ይረዳል።

<u>ለተሳታፊዎች ጥቅሞች</u>

የዚህ ጥናት ግኝቶች ለድርጅትዎ እና በድርጅቱ ውስጥ ለሚሰሩ ሰራተኞች ድርጅታችሁን ከዕውቅና የሚከለክሉትን ተግዳሮቶች በመለየት፣ የመፍትሄ ሃሳቦችን በመስጠት፣ በአመራሮች ላይ ግንዛቤን በማሳደግ እና ሰራተኞቻችን የበለጠ እንዲሰሩ በማነሳሳት ብዙ ፋይዳ ይኖረዋል። እውቅና መስጠት. ነገር ግን በዚህ ጥናት ላይ ተሳታፊዎች እንዳይሳተፉ ምንም የገንዘብ ማበረታቻዎች ወይም ሌሎች ማበረታቻዎች የሉም።

<u>ለተሳታፊ አደጋዎች</u>

ይህ ጥናት ምንም የሚታወቅ ጉዳት፣ ማህበራዊ መድልዎ፣ የፊዚዮሎጂ ጉዳት እና በጥናት ተሳታፊዎች ላይ ኢኮኖሚያዊ ኪሳራ አይኖረውም።

<u>ሚስጥራዊነት</u>

በቃለ መጠይቁ እና በመረጃ አሰባሰብ ሂደት ውስጥ የሚያቀርቧቸው ሁሉም መረጃዎች በስም ምትክ ኮድ በመጠቀም ሚስጥራዊ ይሆናሉ። በዚህ ጥናት ውስጥ ያለዎት ተሳትፎ ሙሉ በሙሉ በፈቃደኝነት ነው። የዋና መርማሪ ማረጋገጫ ለሚሰጡት መረጃ ሀላፊነቴን እንደምወስድ ለማረጋገጥ ፊርሜን ከታች አስቀምጫለሁ።

አብዱልሃቅ አባጀበል (PI)፡ ፊርማ፡ _____ ቀን፡ _____

ማሳሰቢያ፡- ስለዚህ ጥናት ማንኛውም አይነት ጥያቄ ካሎት አሁኑኑ ወይም በማንኛውም ጊዜ በመረጃ ማሰባሰብያ እና የጥናት ጊዜ

በሞባይል ቁጥር፡ **+251917161588** ወይም በኢሜል፡ **abdulhakabajebel@gmail.com** በመደወል መጠየቅ ይችላሉ።

Annex 5: **Amaharic Version of Consent Forms**

<u>የስምምነት ቅጾች</u>

በጅማ ዞን ደቡብ ምዕራብ ኢትዮጵያ በተመረጡ የህዝብ ሆስፒታሎች ለ ISO15189 ዕውቅና የ2021 የህክምና ላቦራቶሪዎች ተግዳሮቶች ግምገማ የትኛዎቹ ሀሳቦች በጥናቱ ላይ ተነግሮኛል ። የጥናቱ አላማ እና አጠቃቀሙ ባጭሩ ተገልጸልኛል። በተጨማሪም በመጠይቁ ውስጥ የተካተቱት መረጃዎች በሙሉ በሚስጥር መያዝ እንዳለባቸው አሳውቆኛል። በተጨማሪም መረጃን የመከልከል፣ የመተባበር እና ከፈለግኩ ጥናቴን የማቋረጥ መብት እንዳለኝ በደንብ ተነግሮኛል። ስለሆነም ለተጠቀሰው ጥናት ሀሳቤን/ እውቀቴን ለመስጠት ለተመራማሪው በፈቃደኝነት በመረጃ ላይ የተመሰረተ ስምምነት ለመስጠት የተስማማሁት ሁኔታውን በሚገባ በመረዳት ነው። ለዚህ ጥናት የተጠየቀውን መረጃ ለመስጠት ፈቃዴን ሰጥቻለሁ።

ፊርማ፡ _____ ቀን፡ _____

Annex 6: Amaharic Version Data Collection Tool

<u>የመረጃ መሰብሰብያ መሳሪያ</u>

ስሜ **አብዱልሃቅ አባጀበል** እባላለሁ በጅማ ዩኒቨርስቲ የድህረ ምረቃ የላብራቶሪ ማኔጅመንት ማስተር ተማሪ ነኝ ። ለመመረቂያ ጥናቴ መነሻ በሆነው" **በደቡብ ምዕራብ ኢትዮጵያ፣ በጅማ ዞን ፣ 2013 በተመረጡ የህዝብ ሆስፒታሎች የ ISO 15189 እውቅና ለማግኘት የህክምና ላብራቶሪዎች ተግዳሮቶች ምዘና**" በሚል ርዕስ ጥናት እሰራለሁ ። በዚህ ጥናት ውጤቶች ላይ ለላቦራቶሪዎ እና ለሌሎች ድርጅቶች ብዙ ጥቅም እናገኛለን ብዬ ተስፋ አደርጋለሁ ። በዚህ ጥናት ውስጥ ለመሳተፍ ከወሰኑ እባክዎ ሁሉንም ጥያቄዎች በተቻለ መጠን በቅንነት ይመልሱ። ተሳትፎ በጥብቅ በፈቃደኝነት ሲሆን በማንኛውም ጊዜ ለመሳተፍ እምቢ ማለት ይችላሉ ። ምላሽ ለመስጠት ምንም ዓይነት ማበረታቻ ወይም የታወቀ አደጋ የለም ። የተሰበሰበው መረጃ ለምርምር ብቻ ይሆናል ።

ስለ ትብብርዎ አመሰግናለሁ!!!

