

**IMPLEMENTATION OF LABORATORY QUALITY MANAGEMENT
SYSTEM AND ITS CHALLENGES IN PUBLIC HOSPITALS IN JIMMA
ZONE, SOUTHWEST ETHIOPIA**

BY: ZELALEM TESFAYE (BSc, MSc CANDIDATE)

**A THESIS SUBMITTED TO THE SCHOOL OF MEDICAL LABORATORY
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**JIMMA UNIVERSITY
INSTITUTE OF HEALTH
FACULTY OF HEALTH SCIENCES
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BY: ZELALEM TEFAYE (BSc, MSc CANDIDATE)

ADVISORS: Dr. TEFAYE KASSA (PhD, Associated professor)

Mr. MITIKU BAJIRO (MSc, Assistance professor)

Mr. DANIEL EMANA (MSc, Assistance Professor)

**JUNE, 2022
JIMMA, ETHIOPIA**

ABSTRACT

Back ground: Quality management system is continuously analyzing, improving, and re-examining of resources, processes and services within a healthcare and its serve to document processes and procedures that allow a laboratory to the benchmark and measure the level of quality which indicates service that meets too the standards.

Objective: To assess the implementation of laboratory quality management system and its challenges in public hospitals in Jimma Zone, Southwest Ethiopia, 2022.

Methods: Public health facility based cross sectional descriptive study was implemented from November 2021 to January 2022, by using quantitative and qualitative study design to assess laboratory QMS implementation and its challenges in public hospitals in Jimma Zone. The quantitative data were collected by WHO-AFRO SLIPTA checklist auditing laboratories and laboratory professionals working in that hospital's by using self-administered questionnaire. The qualitative data were collected by using key informant interview from purposely selected key informants of the five hospitals in Jimma zone.

Result: In this study, 99% questionnaires were responded by laboratory staff and 91.4% key informants from five hospitals were included. The current laboratory QMS implementation status in public hospitals was averagely 76.6%. From those hospitals only Jimma university medical center laboratory was scored 87%, that rating to 4-stars and accredited against EAS that certified in single GeneXpert test since 2019. In this study routine workload, poor equipment quality management, shortage of laboratory supplies, inconsistent mentorship and training, and low attention to quality among the challenges were identified in study area.

Conclusion and recommendation: The study finding showed that the laboratory personnel had information and participation in implementing of laboratory QMS. The overall findings illustrated that there is a need for health facilities resource management and should set a specified budget for laboratory QMS in the hospitals. The hospitals management bodies are better position to understand the importance of laboratory QMS in their hospital and support it for better laboratory auditing outcome for improved health care delivery.

Key words: Quality Management System, Implementation, Public Hospital laboratories, Healthcare workers, Jimma Zone.

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ABBREVIATIONS

AGH	Agaro General Hospital
ASLM	African society for laboratory medicine
CDC	Centers for disease control and prevention
CLSI	Clinical and Laboratory Standards Institute
EAS	Ethiopian accreditation service
EPHI	Ethiopian Public Health Institute
FDA	Us Food and Drug administration
FMOH	Federal Ministry of Health
GLP	Good Laboratory Practice
ICT	Information and communications technology
IQMS	Implementation of quality management system
IRB	Institutional Review Board
ISO	International organization for standardization
JUMC	Jimma university medical center
LGGH	Limmu Genet General Hospital
LQMS	Laboratory quality management system
NCCLS	National Committee for Clinical Laboratory Standards
NLAC	National laboratory accreditation committee
NTRLA	National Tuberculosis Reference Laboratories in Africa
PT	Proficiency testing
QMS	Quality management system
QSE	Quality system essential
SGGH	Shenen Gibe General Hospital
SLIPTA	Stepwise laboratory improvement process towards accreditation
SLMTA	Strengthening laboratory management towards Accreditation
SPH	Seka Primary Hospital
SSOP	System Standard Operating Procedure
TAT	Turnaround time
WHO-AFRO	World health organization-African Regional Office
WHO	World Health Organization

CHAPTER ONE

INTRODUCTION

1.1. Background

Quality is which indicates that a service that meets the standards of the laboratory should meet the needs of patients, and the more acceptable, that a patient who decide when the result meets their expectations. Quality management is concerned with all the activities required to ensure that results and services conform to the standards set by the laboratory that meet expectations of patients/clients. These activities include the steps taken to ensure that high quality is achieved and the actions taken to check that defined quality standards are being achieved and maintained in the laboratory (1).

Laboratory quality can be serving as accuracy, reliability and timeliness of reported test results. The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting; therefore, all of the laboratory procedures and processes are organized into 12 quality system essentials (QSEs). That are a set of coordinated activities to serve as building blocks in quality management and represent the necessary infrastructure in healthcare organizations that to provide care, treatment, and services to patients/clients (2).

Quality management is a system for continuously analyzing, improving, and re-examining of resources, processes, and services within an organization that provides information on which to base strategies for improvement, and quality is achieved by reducing variability by standardizing these processes across the organization (3). It's has been approximately applied for more than 80 years and the quality management system model has been customized to the medical laboratory setting leading. The laboratory leadership was responsible to establish and develop effective policies and procedures in technical and managerial activities (4).

The quality management system serves to formally document processes and procedures that allows a laboratory to benchmark and measure the level of quality; to improve quality within their health care processes, by reduce waste, improve efficiency through continuous training and ensure the patient/s healthcare requirements and it's continually improving the effectiveness following

the requirements to good professional practice, quality examinations, resource management, safety management systems, and continual improvement of the QMS(5). The quality of laboratory is always maintained when quality systems are established and followed by the laboratory personnel that who in turn lead to patient service and confidence leading to increase in performance and results of laboratory (6).

Quality management requirements demand regular management reviews and internal audits to assure that the laboratory's activities adhere to the QMS, and continually meet patients/clients' needs, to identify the opportunities for improvement before issues arise; this prevents personal preferences or management style from inhibiting process and quality improvement(7). Quality management is involved in implementing of QMS; that includes management and technical requirements to ensuring quality test results for their patients/clients in the process of good laboratory practice (8).

The quality improvements process assessment should be reported to provide the improvements that based on assessment findings. Continuous improvement dictates continuous reporting and it shows a dynamic program constantly evolving with the end goal of improving healthcare involvement and community awareness on quality services (9). The process by which an independent and authorized organization accredits the quality system and competence of a laboratory based on certain pre-defined standards, the organizational structure, and resources needed to implement quality requirements(10).

The quality management of clinical laboratories require attention at the local level, which is a role model to use laboratories in developed countries like Ethiopia; insufficient coordination, follow-up system towards accreditation, inadequate resource optimization, and insufficient stakeholders' communication contributed to low-quality performance in health care service(11).

In Ethiopia the adopting of strengthening laboratory management toward accreditation (SLMTA) programme since 2009 to accelerate LQMS and prepare laboratories for accreditation, the SLMTA programme achieved marked progress in the laboratory supply chain, sample referral, instrument maintenance, and data management systems were outweighed by the level of human resources and time commitment required for exit audit and the implementation of LQMS in all tiers of laboratories particularly in the public health facilities that had weak result in poor quality

laboratory services (12). Nowadays SLIPTA programme is available at all hospitals in Ethiopia, so in this study WHO-AFRO SLIPTA check list used for the assessment of implementation of LQMS and its challenges in public hospitals laboratories in Jimma Zone.

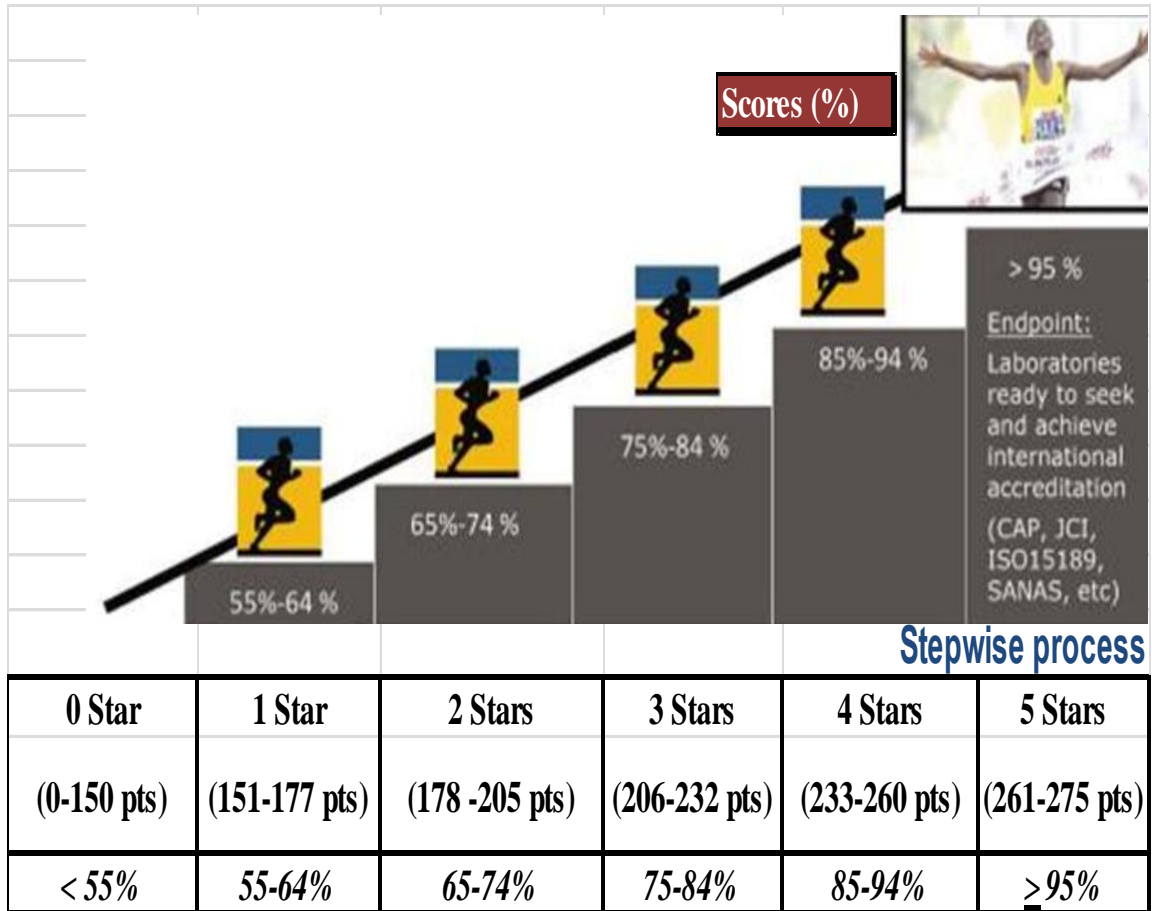


Figure 1: WHO-AFRO, SLIPTA recognition of improvement of the LQMS (5).

1.2. Statement of the problem

Quality in healthcare is a production of cooperation between the patient and the healthcare provider in a supportive environment. Healthcare service quality depends on personal factors of the healthcare service provider and differences in internal and external factors such as availability of resources, collaboration and cooperation among providers affect the quality of care (13).

In world almost all hospitals are not establishing QMS according to expectation WHO standards. That is a challenge on the evaluation laboratory performance at all public hospital laboratories as measured by the SLIPTA scores for implies the LQMS that focus on the strengthening of hospitals laboratories for giving quality healthcare service (14).

In Sub-Saharan Africa the majority of population trusts on government services for health care, public health systems have long remained delicate due to fundamental limitations and lack of prioritization of human, financial and training resources, laboratory infrastructure, resource and management capacity to solve encountered challenges linked to the lack of reliable laboratory support, disease diagnosis, and management of patient care in the facility(15).

The expansion of laboratory diagnostic infrastructure has increased to the extent of meeting the needs of evidence based treatment. Laboratory service in resource limited settings is very weak and quality assurance system practices are either very weak or do not exist at all and Laboratory testing errors can mislead clinicians and cause serious harm to patients, but the errors can be reduced by establishing a comprehensive laboratory QMS(16).

The implementation of a QMS enables the healthcare system to provide reliable services and strengthens for the overall quality of patient care (17). The QMS is one of the most important initiatives changes taken place in the field of the medical laboratory as a comprehensive and transformational strategy to improve the quality of service to respond to the needs and expectations of the society in Ethiopia(18).

The laboratory finding illustrate the need of facility management should set a specified budget for laboratory quality management implementation and consideration on the factors laboratory QMS implementation for the provision of accurate, reliable, and timely results for the method of validation and verification, to root cause analysis, Equipment maintenance related issues, measurement uncertainty analysis and evaluation. The stepwise approach is given for laboratory

grading from No-stars to 5-stars scale in the recognition of evolving fulfillment of the ISO 15189 standard rather than pass-fail grading. Laboratories that fail to achieve an assessment score of at least 55% will not be awarded a star ranking and the laboratories that achieve 95% or more will receive a 5-stars rating (19).

In Ethiopia health facility proficiency testing (PT) is a tool to measure laboratory performance. Participating in PT is crucial for clinical laboratories that will help the participating laboratory to reduce errors, produce accurate patient test results and most importantly improve patient care by taking corrective action accordingly. The Staff resistance for participating on PT is the main challenge to develop an improvement plan based on the feedback of quality service(20). It's an integrated set of activities to establish and control the work processes from pre-analytical through post-analytical processes, manage resources, conduct evaluations, and make continual improvements to ensure consistent quality results in healthcare system(21).

Quality laboratory service is an essential component of the healthcare system but in Sub-Saharan Africa such as Ethiopia, laboratory quality system remains weak due to several factors and it needs more attention to strengthen its capacity and quality system(22). Each system is critical control points have may affect the safety and quality of the outcome; in critical control points for laboratory, operations are being identified from clinical laboratory improvement amendment (CLIA) regulations, accreditation standards, and common laboratory practice (23).

Quality management status should be monitored regularly to identify weaknesses and to plan improvements. Hospital QMS maturity can be measured using several indices, but QMS assessments, using valid and reliable tools, alerts managers to QMS deficiencies and shows hospital managers' efforts to improve service quality and patient safety(24).

The laboratory organizational structure was set primarily to create lines of authority, reporting, and communication, to avoid overlapping of tasks during the implementation process of QMS and samples rejected and TAT was implementation to reach the defined targets. Hospital management became supportive after gaining a clear understanding of the advantages that a proper and functional QMS offers to both patients and the hospital itself (25).

Quality management system (QMS) shall provide for the integration of all processes required to fulfill its quality policy and objectives to meet the needs, requirements to ensure the operation and

control of QMS processes are effective; ensure the availability of resources and information necessary to support the operation and monitoring of QMS processes; monitor, evaluate and implement actions are necessary to achieve planned results and continual improvement of QMS processes (26).

The majority of Ethiopian public health laboratories delivered suboptimal service, and creating a strong commitment to ensure ownership and accountability of the program, team spirit among lab staff and willingness to build a culture focused on quality and problem solving. The challenge which narrated to high turnover of laboratory staff, especially among staff trained in quality-management and SLMTA procedures, and in biosafety, often caused inconsistency in the quality of mentorship and delays in the SLMTA process. Many of them performed poorly, hindered by dilapidated infrastructure, and poor development and implementation of LQMS(27).

1.3. Significance of the study

Public health care providers were trusted by giving the service that has delivered to patients/clients. This study was used to assess the LQMS in public hospitals introducing the program in Jimma Zone that was attempting to reduce the patient defaulting; that may be attributed to a poor-quality service and to assess the level of implementation, gaps and challenges in the laboratories and to give a useful recommendation to the hospital's laboratories to solve the problems and improve a QMS implementation. It also helps the hospital's management bodies to solve challenges at the spot where necessary investments were made in a QMS.

This study will pave the way for the public health facilities to strengthen LQMS successfully and extend further to other public health settings in the Jimma Zone healthcare system. It will also be used as a baseline data for others researchers for further investigations.

CHAPTER TWO

LITERATURE REVIEW

Clinical Laboratory is one of department that needs executive management to actively support the establishment and maintenance of (QMS). The visible participation of the laboratory's management in setting is quality policy, planning for quality, improving patients feedback and acting on the information deriving from quality status reports that essential to the successful implementation of the QMS (28).

Laboratory services provide vital support for disease prevention, diagnosis, treatment management, screening and surveillance. It is therefore an imperative that laboratory operations adhere to best practices and quality standards to ensure generation of accurate, reliable and timely results. ISO 15189:2012 medical laboratories requirements for quality and competence was developed by the international organization for standardization to assist health laboratories in developing their QMSs and assessing their competence (29).

The laboratory has chosen to adopt an integrated approach to quality management that includes aspects linked to prevention and sustainable development (30)., and it has been developed as part of a significant and wide-ranging technology transfer in the area of pre-clinical product development(31).

According to the study conducted by Albert H showed, many factors that are very likely to affect the implementation of a QMS are the availability of funding, the role of laboratory management, training, supply chain and equipment maintenance capacity. This could logically be explained by the fact that resources are needed to build the rest of the QMS. Without the proper resources, the rest of the QMS implementation process cannot be completed properly either; the process of change, strong management, and organization coordinate and facilitate the process to the efficiency of QMS implementation(32).

The finding conducted from Germany showed the documentation of equipment, purchasing and inventory were limited. The processes of documentation were agreed and an equipment and baseline stock inventory were completed. Standardized operating procedures and documentation for validation and verification of new methods were introduced the quality management to

technical, scientific, and administrative staff and visit other laboratories to create an environment of continuous learning, promote critical thinking and motivate for sustained change (33).

A study conducted in India showed, scoring the implementation of quality system in various operational activities of laboratory system by auditing the laboratories using the checklist, QMS implementation has a major role in creating awareness and understanding to implementation of the quality system in a medical laboratory testing. There should be real time training on various aspects of laboratory activities to assess the competency of laboratory staff, and evaluate staff performance to maintain world class service of the laboratory and testing laboratories explicate the need for understanding current standard requirements of quality system implementation and maintenance to improve the quality of service of the laboratories (34).

A study conducted in Mozambique showed, SLIPTA was launched in 6 MOH laboratories, and final audits demonstrated improvements across through the 12 quality system essentials that compared with baseline assessment and its helps a laboratories to improve the quality and reliability of their service even in the absence of full accreditation (35).

A study conducted in Cambodia showed in 12 laboratories have improved their operations in the areas of facilities and safety, organization, personnel, equipment maintenance, purchasing and inventory, testing process management, documentation, and communication. In the laboratory including establishing documentation system to track quality indicators such as specimen rejection rate, turnaround time, and client satisfaction, and it's also improved the visibility of the laboratory within the hospitals; regular meetings, exchanges with leadership and management teams improved the communication between the laboratory and clinical staff (36).

A study conducted in Nigeria showed the baseline SLIPTA audit of health facilities are expressed as: two of laboratories scored 1-star, while four laboratories were at 0-star. At follow-up audit, one lab was at 1-star, two at 3-star, and three at 4-star. At exit audit, four labs were at 4-star, one at 3-star, and one at 2-star rating. One laboratory dropped a star at exit audit, the two lab are weakest elements at baseline that the internal audit are 4% and occurrence management 15% improved, with an exit score of 76% and 81% respectively. The elements of facility and safety were the major strength across the board throughout the audit exercise (37).

Another study conducted from Nigerian medical laboratories showed, the majority of the facilities implementing QMS are those involved in diagnosis, but poor infrastructure, financial constraints, gaps in capacity building, lack of equipment and consumables, and dedicated and motivated personnel have been challenges. Aspiring laboratories need to start gradually and strongly advocating for management support, connect to national regulations and also participate in external quality assurance (EQA). Laboratory personnel should be act positive behavioral change to promote quality in practice (38).

On the other hand the study conducted in Kenya assessed that the top management commitment is a critical factor in the implementation of quality management and the commitment of manager is positively influenced the implementation of quality management by 60% of the respondents. The employee training positively affected the implementation of quality management according to 70% of the respondents and that communication is an important factor with a positive influence in the implementation of QMS (39).

The study conducted in Benin assessed the quality improvement programme included: external baseline SLIPTA evaluation, creation of work plan based on SLIPTA results, execution of improvement projects guided by work plan, assurance of accountability, training of personnel to improve personnel competencies, development of external stakeholder relationships for sustainability and external follow up post SLIPTA evaluation and the laboratory improved the SLIPTA score by 29% through a quality improvement process guided by work plan implementation, QMS documentation, the introduction of new proficiency testing and internal quality control programs, and enhancement of personnel competencies in technical and quality management through training (40).

Such like studies are identified the improvement management of health facilities as the weakest stage with internal audit 8% and occurrence management 16% showing the lowest scores, Studies documented 19%-95% reductions in turnaround times, 69%-93% reductions in specimen rejection rates, 76%-81% increases in clinician satisfaction rates, 67%-85% improvements in external quality assessment results, 50%-66% decreases in nonconformities and 67% increases in staff punctuality (41)

A study conducted in capital city, Addis Ababa showed, QMS of level II laboratories performing CD4 count and AFB microscopy in Addis Ababa does not yet meet the ISO standard 15189. The overall implementation of the 12 quality system essentials was <35% and values slightly over 50% were observed only for equipment, purchasing, inventory and information management. The average point obtained by the 29 level II (district) laboratories was 44.6%. Only 65.5% laboratories were involved in an accreditation process (42).

A study conducted in capital city, Addis Ababa showed, the laboratory audits should be conducted as a first step to developing quality improvement action plans; political commitment and strong leadership are needed to drive accreditation efforts; advocacy will require clear evidence of patient impact and cost benefit and from assessed laboratories are 43.0% had received SLMTA training; however, about 36.7% of NTRLs had received a laboratory audit, a first step in quality improvement and 28.6% of NTRLs had developed strategic plans and budgets which included accreditation (43).

In Ethiopia, the QMS implementation status of performing laboratories demonstrated poor performance as evidenced by the small proportion of the assessed laboratories having One-star level and above while the majority of laboratories had No-star and the staff refuse towards to the implementation of the QMS due to an inadequate human resource, lack of motivation of staffs, replacement of laboratory managers, quality and safety officers due to high staff turnover and also the upper managements not fully cooperating with the laboratory personnel in the QMS(44).

In Ethiopia most of the laboratory professionals have no training on the laboratory management information system (LMIS) and the majority of the health facilities 60.5% were stocked out for at least one ART monitoring and TB laboratory reagents and the highest stock out rate were for chemistry reagents. Expired ART monitoring laboratory commodities were found in 73.5% of facilities and laboratory commodities in the main pharmacy store was 25% and 20.8% of them were updated with accurate information matching with the physical count done at the time of visit for hospitals (45).