አብዱልሃቅ አባጀበል

<u>መጠይቁ አራት የተለያዩ ክፍሎች አሉት ።</u>

ክፍል I. ጠቅላላ ስለተሳታፍው እና ሆስፒታሉ መረጃ

ክፍል II. ከእውቅና አሰጣጥ ሂደት ጋር የተዛመዱ የጥናት ተሳታፊዎች ግንዛቤ ፣ ተሳትፎ ፣ በበለሞያ ድጋፍ ፣ እና የሥልጠና ተሞክሮ ።

ክፍል III. LQMS ን የመተግበር ደረጃ

ክፍል IV. በእውቅና አሰጣጥ ሂደት ላይ ተጽዕኖ የምያሳድሩ ምክንያቶች

የግለሰብ መልሶች በሚስጥር ይቀመጣሉ ፣ እባክዎን በዚህ መጠይቅ ውስጥ ያሉትን ሁሉንም ጥያቄዎች በእውቀትዎ መጠን በቅንነት ይመልሱ እና ማንኛውም ጥያቄ ካለዎት በሞባይል ቁጥር **0917161588** ለመደወል አበመንቱ ወይም በኢሜል ለ **abdulhakabajebel@gmail.com** ይላኩ ።

ለእርስዎ ተሳትፎ በጣም አድናቆት አለኝ።

ክፍል I. ጠቅላላ ስለተሳታፍው እና ሆስፒታሉ መረጃ የሆስፒታል ኮድ _____

<u>መልስዎን በተሻለ የሚገልፅ በቅንነት ከበቡ</u>

1. ፆታ 1. ወንድ 2. ሴት

2. ዕድሜ (በዓመት) _____

3. የትምህርት ደረጃ

1. MSc እና ከዚያ በላይ 2. BSc 3. ዲፕሎማ 4. ሰርተፊከት

4. በዚህ ሆስፒታል ምን ያህል ጊዜ ሰርተዋል? ይግለጹ _____

5. በየትኛው ክፍል / ክፍል ውስጥ ነው የሚሰሩት?

1. ሄማቶሎጂ 2. ክሊኒካል ኬሚስትሪ 3. ማይክሮባዮሎጂ 4. ሳይሮሎጂ

5. ፓራሳይቶሎጂ 6. የሽንት ምርመራ ። 7. ሌላ (ይግለጹ) _____

6. በድርጅትዎ ውስጥ ያለዎትን ሥራ የሚገልጸው የትኛው ነው?

1. ላብራቶሪ ሥራ አስኪያጅ / ኃላፊ 2. ላብራቶሪ ጥራት ሥራ አስኪያጅ 3. ክፍል ኃላፊ

4. የቴክኒክ ሠራተኞች. 5. ሌሎች / ይጥቀሱ_____

ክፍል II. ከእውቅና አሰጣጥ ሂደት ጋር የተዛመዱ የጥናት ተሳታፊዎች ግንዛቤ ፣ ተሳትፎ ፣ በበለሞያ ድጋፍ ፣ እና የሥልጠና ተሞክሮ ። ሆስፒታሎችዎ ለ SLIPTA / ISO 15189 የላብራቶሪዎን ትግበራ

<u>ከሚመለከተው በታች ቦታ ላይ በመክበብ ከዚህ በታች ያሉትን ጥያቄዎች ከልምድዎ ጋር በማዛመድ ይመልሱ ፡</u>

7. የ ISO 15189 የእውቅና ማረጋገጫ እውቅና ለማግኘት የድርጅትዎ ጥረት ያውቃሉ?

1. አዎ 2. አይደለም

8. በጥያቄ ቁጥር 7 ላይ ያለው መልስዎ “አዎ” ከሆነ በእውቅና አሰጣጥ ሂደት ውስጥ ተሳትፈዋል ወይ?

1. አዎ 2. አይደለም

9. ለጥያቄ ቁጥር 8 የሚሰጡት መልስ “አዎ” ከሆነ በሂደቱ ውስጥ ምን ያህል ተሳትፈዋል?

ይግለጹ _____

10. ለጥያቄ 8 መልስዎ “አዎ” ከሆነ በየትኛው መንገድ በእውቅና አሰጣጥ ሂደት ውስጥ ተሳትፈዋል?

1. ውሳኔ አሰጣጥ / አያያዝ 2. ማነቃቂያ / ግንዛቤ. 3. የሰነድ ዝግጅት 4. አዲት ማድረግ

5. ማስተባበር. 6. የማይጣጣሙ ነገሮችን መፍታት 7. ሌላ / ይጥቀሱ _____

11. ከ ISO15189 ዕውቅና ማረጋገጫ ጋር በተያያዘ ሥልጠና ወስደው ያውቃሉ? 1. አዎ 2. አይደለም

12. ድርጅትዎ ጥራት ላለው የስርዓት ትግበራ ለማገዝ የውጭ አማካሪዎችን እስከ ምን ድረስ ተጠቅሟል?

1.አላውቅም 2. በጭራሽ. 3. በጣም ትንሽ መጠን

4. መጠነኛ ወርድ 5. ትልቅ መጠን 6. በጣም ትልቅ መጠን

13. ለጥያቄ 12 መልስዎ በጭራሽ “አይደለም” እና “በጣም ትንሽ” ከሆነ ፣ ምክንያቶች ምንድን ናቸው?

1.ብቃት ያላቸው አማካሪዎች እጥረት 2. ለውጭ አማካሪዎች በቂ በጀት እጥረት

3.የአስተዳደር ድጋፍ ማነስ 4. ሌላ / ይግለጹ ----------

14. ለጥያቄ 12 መልስዎ “በጣም ሰፊ” እና “በጣም በጣም ሰፊ” ከሆነ የሚጠበቀውን የጥራት ድጋፍ አግኝተዋል? 1. አዎ 2. አይደለም

ክፍል III. የ LQMS አተገባበርን ደረጃ በተመለከተ ግንዛቤ

የሚከተሉት ነጥቦች የISO 15189 ዕውቅና ማረጋገጫ ጥረት አካል ሆነው በእርሶዎ ሆስፒታል በምን ደረጃ ተተግብረዋል?							
እባክዎን ከዚህ በታች ባለው ቁልፍ ደንብ የአተገባበርዎን ተሞክሮ በተሻለ በሚገልጽ አምድ ውስጥ ያስቀምጡ። 1= አያውቅም 4 = መካከለኛ ደረጃ 2= በጭራሽ አይደለም 5= ትልቅ ደረጃ 3 = በጣም ትንሽ ደረጃ 6 = በጣም ትልቅ ደረጃ		የትግበራ ደረጃ					
ተ ቁ	የትግበራ ነጥቦች	አያውቅም	በጭራሽ አይደለም	በጣም ትንሽ ደረጃ	መካከለኛ ደረጃ	ትልቅ ደረጃ	በጣም ትልቅ ደረጃ
15.	የተካሄዱ የ ISO15189 ዕውቅና አሰጣጥ ጥቅሞች ላይ በቂ ግንዛቤ መፍጠር እና የሰራተኞችን ግንዛቤ ማሳደግ	1	2	3	4	5	6
16.	ሁሉንም የ ISO ደረጃዎች ለማሟላት የከፍተኛ አመራሮች ቁርጠኝነት በግልጽ ታይቷል	1	2	3	4	5	6
17.	ጥራት ያለው ያጥራት የፖሊሲ መግለጫ እና ዓላማ ያለው የጥራት ማኑዋል ተዘጋጅቶ ተላ ይተገበራል።	1	2	3	4	5	6

18.	ከላቦራቶሪ እና ከአክሲዮን በታች ለማስቀረት የላብራቶሪ አቅርቦቶችን ለማስተዳደር የላብራቶሪ ሎጂስቲክስ ስርዓት ተቋቁሟል	1	2	3	4	5	6
19.	ሁሉንም አስፈላጊ መመዘኛዎች መሟላታቸውን ለማጣራት ላቦራቶሪው በታቀዱ ክፍተቶች ውስጥ የውስጥ ኦዲት እያደረገ ነው	1	2	3	4	5	6
20.	የድርጊት መርሃ ግብር የሚዘጋጀው በውስጣዊ የኦዲት ግኝቶች ላይ በመመርኮዝ ነው	1	2	3	4	5	6
21.	ስልጠና እና ቀጣይነት ያለው ትምህርት ለሁሉም የአስተዳደር ፣ የቴክኒክ እና ደጋፊ ሠራተኞች ውጤታማ በሆነ መንገድ ይተገበራል	1	2	3	4	5	6
22.	ላቦራቶሪው የሥራውን ጥራት ለማረጋገጥ ታስቦ ለሥራው አፈፃፀም የተመደበ ቦታ አለው	1	2	3	4	5	6
23.	ላቦራቶሪ ማቀዝቀዣዎችን ጨምሮ በየጊዜው ቁጥጥር የሚደረግበት ለላቦራቶሪ አቅርቦቶች በቂ የማከማቻ ቦታ አለው	1	2	3	4	5	6
24.	ላቦራቶሪ ለሠራተኞች ማጠቢያ ክፍሎች እና ለደንበኞች በቂ የናሙና መሰብሰቢያ ቦታ አለው	1	2	3	4	5	6
25.	ላቦራቶሪው እንደ መመዘኛው የአካባቢውን ሁኔታ በመደበኛነት እየተከታተለ ነው	1	2	3	4	5	6
26.	ላቦራቶሪ ሥርዓት አለው; የላብራቶሪ አቅርቦቶችን እና መሣሪያዎችን በ ISO መስፈርት መምረጥ ፣ መግዛት እና ማስተዳደር	1	2	3	4	5	6
27.	ላቦራቶሪው ለመደበኛ የሕመምተኛ ምርመራ ሪፖርት ከመጠቀምዎ በፊት ገለልተኛ መሣሪያዎችን የማረጋገጫ ልምድን	1	2	3	4	5	6

	ያካሂዳል						
28.	ላቦራቶሪ ለታካሚ ምርመራ ከመጠቀምዎ በፊት ሁሉንም የላብራቶሪ አቅርቦቶችን ለመመርመር እና ለማጣራት የሚያስችል ስርዓት ይዘረጋል ።	1	2	3	4	5	6
29.	ወደ መደበኛ አጠቃቀሞች ከማስተዋወቅ በፊት ላቦራቶሪ አዳዲስ ዘዴዎችን ያረጋግጣል	1	2	3	4	5	6
30.	ላቦራቶሪ ለሁሉም ምርመራዎች ውስጣዊ የጥራት ቁጥጥርን ያካሂዳል ።	1	2	3	4	5	6
31.	በተፈቀደላቸው ሠራተኞች ተገምግመው ነው የተለቀቁ የላብራቶሪ ምርመራዎች	1	2	3	4	5	6
32.	ላቦራቶሪው የኤሌክትሮኒክ LIS ን ከመጠቀምዎ በፊት ይገመግማል እንዲሁም ያረጋግጣል ።	1	2	3	4	5	6