A study conducted in Ethiopia showed, after the mentorship most of district laboratories improved their scores in client management with an average of 58% from 20% of baseline result, organization and personnel achieved more than 64% scores, management reviews 40%, facilities

and safety 70% and 23% occurrence management from baseline scores. Average scores for implementation of corrective actions were 30% and among the SLMTA participated health institution laboratory the highest score was achieved in the document and record & facility and safety (46).

A study conducted in Oromia region, Ethiopia showed, about 20.2% of the health center laboratories provide improved laboratory service and achieved greater than star zero. Availability of system SOP, proper handling of documents, preventive maintenance, staff regular meetings, review of customer satisfaction, quality plan, verification of results, availability of specimen guideline, and availability of established quality indicators were the predictors of quality of laboratory service. Technical and managerial support by regional laboratories, facility management, and regional health bureau is vital for implementation of LQMS to improve laboratory quality services (47).

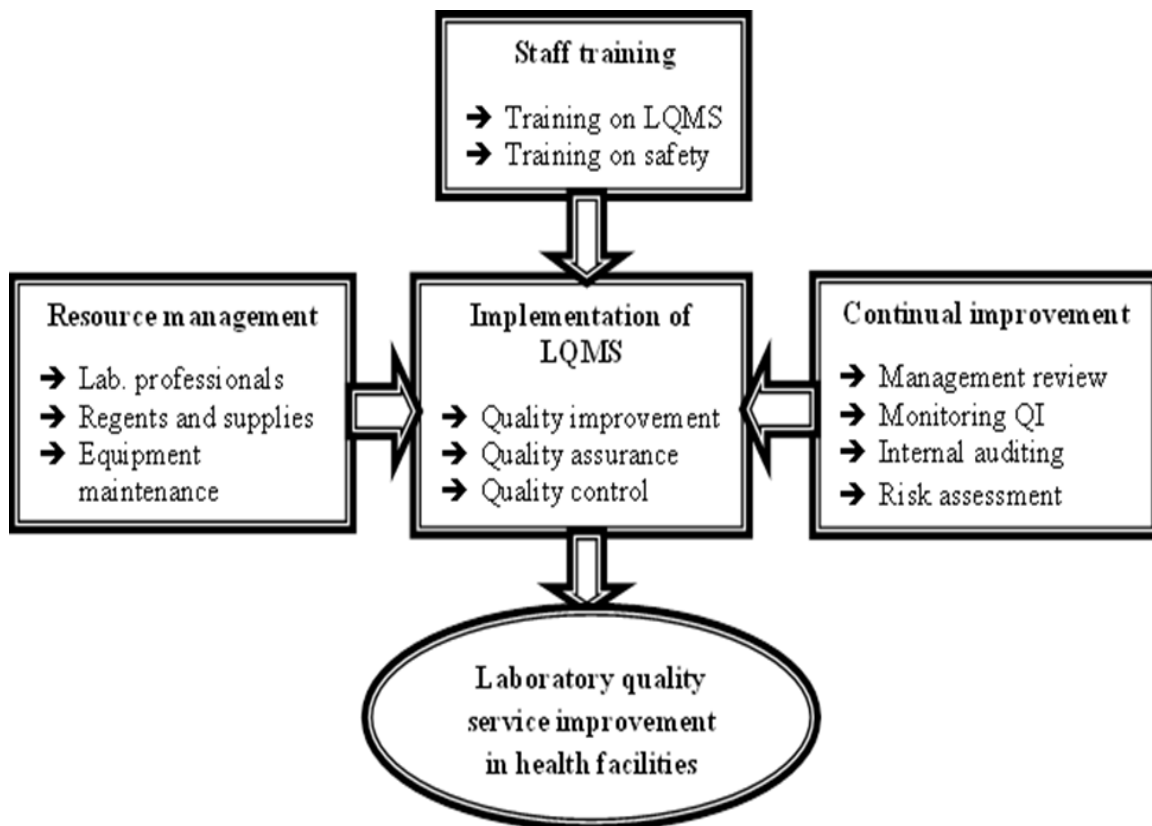


Figure 2: Conceptual frame work of the implementation of laboratory QMS.

CHAPTER THREE

OBJECTIVES

3.1. General objective

- ❖ To assess the implementation of laboratory quality management system and its challenges in public hospitals in Jimma Zone, Southwest Ethiopia.

3.2. Specific objectives

- ❖ To assess the current implementation of LQMS in public hospital laboratories in Jimma zone.
- ❖ To identify the challenges on the implementation of LQMS in public hospital laboratories in Jimma zone.
- ❖ To assess the readiness of clinical management team to sustainable LQMS in public hospital laboratories in Jimma zone.

CHAPTER FOUR

METHODS AND MATERIALS

4.1. Study area

This study was conducted in Jimma Zone in selected public hospital laboratories. Jimma Zone is one of the Zones of Oromia Regional state, located in the southwest Ethiopia. It is located at geographical coordination on $7^{\circ} 40' 24''$ N latitude and $36^{\circ} 50' 3''$ E longitude with a total population of 2,486,155 according to 2007 central statistical agency (CSA) census report. Jimma zone is one of the largest zones in the regional state of Oromia, with an area of 15,568.58 square kilometers. Jimma town is located at 259 KM and 777.29 meters. The miles based distance from Addis Ababa to Jimma is 161.4 miles away from the capital city, Addis Ababa (48). In Jimma Zone there are eight public hospitals; among which five of them implemented LQMS. Jimma university medical center (JUMC) is one of the oldest hospitals in Ethiopia and it is the only teaching and referral hospital in southwest Ethiopia with 800 bed capacity and a catchment population of over 15 million people. Patients are referred from southwestern region of Ethiopia including but not limited to Agaro General Hospital, Limmu Genet General Hospital, Seka Primary Hospital, and Shenen Gibe General Hospital (Personal communication with the Zonal Laboratory Expert).

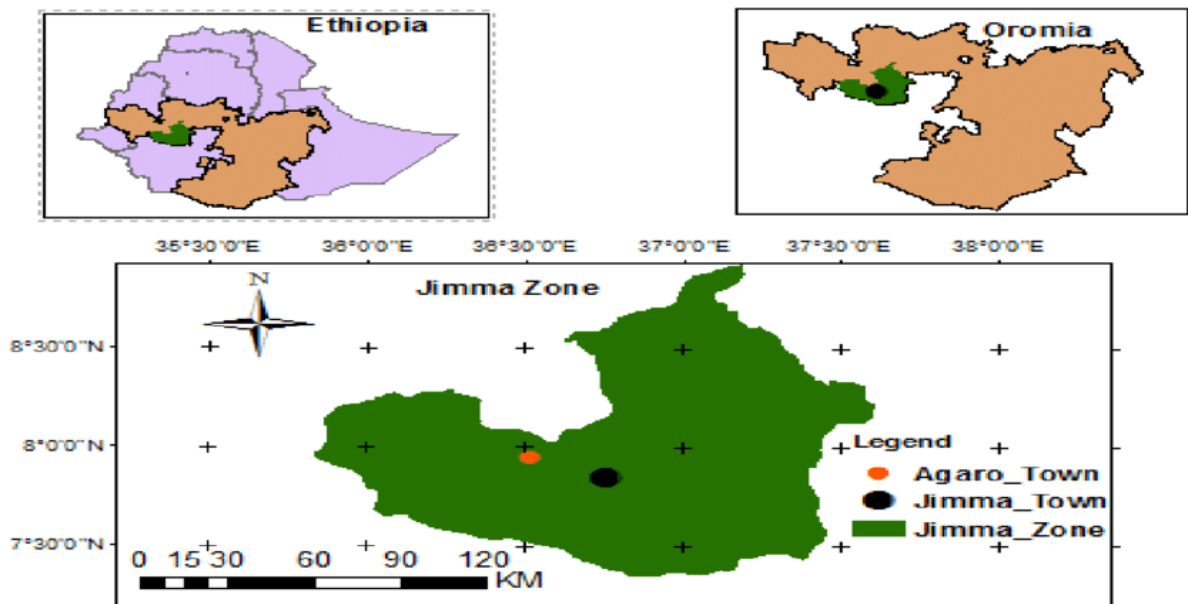


Figure 3: Administrative Map of study area, 2022

4.2. Study design and period

The data was conducted by descriptive cross sectional study design by taking retrospective data from the last audit result that were done by external assessor and the current audit was done by using WHO-AFRO-SLIPTA checklist Version 2:2015(Annex-I), to assess the current status of the implementation of LQMS. Both quantitative and qualitative data design were implemented in this study. The mixed method was selected to support quantitative data and look for new emergent reasons in quality management implementation and the data was collected from November 2021 to January 2022.

4.3. Population

4.3.1. Source population

The source population for the quantitative study was all eight public hospitals in Jimma Zone among which one hospital is under the ministry of health and seven hospitals are under Oromia regional health bureau which begun service provision for more than a year and the qualitative data was used to gather from all key informants of those eight public hospitals in Zone.

4.3.2. Study population

The study population for the study was those public hospitals implementing laboratory QMS at five public hospitals in the zone (by focal personal communication with Jimma Zonal Health Bureau) which include Jimma university medical center, three general hospitals (Agaro general hospital, Limmu Genet general hospital and Shenen Gibe general hospital) and one Primary Hospital (Seka primary hospital). The qualitative study was on the key informants of the selected public hospitals.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

Public hospitals which implemented laboratory quality management system (LQMS) and all laboratories professional that have served for six months or more in the hospital and who have no any managerial position as department head in the hospital was considered for quantitative study. Moreover, the professionals who have no link with the laboratory department were included in the study.

4.4.2. Exclusion criteria

Public hospitals which have not implemented laboratory QMS were excluded. Laboratory professional who serve less than six months and/or on managerial position (department heads, and above) was excluded from the study from laboratory QMS implemented hospitals. In addition, department heads who were not volunteers at the particular hospital and laboratory staff and those who have not been working in that specific duration in laboratory QMS implementation were excluded from the study.

4.5. Sample size determination

From the eight public hospitals in Jimma Zone, five of them were included to study purposively for they implemented LQMS that include one referral hospital laboratory, three general hospitals laboratory and one primary hospital laboratory. The number of laboratory professionals included in this study is calculated as a single population proportion and correction formula was used since the total population is less than 10,000.

The following assumptions were taken to calculate sample size: 95% confidence interval, 5% margin of error, 50% proportion since there was no prior research conducted in study area and 10% non-response rate was considered. Currently there are **104** laboratory professionals working in the five public hospital laboratories in Jimma zone (Personal communication with the Jimma Zonal Laboratory Expert).

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

$$n = (1.96)^2 * 0.5 * 0.5 / (0.05)^2 = \underline{384}$$

Since the calculated sample size was greater than the total expected respondents, the correction factor to be done based on the finite population formula (nf). Therefore, the sample size calculated to:

$$(n) \text{ Corrected formula} = nf = \frac{n}{1+n/N}$$

$$nf = 384 / 1 + 384 / 104 = \underline{82}$$

Considering a 10% non-response rate then the total sample size was = **90**

Purposive sampling technique was used to select the hospitals by considering their implementation of laboratory QMS.

For the reason of confidentiality, code was assigned for each hospital by using abbreviation form. The number of respondents was taken from each Hospital by using simple proportional sampling technique calculation. So, from each hospital the sample was taken randomly by multiplying the number of all laboratory professionals in a given hospital by the ratio of total sample size to the total laboratory professionals i.e. (90/104). From each selected hospital, seven key informants were identified and enrolled quality committee. Therefore, the total sample size was 125 (90 lab professionals plus, 35 key informants that one department head or delegated personnel from the departments which have link with laboratory department were selected from sampled public hospitals in study area).

4.5.1. Sampling technique

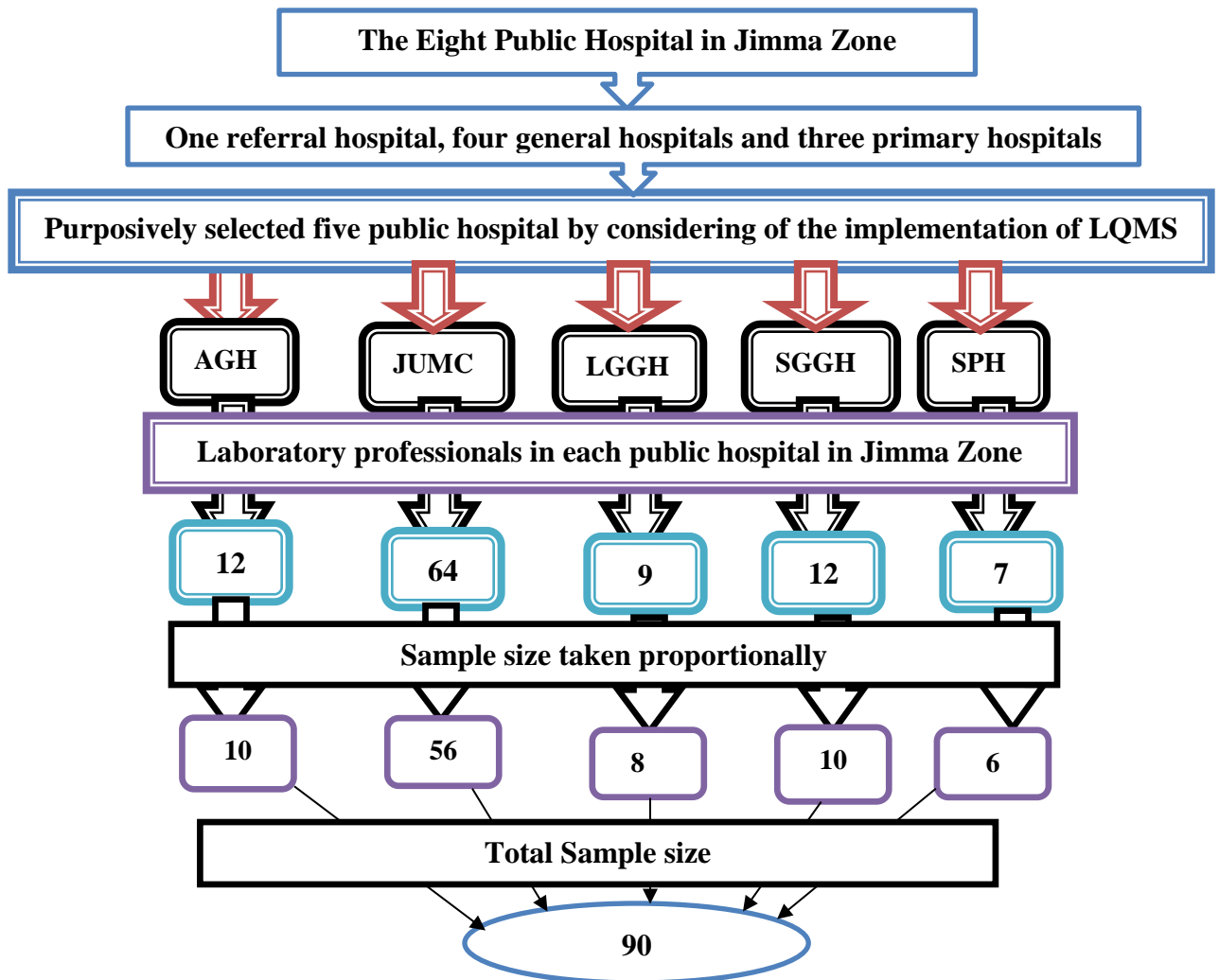


Figure 4: Diagrammatical representation of sampling techniques from five public hospitals in Jimma zone.

4.5.2. Sampling procedures

A random sampling procedure was employed according to the type of the hospitals and after identifying the number of laboratory professionals from each of the three types of hospitals the sample for each hospital was distributed by using the proportional allocation to size formula. Then study participants were proportionally selected by simple random sampling technique from each hospital (**Figure 4**).

Purposive sampling was used to select participants of the qualitative data that a key informant was selected for the interview since they have direct work relation with the study objectives.

4.6. Study Variables

4.6.1. Dependent variables

- ❖ Implementation of laboratory QMS
- ❖ Score of QMS

4.6.2. Independent variable

- ❖ Management Commitment on implementation
- ❖ Monitoring system of QMS activities
- ❖ Mentorship during implementation
- ❖ Professional educational level
- ❖ Supply chain management
- ❖ Staff training
- ❖ Job satisfaction
- ❖ Turnaround time
- ❖ Lack of adequate equipment
- ❖ Equipment Maintenance
- ❖ Resource management

4.7. Data Information

4.7.1. Data collection procedures

The quantitative data on implementation of LQMS was collected by using structured questionnaire (Annex II) from laboratory professionals of the selected hospital laboratories and the data was collected by trained data collectors and supervised by principal investigator. The qualitative data from all key informants of those hospitals were collected by using key informant interview, unstructured interview guide questionnaire prepared in English and translated to local language including Afan Oromo and Amharic to guide the interview (Annex III). The interviews were conducted by the principal investigator (PI) and all the interviews were tape recorded and major points were noted by the PI and each interview has taken averagely 30 minutes for the key informant in sampled hospitals.

4.7.2. Data Management

Data quality was ensured through use of standardized data collection formats and materials for assessing implementation of LQMS. Data were entered, cleaned and analyzed by using Epi-data version 4.6 and exported to SPSS version 23 software for further processing and questionnaire were prepared in English version and translated to Afan Oromo and Amharic version and back to English version to ensure its consistency. Pretesting of the questionnaire were carried out in Dedo Primary Hospital on 5% laboratory professional of the sample hospitals that were not included in the study and the necessary modification was done based on the result obtained and the completeness of the data were checked by the principal investigator after data collection. To protect data manipulation, data was stored in a password protected computer and backup was saved by flash and CD.

4.7.3. Data Analysis

After the quantitative data is checked for completeness, it was coded, entered by Epi Data 4.6 and analyzed using SPSS version 23.0 version. Results from WHO-AFRO SLIPTA checklist were analyzed compare with to baseline audits with performance after current auditing. The quantitative data collected using different techniques were analyzed using simple descriptive statistics. The qualitative data obtained from in-depth interview, were summarized and discussed.

4.8. Definitions of terms

- ❖ **Quality management:** is the act of overseeing different activities and tasks within an organization to ensure that products and services offered. It helps to achieve and maintain a desired level of quality within the organization.
- ❖ **Quality management system:** Management systems that help to direct and control an organization with regard to quality and provides the organizational structure, processes, procedures, and tools for implementing the activities necessary to achieve the quality objectives and requirements.
- ❖ **Quality System Essentials:** coordinated management activities to direct and control an organization with regard to quality.
- ❖ **Quality improvement:** the part of quality management that focused on increasing of the ability to fulfill quality requirements.

4.9. Ethical Consideration

Prior to data collection ethical approval was obtained from research ethics committee of Institute of health, Jimma University. Permission was also obtained from Jimma University and Jimma Zone health bureau and each respective hospital. And also Informed consent was obtained from each study participant. Name or specific address of the study participants was coded and remain anonymous as well as the participants were informed about the risk and benefit of the study and provided with a right of refusing to respond at any time if they are not willing to respond. A code was assigned to assure confidentiality of the hospitals, laboratories and respondents.

4.10. Dissemination of Plan

The result of this study will disseminated to Jimma Zone health Bureau, Jimma University, institute of health, School of laboratory sciences and to those sampled hospitals where the study were conducted. This study finding will be published either on a national or international peer reviewed journal to make it more available for use by any stake holder and other researchers. Attempt will also be made to present on national or international conference or workshop.

CHAPTER FIVE

RESULTS

5.1. Socio-demographic characteristics of the study participants

A total of 89/90 (99%) of laboratory professionals working in the sampled health facilities (one referral hospital, three general hospitals and one primary hospital) participated in this study with only 1% non-response rate. The majority of the participants, 47.2%, were found between 30-39 years of age group. Most of the respondents, 59.6%, were male; and 78.6% were BSc degree holders by educational status. Nearly half of the laboratory professionals, 53.9%, were at a senior professional rank; and 45.0% of them have been serving for the last 6-10.5 years in the health facilities. Most of the study participants, 61.8%, were from referral hospital. From all the health facilities, only one laboratory was accredited by Ethiopian National Accreditation Office (ENAO) requirements in a single (GeneXpert) test and scored SLIPTA 4-stars. Most of (46.1%) laboratory health professionals were serving in all sections of working area in the laboratory. (**Table 1**).

Table 1: Socio-Demographic determinants of the implementation of laboratory QMS in Jimma Zone public hospital laboratories, Southwest Ethiopia, 2022.

Variable	Category	Frequency	Percentage (%)
Sex of the respondent	Male	53	59.6
	Female	36	40.4
Age of the respondent	20-29	40	45.0
	30-39	42	47.2
	40-49	5	5.6
	>50	2	2.2
Educational status	Diploma	12	13.5
	BSc. Degree	70	78.6
	MSc. Degree and above	7	7.9
Laboratory professional status	Junior professional	15	16.9
	Senior professional	48	53.9
	Chief professional	17	19.1
	Expert professional	9	10.1

Working Experience	0.5 Months-2.5 Years	12	13.5
	3-5.5 Years	22	24.7
	6- 10.5 Years	40	44.9
	>11 Years	15	16.9
Types of hospital serving	Referral Hospital	55	61.8
	General Hospital	28	31.5
	Primary Hospital	6	6.7
Laboratory working area	Sample collection working area	13	14.6
	Parasitology working area	6	6.7
	Hematology working area	11	12.4
	Serology working area	2	2.2
	Chemistry working area	9	10.1
	Molecular biology working area	7	7.9
	At all laboratory working area	41	46.1

5.2. Laboratory quality management system implementation

The current LQMS implementation status of Jimma zone was averaged to 76.6%. This baseline assessment was done before starting assessment on QMS implementation challenges. The assessment was done by trained data collators and quality officers after taking training based on the benefit and necessary of the study. The final assessment was done within three months of implementation. Finally one hospital laboratory becomes 4-stars, two hospital laboratories were scored 3-stars (both are general hospitals), and two hospitals laboratories were scored 2-stars.

From the total sampled hospitals, Jimma university medical center scored 87% (4-stars), Shenengibe general hospital scored 83% (3-stars), Limmu Genet general hospital scored 77% (3 stars), Agaro general hospital scored 65% (2-stars) and Seka primary hospital scored 71% (2-stars). From those sampled public health facilities, only JMC laboratory is accredited by ENAO in a single GeneXpert test since 2019. In this study four of the health facilities increase the percentage of their audit scores after past regional auditing feedback, but only Agaro general hospital scored 2-stars from 1-star by taking action of the gap on their laboratory. The average base line and the final result comparing with the scored stars were displayed (**Figure 5**).