ክፍል IV. በእውቅና አሰጣጥ ሂደት ላይ ተጽዕኖ የምያሳድሩ ምክንያቶች

የእውቅና አሰጣጥ ሂደት ላይ በሚከተሉት ነገሮች ምን ያክል ተፅህኖ እንዳሳደሩበት?							
እባክዎን ከዚህ በታች ባለው ቁልፍ ደንብ የአተገባበርዎን ተሞክሮ በተሻለ በሚገልጽ አምድ ውስጥ ያስቀምጡ። 1= አያውቅም 4= መካከለኛ ደረጃ 2= በጭራሽ አይደለም 5= ትልቅ ደረጃ 3= በጣም ትንሽ ደረጃ 6= በጣም ትልቅ ደረጃ		የተፅህኖ ደረጃ					
ተ ቁ	ዝርዝሮች	አያውቅም	በጭራሽ አይደለም	በጣም ትንሽ ደረጃ	መካከለኛ ደረጃ	ትልቅ ደረጃ	በጣም ትልቅ ደረጃ
33.	LQMS ን ለመተግበር ከፍተኛ ወጪ ስለምያስፈልግ ፣	1	2	3	4	5	6
34.	የድርጅቱ የስራ ባህል.	1	2	3	4	5	6
35.	የሰራተኞች ተሳትፎ እጥረት	1	2	3	4	5	6
36.	ለውጥን የሚቃወሙ ሠራተኞች	1	2	3	4	5	6

37.	ከከፍተኛ አመራር ድጋፍ ማጣት	1	2	3	4	5	6
38.	በ LQMS እና በሌሎች አግባብነት ያላቸው ስልጠናዎች ላይ የማያቋርጥ ሥልጠና እጥረት	1	2	3	4	5	6
39.	የ LQMS እና የ ISO መስፈርቶችን በሰራተኞቹ አለመረዳት	1	2	3	4	5	6
40.	ፖሊሲዎችን እና መመሪያዎችን ለማበጀት የሚያስፈልጉ ደረጃዎች እና የማጣቀሻ ሰነዶች እጥረት	1	2	3	4	5	6
41.	በ LQMS ጥቅሞች እና ዕውቅና መስጠት ላይ የግንዛቤ እጥረት ።	1	2	3	4	5	6
42.	በ LQMS ትግበራ ውስጥ ትክክለኛ እቅድ አለመኖር	1	2	3	4	5	6
43.	የሰለጠኑ ሰራተኞችን መለዋወጥ ።	1	2	3	4	5	6
44.	ድርጅታዊ መዋቅር; በመግባባት እና በውሳኔ አሰጣጥ ሂደት ውስጥ ችግር ፡	1	2	3	4	5	6
45.	በድርጅቱ ውስጥ የሂደቶች ውስብስብነት	1	2	3	4	5	6
46.	የእውቅና አሰጣጡን ሂደት የሚመሩ ብቃት ያላቸው ሠራተኞች እጥረት	1	2	3	4	5	6
47.	ወደ ዕውቅና አሰጣጥ ሂደት የአስተዳደር ግምገማዎች እጥረት	1	2	3	4	5	6
48.	በእውቅና አሰጣጡ ሂደት ላይ የማነቃቂያ እጥረት	1	2	3	4	5	6
49.	የዕውቅና አሰጣጡን ሂደት ለመተግበር የገንዘብ አቅርቦት አለመኖሩ	1	2	3	4	5	6
50.	በቂ የመሠረተ ልማት እጥረት; የስራ ቦታ ፣ የማከማቻ ቦታ ወዘተ	1	2	3	4	5	6
51.	በደረጃው ግዙፍ የሰነድ መስፈርቶች	1	2	3	4	5	6
52.	ከከፍተኛው የደረጃ ደረጃዎች መደበኛ የአማካሪነት እና የቴክኒክ ድጋፍ እጥረት ።	1	2	3	4	5	6
53.	በቂ የመሠረተ ልማት እጥረት; የስራ ቦታ ፣ የማከማቻ ቦታ ወዘተ	1	2	3	4	5	6
54.	የዕውቅና አሰጣጡን ሂደት ለመተግበር የገንዘብ አቅርቦት አለመኖሩ	1	2	3	4	5	6
55.	ያልተቋረጡ የላብራቶሪ ምርመራዎችን ለማቅረብ በቂ መሣሪያ እና አቅርቦቶች እጥረት	1	2	3	4	5	6
56.	መደበኛ የሥራ ጭና	1	2	3	4	5	6
57.	የኤሌክትሪክ ኃይል መቋረጥ	1	2	3	4	5	6

58. ህክምና ላቦራቶሪ ዕውቅና ለመስጠት ምን ተጨማሪ ከባድ ፈተናዎች ናቸው?

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59. እባክዎን በ ISO 15189 እውቅና አሰጣጥ ሂደት ወቅት ያጋጠሙትን ተግዳሮቶች ክብደት ለመቀነስ የወሰዱት የአስተዳደር ወይም ሌላ አካል ሊሆን ይችላል ብለው ያሰቡትን መፍትሄ ይግለጹ ።

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60. በአስተያየትዎ እባክዎን LQMS ን ለመተግበር እና ሁሉንም የ ISO መመዘኛዎችን ለመተግበር ዕድል ካለ ይጥቀሱ?-

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ለጊዜዎት በጣም አመሰግናለሁ!!!