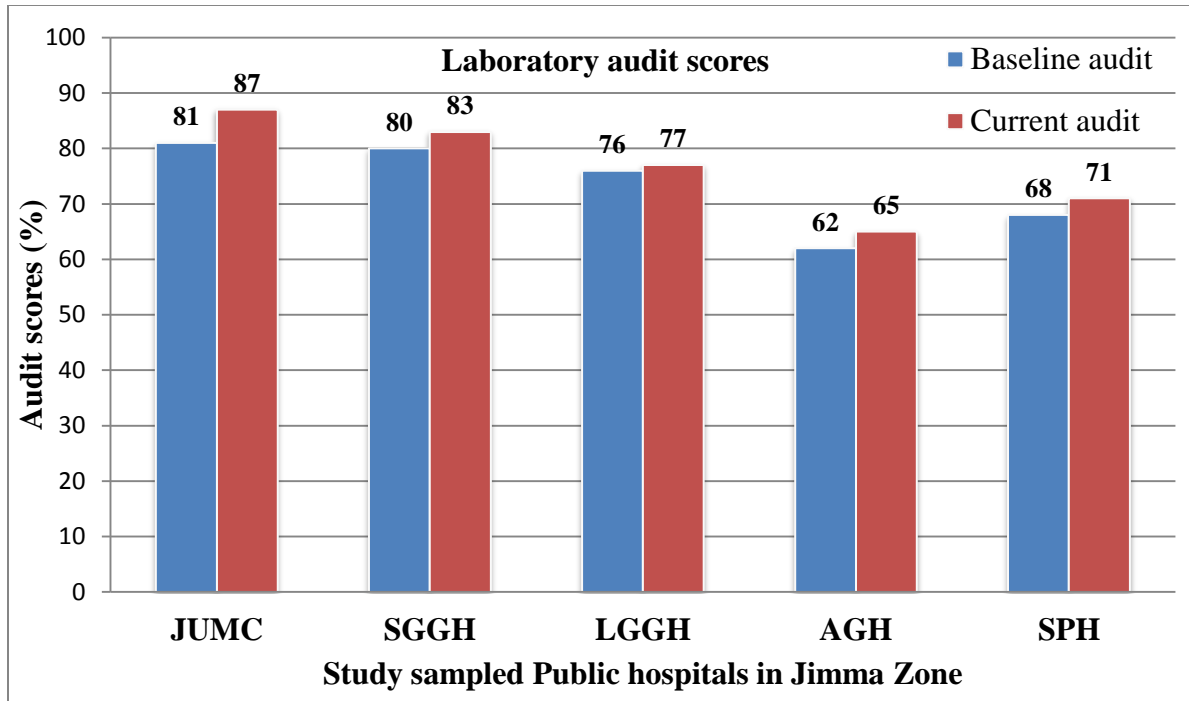


Figure 5: Performance of the sampled public hospitals laboratories SLIPTA scores and star ratings.

Key: *JUMC: Jimma University Medical Centre, SGGH: Shenene Gibe General Hospital, LGGH: Limmu Genet Hospital, AGH: Agaro General Hospital, SPH: Seka Primary Hospital.*

5.2.1. Laboratories status based on 12 quality system essentials

In this study, the all public hospitals comprehensive finding of the laboratory QMS implementation on the twelve quality system essentials has appeared for the major improvements of the hospital laboratories. Documents & records, 86.4%; management reviews 71.4%; organization & personnel 83.6%; client management & customer service 84.0%; equipment management 82.9%; evaluation and audits 66.7%; purchasing & inventory 75.8%; process control 69.4%; information management 66.7%; identification of non-conformities, corrective and preventive actions 57.9%; occurrence/incident management & process improvement 73.3%; and facilities and bio-safety 84.2% (**Table 2**).

Table 2: Current implementation status of LQMS assessment results of sampled public hospital laboratories in Jimma Zone, Southwest Ethiopia, 2022.

The 12 quality system essentials	WHO-AFRO SLIPTA score points	Laboratories score					Comprehensive finding of 12 QSEs
		JUMC	SGGH	LGGH	AGH	SPH	
Documents & Records	28	27(96%)	21(86%)	25(89%)	22(79%)	26(93%)	24.2(86.4%)
Management Reviews	14	14(100%)	10(71%)	10(71%)	2(14%)	14(100%)	10(71.4%)
Organization & Personnel	22	20(91%)	20(91%)	20(91%)	14(64%)	18(82%)	18.4(83.6%)
Client Management & Customer Service	10	8(80%)	10(100%)	9(90%)	8(80%)	7(70%)	8.4(84.0%)
Equipment	35	33(94%)	26(74%)	30(86%)	30(86%)	26(74%)	29(82.9%)
Evaluation and Audits	15	15(100%)	15(100%)	11(73%)	7(47%)	2(13%)	10(66.7%)
Purchasing & Inventory	24	21(88%)	21(88%)	13(54%)	18(75%)	18(75%)	18.2(75.8%)
Process Control	32	24(75%)	27(84%)	21(66%)	19(59%)	20(63%)	22.2(69.4%)
Information Management	21	14(67%)	15(71%)	14(67%)	13(62%)	14(67%)	14(66.7%)
Identification of Non-Conformities, Corrective and Preventive Actions	19	13(68%)	16(84%)	13(68%)	5(26%)	8(42%)	11(57.9%)
Occurrence/Incident Management & Process Improvement	12	9(75%)	12(100%)	9(75%)	8(67%)	6(50%)	8.8(73.3%)
Facilities and Bio-safety	43	40(93%)	36(88%)	36(93%)	33(80%)	36(88%)	36.2(84.2%)
Total Score	275	238/275 87%	229/275 83%	213/275 77%	179/275 65%	195/275 71%	383/5(76.6%)

Key: *JUMC: Jimma University Medical Centre, SGGH: Shenen Gibe General Hospital, LGGH: Limmu Genet Hospital, AGH: Agaro General Hospital SPH: Seka Primary Hospital.*

The twelve quality system essentials have three framework used to analyses to which extent the content of quality documents covers all aspects of total quality management. The finding of the laboratory QMS implementation by the 12 quality system essentials has appeared for the major improvements of the hospital laboratories. Process management (Documents & records scored 86.4%; customer service scored 84.0%; process control 69.4% and information management scored 66.7%); Resource management (management reviews scored 71.4%; organization and personnel 83.6%; equipment scored 82.9%; purchasing and inventory scored 75.8% and facilities and safety scored 84.2%); Improvement management (evaluation and audits scored 66.7%; preventive actions scored 57.9% and occurrence management scored 73.3%); (**Figure 6**).

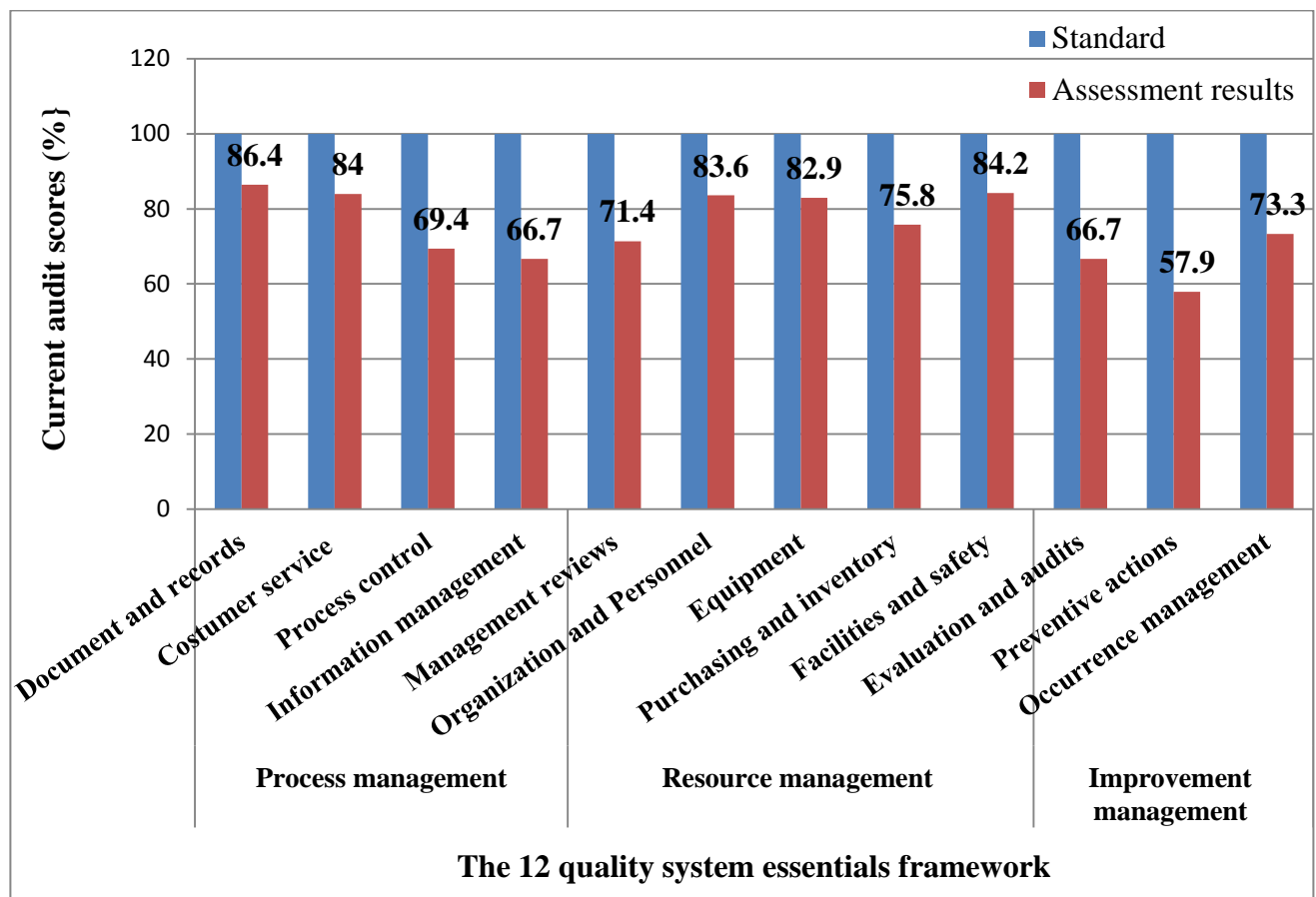


Figure 6: Implementation status of LQMS assessment results based on the twelve QSEs.

5.2.2. Perception of staff on the degree of implementation of LQMS

From the majority of 51.7% the respondents, the professionals had information agreed and 33.7% of them were responded strongly agreed on the implementation of LQMS in their laboratories, while 12.3% of the lab staffs responded partially agrees and 2.2% participants had no information and knowledge of the LQMS implementation.

Nearly half of the respondents 51.7% strongly agree that laboratory QMS is important to the laboratory services, while 42.7% of them affirmed as agree. On the other hand, 41.6% of laboratory professionals agreed to perform the laboratory activities according to the duty roster and still another 21.3% of the respondents strongly agreed to it. However, 18.4% of the study participants did not agree on the rotation of laboratory activities according to the duty roster.

From total study participants, about 49.4% agreed that in their hospital all laboratory personnel had a job description based on the services delivered. Another 24.7% of them responded to strongly agreed on a job description based on services delivered. About 76.4% study participants agreed that there are sufficient laboratory professionals in the sampled hospitals.

The laboratory professionals in the sampled hospitals, majority 93.4% of them have agreed that manuals, policies and procedures available in the laboratory have been written and updated. About eight two percent of the study participants agreed that their laboratory applied to national or international accreditation bodies. About 50.6% of the respondents agreed and about 33.7% of them strongly agreed on their laboratories have well organized documentation and recording system, while 19.7% of the study participants disagreed on the laboratory had turnaround times for all test parameters. Majority of the lab professionals 65.2% responded agree on the establishment of laboratory logistic systems available with sufficient equipment's and reagents to avoid stock out, while 20.2% of them responded partially agree and 14.6% disagreed. Most of 74.1% the respondents agree on the presence of appropriate maintenance system of laboratory equipment.

Almost 53.9% of respondents perceived agreed they are taking customer's complain on the laboratory service delivered in the hospitals, while the other 24.7% of them responded it was at partially agree. About 72% of the participants agreed the hospital management controls and supports the laboratories, while 2.2% responded disagree. About 61.7% of the respondents agreed

the laboratories had comfortable working environment, while 31.5% of them responded to partially agree. About three fourth of the laboratory professionals agreed on the satisfaction gained being in the laboratory profession. In this study 88.8% of participants agreed about the laboratory professionals adhered to the available of SOPs on the bench mark.

Almost 92.1% of the study participants agreed, there are a high work load in the laboratories, while 6.7% of them partially agreed on the presence of high work load. About 70% of them agreed on the continual improvement activities are being done in the laboratories and almost nearly to half of them 48.3% agreed for quality review meeting conducted in the laboratory, while 39.3% respondents were neutral.

Majority of the study participants 66.3% agreed on the risk analysis and management system, whereas 21.3% responded to partially agree and 12.4% of the respondents were disagreeing. In the sampled hospital laboratories, most of professionals 68.6% agreed on the importance of internal audit system for the diagnosis of the QMS progress and 52.8% responded agree on ICT department delegated for laboratory department to process laboratory tests free from any requisition paper, while 20.2% was them are partially agreed, and 28.1% of them responded disagree to the computerized hospital management information system (HMIS) in the laboratory (Table 3).

Table 3: Perception of staffs on degree of implementation of LQMS at public hospitals of Jimma Zone, Southwest Ethiopia, 2022.

Variables	SA	A	PA	D	SD
	<u>N_o</u> (%)	<u>N_o</u> (%)	<u>N_o</u> (%)	<u>N_o</u> (%)	<u>N_o</u> (%)
Staff information of the implementation of LQMS	30(33.7)	46(51.7)	11(12.4)	1(1.1)	1(1.1)
Staff readiness and participant on implementing of (LQMS)	33(37.1)	44(49.5)	10(11.2)	1(1.1)	1(1.1)
LQMS is important in the laboratory	46(51.7)	38(42.8)	2(2.2)	1(1.1)	2(2.2)
There are sufficient laboratory personnel in this hospital	32(36.0)	36(40.4)	12(13.5)	7(7.9)	2(2.2)

There laboratory professionals perform the laboratory activities according to the duty roster	19(21.3)	37(41.6)	16(18.0)	15(16.9)	2(2.2)
All laboratory personnel have a job description based on service delivered	22(24.8)	44(49.4)	19(21.4)	2(2.2)	2(2.2)
The laboratory applies national or international standard system (ISO) in laboratory	32(36.0)	41(46.1)	14(15.7)	2(2.2)	0(0)
The laboratory has written manual, policies and procedures available in laboratory	38(42.7)	46(51.7)	5(5.6)	0(0)	0(0)
The laboratory has well organized documentation and recording system in laboratory	30(33.7)	45(50.6)	13(14.6)	0(0)	1(1.1)
The laboratory professionals adhere to the available SOPs	32(36.0)	47(52.8)	9(10.1)	1(1.1)	0(0)
Continual improvement activities are being done in the laboratory.	18(20.2)	44(49.4)	23(25.9)	4(4.5)	0(0)
Quality review meeting conducted in the laboratory	17(19.1)	26(29.2)	35(39.3)	8(9.0)	3(3.4)
Sufficient working equipment's and reagents for working	21(23.6)	37(41.6)	18(20.2)	10(11.2)	3(3.4)
Appropriate maintenance system for laboratory equipment	14(15.7)	52(58.4)	18(20.3)	5(5.6)	0(0)
Hospital management controls and supports the laboratory	16(18.0)	48(53.9)	17(19.1)	1(1.1)	1(1.1)
Customer's complain taking system on the service delivered in the laboratory	14(15.7)	48(54)	22(24.7)	4(4.5)	1(1.1)
Laboratory has comfortable working environment for the professionals	19(21.4)	36(40.4)	28(31.5)	6(6.7)	0(0)
Your satisfaction in laboratory profession	26(29.2)	41(46.1)	17(19.1)	4(4.5)	1(1.1)
High work load in this laboratory	44(49.4)	38(42.7)	6(6.8)	1(1.1)	0(0)
The laboratory has TAT for all tests	21(23.6)	25(28.1)	25(28.1)	14(15.7)	4(4.5)
Risk analysis and management system in this	11(12.4)	48(53.9)	19(21.3)	8(9.0)	3(3.4)

laboratory					
Clinical audit system in this laboratory	16(18.0)	45(50.6)	18(20.2)	10(11.2)	0(0)
ICT department delegated for laboratory department	5(5.6)	42(47.2)	35(39.3)	7(7.9)	0(0)
Computerized hospital management information system (HMIS) in the laboratory	6(6.7)	26(29.2)	32(36.0)	17(19.1)	8(9.0)

Key: SA: Strongly agree, A: Agree, PA: Partially agree, DA: Disagree and SD: Strongly disagree

5.3. Results finding from in-depth interview

5.3.1. In-depth interview Participants socio-demography

From total number of respondents participated in the in-depth interviews, who were department heads that have direct link with the laboratory system, 23(71.9%) were males and 9(28.1%) were females. Age wise, participants range from 28-46 years with mean age of 37 and those between 31-41 years of age were the majority of them 26(81.3%). In this study the educational backgrounds of the study participants 3(9.4%) were medical doctors, 6(18.8%) were master degree, 21(65.6%) were BSc degree and 2(6.2%) were diploma holders. Majority of 30(93.5%) of the professional's level were senior manager in sampled public hospitals and had knowledge on the management of QMS in the laboratories.

5.3.2. Implementation of laboratory QMS in the hospitals

Data were collected from key informants of the five sampled hospitals with considering to support the quantitative data, key informants interview were conducted and collected from the laboratory heads, quality officers, safety officers and health facilities top management members by using an open-ended in nature that primarily focused on factors affecting for the implementation of the QMS, the involvement of professionals in LQMS implementation, accountability for laboratory QMS system and therefore the key informants was the highest influential of the QMS for all departments' of hospital professionals.

“I can say that the quality management system is implemented altogether departments of the hospital which is evidenced by progressive improvement of quality indicators within the hospital like laboratory, Emergency care center, outpatient care center, maternity and child care center and Chronic diseases care center”.

“I can able to see during this hospital management that the laboratory QMS is implemented within the hospital and therefore the laboratory scores star-II SLIPTA which it’s evidenced by progressive improvement of quality indicators within the laboratory and brought from the external assessors”.

“I can say that the quality management system is implemented altogether, But in this hospital lack of staff awareness supported QMS and negligence of the staff it influences the standard of tests”.

“I had more experience on the position of hospital managers and that I had more experienced on the implementation of QMS as a clinical management, so that the QMS is implemented altogether departments of the hospital which is evidenced by progressive improvement of quality indicators the hospital. In this hospital we sustaining the baseline SLIPTA score stars and develop to stars-III and above by solving the issues that rewarded by external assessors by keeping the internal auditing as a standard schedule”.

5.3.3. Laboratory professional involvements in QMS in the hospitals

The key informants blame the health professionals participation in the implementation of laboratory QMS is for that come to low in study area and but on the other hand most of the key informants agree that laboratory had better participation to achievement of the implementation of LQMS which the participation of laboratory in laboratory QMS was explained by document registration/event registration.

“I wouldn’t say that laboratory professionals are participated within the QMS of the hospital, because the sole way professionals involved in QMS is document registration and reporting, which is difficult to mention professionals are participated in QMS implementation”.

“The weak monitoring system of hospital employees and all departmental activities are indicated in low participation of professional’s due to several problem and also lack of

opportunity to training employees regarding to laboratory QMS and safety may cause of employee resistance to attend work time tests toward the QMS”.

5.3.4. Challenges facing the implementation of QMS in the hospitals

All of key informants of the hospitals mentioned that budget had always been a controversy in implementing QMS in the hospital. Therefore the communications of QMS across the hospital were the opposite challenges determine the implementation and also the mostly mentioned the lack commitment of top managers in managing quality effectively with the stake-holder of quality.

“In our hospital there are many challenges which might identify within the implementation of QMS in the hospital, specifically the most challenges which determine for the implementation of QMS is budget, reagent supply, and there is no budget allocation for quality indicators program in this hospital, so, it's a challenge to implement it quality as standards.”

“An implementation of laboratory QMS in our hospital an interested and really good habit, but still we've got a spot on the knowledge and readiness to continual skills of staff on the requirement of laboratory QMS training, shortage of supply chain, staff commitment, high work load, layout of skilled man power from our hospital are a challenges to achievement of SLIPTA score rank form the baseline to use on the ISO:15189 supported standard and most of our staffs had an honest commitment to fill the gap of laboratory QMS”.

“Laboratory QMS is a very important program; but because of the irregular laboratory reagents, supplies and consumable supply system in Jimma Zone, and there are clear gaps regarding method of validation/verification, performing a root cause analysis, measurement uncertainty and also on metrological traceability among our laboratory professional, despite these there's high adjustment rate of trained laboratory staffs”.

“We have irregular mentoring and training program from the regional laboratory, but it is not strong because we are involved in many duties within the hospital including the routine and also the assigned mentors were come to as without preparation, so that in this hospital there are skill between staff this is the main challenge to implement quality as standard”.

5.3.5. Readiness of the clinical management team to sustain laboratory QMS in the hospitals

In this study the clinical management teams of hospitals are expected to have access to accurate, clinically relevant information that can be understood and used in a timely manner. Laboratory professionals need assurance of laboratory responsibility throughout the testing process, including pre-analytical steps, analytical process and post-analytical process. Most medical directors and hospital managers who participated during this study revealed that;

“In these hospitals the quality of laboratory tests is incredibly energetic and had the right-hand role for the medical decision and sustains our hospital SLIPTA scores, this quality status isn't in an exceedingly good standard and will be enhanced into international standard, score the top rank of SLIPTA and achieve the ISO15189 accreditation”.

CHAPTER SIX

DISCUSSION

This study was designed to assess the implementation of laboratory quality management system and its challenges in Jimma zone public hospitals, Southwest, Ethiopia. This study audit finding showed one referral hospital laboratory rating 4-stars, two general hospital laboratories was rating 3-stars and one general hospital laboratory and one primary hospital laboratory were rating 2-stars. Most of the respondents 59.6% were male; while the most of 47.2% the study participants were found between 30-39 age groups and 78.7% were as BSc. degree holders. In this study the researcher reviewed the baseline assessment by internal and external assessors before starting auditing of LQMS implementation in all health facilities. Overall assessment was done by supervisor with the laboratories quality officer. The twelve QSEs was the main and core in this SLIPTA audit to address the assessment of QMS in the laboratories. In an extremely QMS, all aspects of the laboratory operation, including the organizational structure, processes and procedures, have to be addressed to assure quality.