<u>ለቁልፍ መረጃ ሰጪዎች የተዘጋጀ በጥልቀት ለምመልሱ መጠይቆች</u>

1. በዚህ ሆስፒታል ውስጥ ያለዎት የስራ ድርሻ ምንድነው?,nb
2. እባክህ በሆስፒታሉ ውስጥ ያለዎትን ሚና በአጭሩ ይዘርዝሩልኝ።
3. ይህ ሆስፒታል ለ SLMTA / SLIPTA ተሳትፎ ወይም ለ ISO 15189 ዕውቅና አሰጣጥ ሂደቶች የጀመረው መቼ ነው?
4. በሆስፒታሉ ውስጥ የ SLIPTA / ISO 15189 እውቅና ማረጋገጫ ዓላማ ምንድን ነው?
5. ሰራተኞቹ ስለ ዕውቅና አሰጣጡ ሂደት በቂ ግንዛቤ ተሰጥቷቸው ነበር?
6. እርስዎ እና ሌሎች ሰራተኞች የ ISO እውቅና አሰጣጥን በተመለከተ ምን ስልጠና አግኝተዋል?
7. በእርስዎ አመለካከት የ ISO እውቅና አሰጣጥ መጀመረው የሰራተኞቹ ምላሽ ምን ነበር?
8. ሰራተኞቹ የእውቅና አሰጣጡን ሂደት ያለምንም ችግር ተቀበሉ?
9. በ LQMS አማካሪዎችና አጋሮች የሚሰጠው ድጋፍ ምን ያህል ነበር?
10. አመራሩ ለሂደቱ የምያደርገዉ ድጋፍ ምን ይመስላል/ እንደት ነበር?
11. የሚመለከታቸው አካላት የሚፈለገውን ድጋፍ ሁሉ ለማድረግ በሚያስችል ሁኔታ ላይ ነበሩ?
12. የ SLIPTA / ISO 15189 ዕውቅና አሰጣጥ ሂደት ጥቅሞች እና ጉዳቶች ምንድናቸው?
13. ከዚህ ሂደት አንፃር ላቦራቶሪው ምን ሌሎች ተግዳሮቶች አጋጥመውታል?
14. በእርስዎ አመለካከት ለእነዚያ ተግዳሮቶች ምን ዓይነት መፍትሔዎች ይሆናሉ?
15. ሌላ ማንኛውም አስተያየት ወይም አሰብ አለዎት?

Annex 7: Afaan Oromo Version of Participant Information Sheet

Formii hubbanno hirmatootaf kennamu

Jimma University Institute of Health, Faculty of Health Sciences, School of Medical Laboratory Science, Department of Laboratory Management Jimma, Ethiopia.

Maqaan koo **Abdulhaq A/Jabaal** jedhama. Yeroo amma baraata digirii lamaafa Laaboratoorii Maanajiimeenti yammun ta'u. Waraqaa qorannaa dhumaa eebbaaf ta'u mata dure, **"Assessment of Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Public Hospitals of Jimma Zone South West, Ethiopia, 2021"** jedhamu irraati waanan hojjechaa jira.

Akkuma beekamu laboratooriin qulqullina fi sii'a'inan hojjatuf beekamittin adda ta'e dhabbata of danda'a ta'een beekamtiin labooratorii kan keennamuf ta'a. Fayyidan isaas bu'aan qorranno laboratorii akka qulqullinana bahuu, rakkon qorranno laboratorrii ilaalchise jiru akka addan bassufi furmata kennu dha. Qorrannon kan inni qopha'e gaafii afaanii gabaaba fi gaafii filanno sirrnawa ta'en kan funnanamu dha. Qabiyyeen gaafiiwanis wa'e informashiini hirmatoota, rakkoo hoojjiimata beekamtiin wal qabate fi rakkoo kanaaf furmata ta'u kan danda'u ni gaafatamu.

Kayyo Qorrannicha

Kayyoon qorranno kana rakkoowaan laboratoorii qunnama ture yero beekamti ISO 15189 dalaagan keessati sakata'u fi furmata barbachisa ta,e heruuf gargaara.

Fayyidaa hirmatootaf

Hubbanno rakkowaan yeroo beekamti laboratoorii qunnaman hojjattota fi hoggansaaf heeru fi yaada furmata kennu ta'a. Hirmatootaf garuu fayyidan dhunfaan waanti kennamu hin jiru

Rakkowaan muddatan

Rakkowaan qorranno kanan hirmatoota irraa gahu tokko iyyu akka hin jire mirkana'eera.

Icciitti: Yaadni isiin keenitan maqaa keessanin oso hin ta'iin koodi bakka waan bu'uf icciittiin qorranno kana kan eegamu ta'u isaa maqaa kootif mallato kootiin nan mirkaneessa.

Maqaa Abdulhak Abajebel Mallato_____ Guyyaa_____

Lakk. Bilbila **+251917161588** Email: **abdulhakabajebel@gmail.com**

Annex 8: Afan Oromo Version of Consent Forms

Formii waligaltee

Kaayyoo fi faayidaan qorrannoo "**Assessment of challenges of medical laboratories for ISO15189 accreditation in selected public hospitals of Jimma Zone South West, Ethiopia, 2022"** , jeedhu haala gahaan naf ibsaame jiraa. Ragaan anni kennu iccittiin isaa akka eegamuus naf ibsaameera. Akkasumas miirgii hirmaachuu dhiisuu fi yeroon barbaaddetti addaan kuuttu akkan dandaa'u nati himaameeraa. Kanaafuu waannan guutumaan guututti yaada qorrannoo kana huubadheef yaada fi beekumsaan qabu feedhii kootiin keennuf mallatoo kootiin nan mirkaaneessa.

Mallatoo_____ Guyyaa_____

Annex 9: Afan Oromo Version Data Collection Tool

Foormii dataan ittin funnanamu.

Maqaan koo **Abdulhaq A/Jabaal** jedhama. Yeroo amma baraata digirii lamaafa Laaboratoorii Maanajiimeenti yammun ta'u. Waraqaa qorannaa dhumaa eebbaaf ta'u mata dure, **"Assessment of Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Public Hospitals of Jimma Zone South West, Ethiopia, 2021"** jedhamu irraati waanan hojjechaa jiruuf bu'an qoranna kana fayidaa gudda dhaabbata keessaanifis ta'e kan biraatif waan qabuuf feedhii keessan yoo ta'e dhibba tokkoo malee yoo hirmaachuuf murteesitan kabajaa waliin hanga danda'ameen gaffiiwwan dhihatanif ammantuman akka deebiftanu isiin gafaadha. Hirmachisumman qoranna kana fedhiin keessaan qofa waan ta'eef yeroo addan kuutuf barbaadan hundaatti addan kutu ni dandeessu. Akkasumas yaadini isin kennitan kun sabaaba qorannaf qofa kan oluudha. Hirmatootaf fayidaan adda ta'e waanti kennamuf hin jiru akkasumas sabaaba hirmaanaa keessani dhiibaanis ta'e rakkoon adda isaanirraa gahu tokko hin jiru.

Hirmaanaa keessaanif galatoomaa!!!

Abdulhaaq A/Jabaal.

Hirmatootaf akka mija'uutti gaffiiwwan jiraanu kutaalee Afurit addan qoodamani jiru.

- **Kutaa 1ffaa:** Seena hirmata fi hospitaalichaa.
- **Kutaa 2ffaa:** Hubbanno, Hirmmana, gargarsaa ogessa fi Leenjii fi muxxanno hirmatoota yero dalaaga beekamti laboratoriif dalaagaan keessatti kan wal qabate.
- **Kutaa 3ffaa:** Hangaa Raawii kan LQMS ilaalchise.
- **Kutaa 4ffaa:** Tattewaan yero dalaaga beekamti laboratoriif dalaagamu hubban/miidhan.

Iccittiin deebii keessani waan eegamuf, dhifama wajjiin hangaa dana'amen beekumsa keessan irratti hunda'un guutuma gaffiicha akka deebiftan kabajaan isiin gaafadha. Yoo gaaffii qabatan yeroo barbaadanitti bibila: **0917161588** kana irratti bilbilu ni dandessu akkasumas gaffii qabdan karaa "email" **abdulhakabajebel@gmail.com**. kana irratti ergu dandeessu. Hirmaanaan keessan baayyee kan jajjabeefamudha.

Galatooma!!!

Kutaa 1ffaa: Seena hirmaataa fi hoospitaalicha**.** **Koodii hospitaala** _____

Dhifama wajjiin deebii koo naf ibsaa kan jettanu irratti marra.

1. S aala 1. Dhiira. 2. Dhalaa.
2. Ummurii (waggaan) _____
3. Sadarka barumsa 1. MSc fi isa ol. 2. BSc 3. Dipilooma. 4. Sartafiketii.
4. Hospitaala kana keessa erga dalaagu jalqabde hagaamii? Ibsii _____
5. Garee kam keessati dalaagda?
   1. Hemaatolojii 2. Kilinikal kemistrii 3. Mayikro bayilojii 4.Seeroolojii
   5. Paarasayitoolojii 6. Yuriinanalayisis. 7. kan bira/ibsii _____
6. Dhabbata kana keessati kan arman gadi keessa kaamtu saadarka hojjii keeti ibsa?
   1. Dura bu'a laboratorii 2. Qondaala qulqullina laboratoorii 3. Dura bu'a garee
   4. Takniishala laboratoorii. 5. Kan biraa/ibsii_____

Kutaa 2ffaa: Hubbanno, Hirmmana, garggarsaa ogessa, leenjii fi muxxanno hirmatoota yero dalaaga beekamti laboratoriif dalaagaanin kan wal qabate.

Gaffii arman gaddiitiff muxxanno yero dalagaa beekamti "SLIPTA/ISO 15189" irratti hunda'un deebii sirriidha jettanu irraatti marra.

7. Caaraqiin dhabbatni kee godhu beekamtti "ISO 15189" argaachuuf barbacha akka ta'e ni beekta? 1. Eeyyen 2. Hin beeku
8. Deebiin kee gaaffii 7 Eeyyen yoo ta'e caaraqiin inni beekamti barbachaaf godhu keessatti hirmata turte? 1. Eeyyen 2. Hin ture.
9. Deebiin kee gaaffii 8 eeyyen yoo ta'e yero hagaami erga itti hirmate? Ibsii _____
10. Deebiin kee gaaffii 8 eeyyen yoo ta'e haala kammiin itti hirmata turte?
    1. Murtee kennun /Manajiimanti. 2. Sochii/Hubbanno ummu. 3. Dokuumaantii qopheessun.
    4. Gamagama hojjii (Auditing) 5. Qindessuma. 6. Rakko muddate furu irratti.
    7. Kan bira /ibsaa _____
11. Leenjii beekamti "ISO15189" wal qabate fudhate beekta ? 1. Eeyyen 2. Hin beeku
12. Hangaam takka dhabbatni keessan garsaa ogessa dhabbatan alaati faayadame dalaaga qulqullina qabu rawaachu keessatti ?
    1. Hin beeku. 2. Waama iyyuu. 3. Hangaa baaye xiqqoo.
    4. Hangaa giddu galeessa. 5. Hangaa gudda. 6. Hangaa baaye gudda

13. Yoo deebiin kee gaaffii 12 Waama iyyuu fi Hangaa baaye xiqqoo ta'e, sabaabni isaa maali
    1. Ogeessa ga'umssa qabu kan goorsa kennu dhabu. 2. Bajjata gaha ta'e goorsa alatiif dhabu.
    3. Gargarssa manajiimanti dhabu. 4. Kan bira/ibsaa_____
14. Yoo deebiin kee gaffii 12 Hangaa gudda fi Hangaa baaye gudda yoo ta,e, gargarsa qulqullina qabu hangaa tilmamamte argateeta? 1. Eeyyeen 2. Miiti.

<u>Kutaa 3ffaa:</u> Hubbano hangaa raawii LQMS ilaalchise.