6.1. Laboratory QMS implementation status

In this study majority 85.4% of the laboratory professionals study participants had an information of the implementation of LQMS in their laboratories, that are given for the staffs strong motivation to boost the hospitals quality that helps to determine a QMS for the advance of hospitals scores and laboratory team work most beneficial for the measurement of performance on scheduled period and plan, prepare document and writing quality manual for the communication of external audit scores results and feedback to sustainable the QMS based on standard. While clinical laboratory support the establishment and maintenance of QMS that had visible setting of quality policy, planning for quality, improving and acting on the information deriving from quality status reports that essential to the successful implementation of the QMS in health facilities (30).

In the Zone, all hospitals laboratories need man power, continuous power supply and water to the suitability of their activities. Most often, within the study area the laboratories are hampered in their operation due to limited space or inefficient use of the space available. This can be because insufficient attention has been given to the planning of the laboratory working bench to try and do

the laboratory service smoothly. So that, laboratory professionals must be able to communicate well on service givers and the workload capacities of a laboratory don't seem to be matched to the quantity of staff and to their level of coaching, size of the laboratory department and its facilities.

Majority of study participants have agreed on high work load within the laboratories, its default to correct problem occurring within the laboratory and lack of root cause analysis for minimizing of risk and monitor quality instrument that takes an objective approach to problem solving without necessarily using additional resources and management system. But the combination of all laboratory processes required to meet its quality tests by solving the matter that happened within the lab and to fulfill the desires of users to see the sequence and interaction of the processes and make sure the availability of resources because the information necessary to support the operation and monitoring of the processes, evaluate these processes and implement actions necessary to realize planned results and continual improvement of those processes (26).

In the sampled hospitals, majority of the quality officers responded that hospital laboratories had written manual, policies and procedures available in laboratories. This study finding had similarity with the SOPs documentation for validation and verification of QMS in a technical and scientific process to make an environment of continuous learning, promote critical thinking and motivate for sustained change (33). While the other research had support the finding scoring of QMS implementation of laboratories by using checklist and for ultimate audits demonstrated and improvements across the twelve QSEs. The another also support the finding of this study, by the laboratory auditing practices of QMS by the documentation system establishment, assign quality indicators in the laboratory and improved the laboratory quality in the hospitals (34, 35, 36).

Most sampled hospitals respondents perceived for taking customer's complain on the laboratory service delivered within the hospitals laboratories, whereas 61.7% of the laboratories professionals had comfortable working environment, 75.3% of laboratory professionals were satisfied on their profession and about 88.8% of participants adhered to the available SOPs on the bench mark. There was similar results with a critical factor in the implementation of quality management and the commitment of manager is positively influenced the implementation of quality management as by 60% of the respondents. The employee training positively affected the implementation of quality management with 70% of the respondents agreed and that communication is an important factor with a positive influence in the implementation of QMS (33,39).

From the sampled hospitals, only one hospital was score 4-stars, two hospitals were scores 3-stars, and two hospitals were scores 2-stars. But the only Jimma university medical center laboratory is accredited in single GeneXpert ENAO since 2019, this had similar with the study conducted in Nigeria showed the baseline audit is 2 of the laboratories attained 1-star while the remaining four were at 0-star. At follow-up audit, one lab was at 1-star, two at 3-star, and three at 4-star. At exit audit, four labs were at 4-star, one at 3-star, and one at 2-star rating. One laboratory dropped a star at exit audit; the weather of facility and safety were the foremost strength across the board throughout the audit exercise (39).

In the Zone, an assessed hospitals laboratories were applied and on process to applied to Ethiopian accreditation service (EAS) for the accreditation of their laboratory; to well organized laboratory documentation and developed formal recognition platform to perform quality activities in all section working area (33). The other research that done in Oromia region, Ethiopia, illustrate the finding of this study by proper handling of documents, quality plan, verification of results, availability of specimen guideline, are similar with this study and availability of established quality indicators were the predictors of quality of laboratory service (47).

The laboratory professions responded on the establishment of laboratory logistic systems arrested sufficient equipment's and reagents to avoid stock out and conform to the acceptable maintenance system of laboratory equipment, while as the study done in capital city showed the most common challenges identified included lack of commitment from facility management and laboratory staff, turnover of trained staff, insufficient regular mentorship and inadequate laboratory infrastructure, and the performing laboratories demonstrated poor performance as evidenced by the small proportion of the assessed laboratories having One-star level and therefore the staff refuse towards the implementation of the QMS thanks to an inadequate human resource, lack of motivation of staffs, replacement of laboratory managers, quality and safety officers thanks to high staff turnover and the rest of the QMS implementation process cannot be completed properly either; the process of change, strong management, and organization coordinate and facilitate the process to the efficiency of QMS (32, 36, 47).

6.2. Challenges of laboratory QMS implementation

6.2.1. Job dissatisfaction

In the current findings, as a most of respondent's opinion they were giving priority for the laboratory because they don't have knowledge about laboratory work and its demand. About 24.7% of respondents neutral on perceived taking of customer's complain on the laboratory service delivered within the hospitals because 5.6% of the study participants disagree customers complain, 28.1% of the participants disagree the hospital management controls and supports the laboratory, were as 6.7% of the respondents disagree that laboratories had not comfortable working environment, 19.1% of laboratory professionals was neutral felling and 5.6% not had satisfaction for her profession. Even though most of them were no satisfied on lab profession, that the foremost of the staffs were dissatisfied on work environments due to high workload, such like issues are, they may explanation for dissatisfaction of employee and it creates negative influence on giving fast response for his or her customers; this finding while similar from assessed laboratories are 43.0% had received SLMTA training; however, about 36.7% of NTRLs had received a laboratory audit, a first step in quality improvement and 28.6% of NTRLs had developed strategic plans and budgets which included accreditation (43).

6.2.2. Staff demotivation

From all laboratory professionals in this study, 92.1% of them responded as there was high work load within the laboratories. Such forms of overload works increases the staff intention and staff demotivated to serve in the laboratory. About 12.4% of laboratories staffs are disagreed on the laboratory quality review meeting and 39.3% of them partially agreed to the review meeting on the laboratory standard; while in the another study in healthcare system had similarity within the laboratory management reviews had not plan on staffs training, managing shortage of laboratory supply and equipment maintenance which demotivate health professionals (32).

On another hand most of the study respondents was perceived for taking customer's complain on the laboratory service delivered in there hospitals, but there's not addressing all service due many factors: shortage of budge, lack of supply chain, and lack of management commitment, so such like complain and feedback is demotivating the staff, that has impact on the standard service delivers. So that, during this study the laboratory complexity working system is requires that a lot

of factors must be addressed to assure quality within the laboratory in sampled hospitals (37,44,45).

6.2.3. Personal and Improvement management

In terms of educational level and year of experience of the staffs has from Diploma up to Master Level. From the total respondents 76.4% said there were sufficient laboratory personnel and the 13.5% partially agreed to sufficient laboratory personnel, but 10.1% said there is a shortage of personal power. In addition, as confirmed from the observation of hospitals there are the shortages of supportive staffs and were discussed with top management of hospitals while another study support this finding top management commitment is a critical factor and positively influences implementation of QMS (39, 40).

As a study result, porters/patient assistance and clerks of employees were discontinued from their work, which makes interruption of registration and TAT sample tracking sheet in the hospitals, but in sampled hospitals the laboratories had a good practices of continual improvement activities like internal audit, measurement uncertainty and root cause analysis that were better to QMS implementation and continual improvement monitoring system. While the same study support this study finding were laboratory professionals not trained on LMIS; that increase the laboratory TAT test tracking (45).

CHAPTER SEVEN

STRENGTH AND LIMITATION

7.1. Strength of the study

- ❖ This study is often used as a spring board for further study because this is often the primary study within the Zone.
- ❖ To strengthening the secondary data, a primary data collection method was employed.

7.2. Limitation of the study

- ❖ This study was conducted only governmental health institutes' so; it doesn't illustrate the private health situation.
- ❖ Audit Assessment done by researcher using WHO-AFRO checklist was after six months of baseline assessment which have a difference of three months from current assessment done by the researcher.
- ❖ Lack of comparable publishable study in the same topic within the zone to check the results.

CHAPTER EIGHT

CONCLUSION AND RECOMMENDATION

8.1. Conclusion

The study was conducted on laboratory quality management system implementation status and its challenges in Jimma Zone public hospital laboratories, Southwest, Ethiopia. The LQMS implementation status within the study area public hospital laboratories was 76.6%. Therefore the finding shown that the laboratory personnel satisfaction by their profession, staff interest and participation in implementing of LQMS, document preparation, internal auditing management review, monitoring quality indicators, risk assessment, root cause analysis, resource management, participation in an external quality assessment program, measurement uncertainty analysis, evaluation and assessment, trained staff turnover were the main factors affecting of laboratory QMS implementation of Jimma Zone hospitals laboratories.

In the hospitals, all working area section were influenced on the laboratory staffs rotation and experienced staffs move from the hospital for better job opportunity and education status of staffs were reported to mainly affect the implementation process. High turnover of trained professionals, huge routine work load, poor equipment quality management, and shortage of laboratory supplies, inconsistent mentorship and training, absence of strict assessment process and low attention and commitment from top management were among the implementation challenges identified in study area.

In terms laboratory services at study area well done based on the standard that based on quality manual in all laboratory functions and standards for specific aspects of laboratory work which account to the nationally Ethiopian accreditation service (EAS) and internationally recognized standards that set by the international organization for Standardization (ISO), and standards set by the clinical laboratory standards institute (CLSI) for implementation of QMSs and accreditation of clinical laboratories.

8.2. Recommendation

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

- ❖ The regional laboratories are better to mentors the hospitals laboratories within the update information related to SLIPTA audit and QMS implementation.
- ❖ The hospital management is better to understand the importance of QMS in their hospital and support it for better laboratory auditing outcome for better health care delivery and better to do on standard management system which looks at the whole system is extremely important for achieving good laboratory performance within the hospitals.
- ❖ Laboratory management and the staffs are better to be faithful to their profession and strive to increase the reputation of their profession.
- ❖ The Zonal health bureau supply management focus on equipment and reagent supply system is better to go beyond supplying laboratory commodities and give attention special consideration for laboratory service under quality tests and QMS implementation.
- ❖ Jimma University is better to revise their the hospital curriculum and incorporate the concepts of LQMS and SLIPTA audit to make ISO 15189 in the zonal hospitals and give training for laboratory professionals more informed and competent regarding the issue of LQMS and SLIPTA audit at Zonal level.