Dalaaga beekamti "ISO 15189" dalaagamu keessatti rawiin waantota arman gadii hanga kammii?							
Furtuu arman gaddi siif kenname irraatti hunda'un muxxaanno raawii keetii isaa baaye walsimutti marrii. 1 = Hin beeku. 4= Hangaa giddu gallessa. 2 = Waama iyyuu. 5= Hangaa gudda. 3= Hangaa baaye xiqqo. 6 = Hangaa baayee gudda.		Hangaa Raawii					
		Hin beeku	Waama iyyuu	Hangaa baaye xiqqo	Hangaa giddu gallessa	Hangaa gudda	Hangaa baayee gudda
Lakk	Waantoota rawaataman						
15.	Fayyidaa beekamti "ISO15189" irratti hubbano ummu fi sochiin gahaan hojjatootaaf godhameera.	1	2	3	4	5	6
16.	Gutuman guututi istandardiin "ISO" dalaagamu isaatif kakka'umsi manajimentii guba wabii dha.	1	2	3	4	5	6
17.	Manuwaliin "Quality" keyyata poolisii iffaa ta'ee fi kayyo of keessa qabu qopha'ee ittin dalaagama jira.	1	2	3	4	5	6
18.	Laboratoriin seera dhihessii laboratorii ittiin to'atamu akka dhiheesiin hanga barbadamu irraa hin baayane fi hin hir'ane gargaru qophessera.	1	2	3	4	5	6
19.	Laboratorii gamagama keesso haala karoora ka'amen ni rawaata akkasuma hir'inni jiru hundii haala istandardiin gafaatun ni sakata'ama.	1	2	3	4	5	6
20.	Bu'a gamagama keessoo irratti hunda'un karoorii gocha qopha'adha.	1	2	3	4	5	6

21.	Manajeraaf, Hojjatota tekniika fi gargaraa hundaf leenjii fi barumsii itti fuufinsan haala gariin ni gageefama.	1	2	3	4	5	6
22.	Laboratoorii iddo gaha ta'e qopha'eef kan hojjiin qulqullina qabu dalagaamuuf wabii ta'e qaba.	1	2	3	4	5	6
23.	Laboratooriin iddo gaaha ta'ee dhihesiin laboratorii kufamu firiijii dabalate akkasumas to'annan yero yeroon godhamuf qaba.	1	2	3	4	5	6
24.	Laboratoriin iddo dhiiqanna hojjatota fi iddon gaha ta'e kan samuudni dhukkubsataaf fudhamu qaba.	1	2	3	4	5	6
25.	Laboratorii akka istandardittin yero yeroon to'ana haala nanno ni godha.	1	2	3	4	5	6
26.	Laboratooriin seera istaandardoota "ISO" irratti hunda'ee dhihessi fi meeshale laboratorii ittin filatuu,bittu fi to'aatuu q	1	2	3	4	5	6
27.	Laboratoriin meeshale oso hojjii idile bu'a qorranno dhukkubsataf hin fayyadamin dura mirkanessa of danda'a ta'e irratti ni dalaaga.	1	2	3	4	5	6
28.	Tarsimo Sakata'insa fi mirkannesi gaahan godhamu dhihessi hundaf oso qorrano dhukkubsatootaaf hojjii irraa hin oliin dura qopheesseraa.	1	2	3	4	5	6
29.	Haali qorrannon har'an oso laboratorii keessatti hojjii idilee irraa hin oliin ni mirkennefamu.	1	2	3	4	5	6
30.	Qorrano laboratorii keessatti dalaagamu hundaf sakata'insii qulqullina keesso ni dalaagama.	1	2	3	4	5	6
31.	Bu'aan qorrano laboratoorii oso hin kennamin nama atoomamen ni mirkanefama.	1	2	3	4	5	6
32.	Laboratoriin oso elektronik "LIS" hin fayyaadamin dura gamagaama fi mirkanessi ni godhamafi.	1	2	3	4	5	6

<u>Kutaa 4ffaa:</u> Tattewaan yero dalaaga beekamti laboratoriif dalaagamu hubban/miidhan.

Waantootni arman gaddii hangaam takkan dalaaga beekamti laboratorii "ISO" hubban?							
Qajeelfaama armaan gaddi siif kenname irratti hunda'un deebii sirriidha jettu irratti marrii. 1 = Hin beeku. 4 = Hangaa giddu gallessa. 2= Waama iyyuu. 5= Hangaa gudda. 3= Hangaa baaye xiqqo. 6= Hangaa baayee gudda.		Hangaam akka hubban.					
Lakka	Ibsaa	Hin beeku	Waama iyyuu	Hangaa baaye xiqqo	Hangaa giddu gallessa	Hangaa gudda	Hangaa baayee gudda
33.	Qarshii gudda raawiii LQMS waan barbaaduf.	1	2	3	4	5	6
34.	Aadda dhabbaticha.	1	2	3	4	5	6
35.	Hirmmanan hojjatoota waan hin jireef.	1	2	3	4	5	6
36.	Hojjatoni jijjiramaf qophii ta'u dhabu.	1	2	3	4	5	6
37.	Gargarsa manajiimantii guba irraa dhabu.	1	2	3	4	5	6
38.	Leenjiin itti fufa ta'e "LQMS" fi kan bira irraatti dhabbamu.	1	2	3	4	5	6
39.	Hojjatoni hubbano fi barbachisuma "LQMS and ISO" dhabu.	1	2	3	4	5	6
40.	Polisii fi manuwaali qopheessuf estandardota fi dokumentii akkekka dhabu.	1	2	3	4	5	6
41.	Hubbano wa'e fayyidaa "LQMS" fi beekamti "ISO" dhabu.	1	2	3	4	5	6
42.	Karoora sirrii ta'ee rawii "LQMS" dhabu.	1	2	3	4	5	6
43.	Hojjatan leenjii qabu hojjii lakkisu.	1	2	3	4	5	6
44.	Haali qindomina dhabbaticha; marii fi murtee keenuf kan hin mijjofne ta'u.	1	2	3	4	5	6
45.	Haali dalaagaa dhabbaticha walxaxxaa ta'u.	1	2	3	4	5	6
46.	Ogessa ga'umsa qabun dalaagan beekamti "ISO" dursamu dhabu.	1	2	3	4	5	6
47.	Dalaagan beekamti "ISO" manajiimentiin gamagamu dhabu.	1	2	3	4	5	6
48.	Dalaaga beekamti "ISO" irratti kakka'umsi godhamu dhabu.	1	2	3	4	5	6
49.	Dalaaga beekamti "ISO" fandiin ykn arjoomiin jirachu dhabu.	1	2	3	4	5	6
50.	Waantootni hojjii kanaaf barbachiso ta'an gahaan dhabamu.	1	2	3	4	5	6
51.	Waan dokumeentoni heddun akka standardiiti barbachisuuf.	1	2	3	4	5	6

52.	Waan gargarsii ogessa fi manajimenti guba hojjii tekinikaaf hin goneef.	1	2	3	4	5	6
53.	Waantootni hojjii kanaaf barbachiso ta'an gahaan dhabamu.	1	2	3	4	5	6
54.	Dalaaga beekamti "ISO" fandiin ykn arjoomiin jirachu dhabu.	1	2	3	4	5	6
55.	Meeshaalee gahaani fi dhihesiin qorranaf barbachisu kan addan hin cinne waan hin jireef.	1	2	3	4	5	6
56.	Heddumina hojjii yero idilee hojjii.	1	2	3	4	5	6
57.	Addan cicciitu humana elektrikii.	1	2	3	4	5	6

58. Rakkon baaye rakkisa ta'e beekamti laboratorii "ISO" tif jettu maali?

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59. Rakko kanaaf furmata ni ta'a oso manajiimanti gubba fi namootni dhimmi kun ilaalatu dhagahani fudhatani rakkina beekamti "ISO 15189" jiru kana ni hir'isu ykn ni hikkuu waan jette yaduu ibsii?

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60. Akka yaada keettit carraan biraa ati dalaaga "LQMS" fi istaandardoota "ISO" guutumatii rawwachuf ni gargaraa kan jettu yoo jirate barreessi?

Galatoomaa!!!

Gaaffii marii gadii fagenyaan namoota xiyyefatamani wajjiin godhamu.

1. Sadarkaan hojii keessani hospitaala kanaa keessatti maal fakkataa?
2. Dhifaama waliin, gaheen hojii keessani hospitaala kana keessatti maal akka ta'e gabaabinaan naf ibsuu dandeessuu?
3. Hospitaali kun yoom hirmaanaa "SLMTA/SLIPTA" ykn beekamti "ISO 15189" jalqaabe?
4. Kaayoon beekamti "SLIPTA /ISO 15189" hospitaala keessan keessatti maal fakkataa?
5. Wa'ee beekamti "ISO 15189" irratti hojjatooni hubannon gaha ta'e argaatani jiruu?
6. Isini fi hojjetooni hospitaala keessani wa'ee ISO ilaalchise leenjii akkami fudhaatani jirtuu?
7. Jalqaabi beekamti "ISO" ilaalchise akka yaada keetitti dub-deebiin hojjatoota maal ture?
8. Dadhabbi male haala salphaan hojjattoni beekamti "ISO" fudhatani/eegalani?
9. Deeggarsii ogessa fi gargarsii "LQMS" irratti isiif godhamee hangaami?
10. Manajiimentiin dalaaga kanaaf gargasrii inni godhu maal fakkaata turee?
11. Gargarsaa barbaachisu hunda kennu kan dandaa'u nama dhimmi kun ilaalatutti iddo isa irra jiraa turee?
12. Faayidaa fi midhaan dalaagan beekamti "SLIPTA /ISO 15189" qabu maali?
13. Akka yaada keetitti rakkoon biroon dalaaga kanaf laaboraatoorii mudaate maali jetaa?
14. Akka yaada keetitti rakkoo kanaaf furmaata ni ta'a kan ati jettu maalidha?
15. Yaada ykn ibsii ati kennu barbaadu jira?

Approval Sheet

School of Graduate Studies, Faculty of Health Science

Institute of Health, Jimma University

MSc Thesis Submission form

Name of Student: Abdulhak Abajebel

Program of Study: Laboratory Management

Title:"**Challenges of Medical Laboratories for ISO 15189 Accreditation in Selected Public Hospitals of Jimma Zone, South West Ethiopia"**

I have completed my thesis paper and it has been evaluated and accepted by my advisors. Hence, I hereby kindly request the Laboratory School to allow me to present my thesis paper.

Name of student: Abdulhak Abajebel Signature _____Date_____

We have agreed to supervise the study of research work; we have evaluated the content of the research, found to be satisfactory, complete and according to the standards and formats of the university; we have also verified that the work has not been done anywhere else before.

Advisors: Professor Gemeda Abebe (PhD) Signature _____Date_____

Mr. Mekidim Mokennen (MSc) Signature _____Date_____

Mr. Abebaw Tiruneh (MSc) Signature _____Date_____

Examiner(External): Dr. Abay Sisay (PhD) Signature_____Date_____

Examiner(Internal): Mr. Sintayehu Asaye (MSc.) Signature_____Date_____

Department Head: Dr. Teshome Degefa (PhD) Signature_____Date_____