REFERENCE

1. Armstrong M. (2009) *Armstrong's handbook of management and leadership a guide to managing for results*. Kogan; 2009.
2. World Health Organization (WHO), (2011), *Library Cataloguing in Publication Data Laboratory quality management system, handbook*.
3. Lynne S. Garcia (2014), Editor in Chief LSG & Associates, Santa Monica, California, *Clinical laboratory management, 2nd edition textbook*.
4. Alharouny E, Elbanna AA, Elgarihy S, Aref NI, Abdalla A, Hassanien SA, et al.(2021), *Implementing Laboratory Quality Management Standards to Improve Clinical Diagnostic Services in Portsaid Governmental Hospitals*. *Medicine Updates*. 2021; 5(5):60–77.
5. World health organization regional office for Africa (2020), *Guide for the Stepwise Laboratory Quality Improvement Process towards Accreditation (SLIPTA) in the WHO African Region-Revision 2*, ISBN: 978-929023441-8.
6. World health organization (WHO), (2008), *Guidelines on establishment of accreditation of health laboratories, WHO-regional office for South-East Asia*.
7. Frank. S, Caroline. M, and Richard C. Friedberg (2017), *International Organization for Standardization ISO: 15189* Caroline Maurer College of American Pathologists, 325 Waukegan Road Northfield, IL 60093, USA; *Ann Lab Med* 2017, 37:365-370, <https://doi.org/10.3343/alm.2017.37.5.365>.
8. James. O, Sten A. (2014), *Basic Quality Management Systems; Essentials for Quality Management in the Medical Laboratory* Library of Congress Control Number 2014, 903024, ISBN 1-886958-28-9 textbook.
9. Garfolo BT, L'Huillier B. (2015), *Demystifying Assessment: The Road to Accreditation*. *Journal of College Teaching & Learning*. 2015; 12(3):151-70.
10. Manickam TS, Ankanagari S. (2015), *Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation*. *Journal of Medical Laboratory and Diagnosis*. 2015; 6(5):27-35.
11. Rusanganwa V, Gahutu JB, Evander M, Hurtig AK.(2019), *Clinical referral laboratory personnel's perception of challenges and strategies for sustaining the laboratory quality management system: a qualitative study in Rwanda*. *American Journal of Clinical Pathology*. 2019; 152(6):725-34.
12. Lulie AD, Hiwotu TM, Mulugeta A, Kebede A, Asrat H, Abebe A, et al.(2016), *Perceptions and attitudes toward SLMTA amongst laboratory and hospital professionals in Ethiopia*. *African Journal of Laboratory Medicine*. 2016; 5(2):1-6.
13. Mosadeghrad AM. (2014), *Factors affecting medical service quality*. *Iranian journal of public health*. 2014; 43(2):210.
14. Agboli E, Kye-Duodu G, Quaye L, Adeze-Kpodo R, Lokpo S, Atadja P, et al.(2018), *Gaps in Laboratory Quality Management Systems in the Volta Region of Ghana*. *AJMAH*. 2018 Feb 1; 10(1):1-9.
15. Perovic O, Yahaya AA, Viljoen C, Ndiokubwayo JB, Smith M, Coulibaly SO, et al. *External quality assessment of bacterial identification and antimicrobial susceptibility testing in African national public health laboratories, 2011-2016*. *Tropical Medicine and Infectious Disease*. 2019; 4(4):144.
16. Ikranbegiin R, Schmid G, Hoos D, Young A, Della-Latta P, Spearman P, et al.(2019), *Challenges and solutions for instituting an efficient maintenance program for laboratory*

- equipment in Central Asian, and developing world, countries. *BMC Public Health*. 2019; 19(3):1-9.
17. Getahun MS, Yemanbrhane N, Desalegn DM, Kitila KT, Dinku TT, Wondimagegnehu DD, et al. Medical laboratory accreditation in a resource-limited district health centre laboratory, Addis Ababa, Ethiopia. *African Journal of Laboratory Medicine*. 2019; 8(1):1-5.
 18. Mesfin EA, Taye B, Belay G, Ashenafi A. (2015), the status of medical laboratory towards of AFRO-WHO accreditation process in government and private health facilities in Addis Ababa, Ethiopia. *Pan African Medical Journal*. 2015; 22(1).
 19. Sisay A, Gurmessa A, Liknew W (2020), Factors Affecting Implementation of Laboratory Quality Management System in Addis Ababa Public Health Laboratories, Addis Ababa, Ethiopia.
 20. Gurmessa, A., Sisay, A., (2017), Proficiency test feedback utilization at government hospitals laboratory, Addis Ababa, Ethiopia. *J Med Diagn Meth* 6, 2.
 21. Carey, R.B., Bhattacharyya, S., Kehl, S.C., Matukas, L.M., Pentella, M.A., Salfinger, M., Schuetz, A.N., (2018), Practical guidance for clinical microbiology laboratories: Implementing a quality management system in the medical microbiology laboratory. *Clinical microbiology reviews* 31, e00062-17.
 22. Mesfin, E.A., Taye, B., Belay, G., Ashenafi, A., Girma, V., (2017), Factors affecting quality of laboratory services in public and private health facilities in Addis Ababa, Ethiopia. *Ejifcc* 28, 205.
 23. Lucia M. Berte (2018), Quality systems consultant in Elmhurst, Quality Management for the Laboratory <https://academic.oup.com/labmed/article/27/4/232>.
 24. Zarei, E., Karimi, S., Mahfoozpour, S., Marzban, S., (2019), assessing hospital quality management systems: evidence from Iran. *International Journal of Health Care Quality Assurance*.
 25. Beyanga M, Gerwing-Adima L, Jackson K, Majaliwa B, Shimba H, Ezekiel S, et al. (2018), Implementation of the laboratory quality management system (ISO 15189): Experience from Bugando Medical Centre Clinical Laboratory-Mwanza, Tanzania. *African Journal of Laboratory Medicine*. 2018 Jul 31; 7(1):6.
 26. ES ISO-15189:2013, (2013), Ethiopian Standard, Published by Ethiopian Standards Agency Medical Laboratories Requirements for quality and competence Second edition.
 27. Beyene K. (2015), Assessment on the Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) Implementation in Selected Public Hospital Laboratories in Ethiopia. Addis Ababa University.
 28. CLSI. (2011), Quality Management System: A Model for Laboratory Services; Approved Guideline.
 29. World Health Organization (2016), Stepwise implementation of a quality management system for a health laboratory, WHO, Regional Office for the Eastern Mediterranean, ISBN: 978-92-9022-143-2-5.
 30. Molinéro-Demilly V, Charki A, Jeoffrion C, Lyonnet B, O'Brien S, Martin L.(2018), An overview of Quality Management System implementation in a research laboratory. *International Journal of Metrology and Quality Engineering*. 2018; 9:2.
 31. Morgan J. (2011), GLP Protocols and Study Conduct-It Just Takes a Little Planning. *Journal of GXP Compliance*; 15(3):54.

32. Albert H, de Dieu Iragena J, Kao K, et al. (2017), Implementation of quality management systems and progress toward accreditation of NTRLA. *Afr J Lab Med.* 6(2), a490.<https://doi.org/10.4102/ajlm.v6i2.490>.
33. Homolka S, (2019), Introduction of quality management in a National Reference Lab in Germany. *PLoS*, one 14(10): e0222925, <https://doi.org/10.1371/journal.pone.022292.35>.
34. Tamil S. Manickam and Srinivas. A (2015), Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation. *Journal of Medical Laboratory and Diagnosis.* Vol. 6 (5), pp-27-35.
35. Beth Skaggs et.al. (2016), Implementing Laboratory Quality Management Systems in Mozambique. The Becton Dickinson-US President Emergency Plan for AIDS Relief Public-Private Partnership Initiative, the *Journal of Infectious Diseases*; 213 (S2) S47-52.
36. Lucy A Perrone et al. (2016), Implementation research: a mentoring programme to improve laboratory quality in Cambodia *Bull World Health Organization*, 94-743-751: doi <http://dx.doi.org/10.2471/BLT.15.163824>.
37. Mbah H, Ojo E, Ameh J, Musuluma H, Negedu-Momoh OR, Jegede F, et al.(2014), Piloting laboratory quality system management in six health facilities in Nigeria. *PLoS One.* 2014; 9(12):e116185.
38. Nwaokorie FO, Ojo EA, (2018), Overview of the Implementation of Quality Management System in Nigerian Medical Laboratories, *University of Lagos Journal of Basic Medical Sciences Volume 6, Numbers 1 & 2.*
39. Maingi Luke Nthenge (2016), Factors Affecting Quality Management in Public Institutions: A Case Study of Machakos University, Kenya; *Food Science and Quality Management*, ISSN 2224-6088 (Paper) ISSN 2225-0557 (Online), Vol.58.
40. Zohoun A., et al. (2021), from benchmarking to best practices Lessons from the laboratory quality improvement programme at the military teaching hospital in Cotonou Benin. *Afr J Lab Med.* 2021, 10 (1), a1057. <https://doi.org/10.4102/ajlm.v10i1.1057>.
41. Luman ET., (2014), a comprehensive review of the SLMTA literature part 2: Measuring success. *Afr J Lab Med.* 2014, 3(2), Art. #276, pages 8. <http://dx.doi.org/10.4102/ajlm.v3i2.276>.
42. Mogessie, H., Medhin, G., Aseffa, A., (2014), Quality management system of level II laboratories providing CD4+ T cell count and AFB microscopy services in Addis Ababa, Ethiopia. *The Ethiopian Journal of Health Development* 28.
43. Mekonen, T., et.al. (2017), Implementation of quality management systems and progress towards accreditation of national tuberculosis reference laboratories in africa. *African Journal of Laboratory Medicine* 6, 1-8.
44. Mogese H. (2013), Laboratory Quality Management System Assessment of Level II Laboratories Providing CD4 Testing and AFB Microscopy Services in Addis Ababa, Ethiopia.
45. Desale, A., Taye, B., Belay, G., Nigatu, A., (2013), Assessment of laboratory logistics management information system practice for HIV/AIDS and tuberculosis laboratory commodities in selected public health facilities in Addis Ababa, Ethiopia. *Pan African Medical Journal* 15.
46. Abay S, et al. (2015), assessing the outcome of Strengthening Laboratory Management towards Accreditation (SLMTA) on laboratory quality management system in city government of Addis Ababa, Ethiopia, *Pan African Medical Journal.* 20, 20:314+doi: 10.11604/pamj. 2015.20.314.537.

47. Mulleta, D., Jaleta, F., Banti, H., Bekele, B., Abebe, W., Tadesse, H., Eshetu, L., Zewdu, A., Botoré, A., Tadesse, L., (2021), The Impact of Laboratory Quality Management System Implementation on Quality Laboratory Service Delivery in Health Center Laboratories of Oromia Region, Ethiopia. *Pathology and Laboratory Medicine International* 13, 7.
48. http://distancebetween2.com/addis_ababa/jimma.

ANNEXES

Annex I: SLIPTA Checklist-V-2:2015

WHO-AFRO SLIPTA Checklist Version 2:2015 used to assess the implementation of laboratory QMS in comparison with the previous assessment baseline results and to identify non conformities encounter during the assessment of medical laboratory.

<https://apps.who.int/iris/handle/10665/204423>

Annex II: Quantitative questionnaires

JIMMA UNIVERSITY, INSTITUTE OF HEALTH, SCHOOL OF MEDICAL LABORATORY SCIENCE, DEPARTMENT OF CLINICAL LABORATORY MANAGEMENT.

Questionnaires for the laboratory professional study participant

This questionnaire uses to assess the implementation of laboratory QMS and its implementation challenges in public hospitals in Jimma Zone, Ethiopia, 2021.

Study participant Consent

My name is **Zelalem Tesfaye**, I am Postgraduate Student in Clinical Laboratory Management at, Institute of Health, Jimma University. I prepare this questionnaire to assess the implementation of laboratory quality management system and its challenges in public hospitals in Jimma Zone. The purpose of this study is to get information on the implementation of QMS and challenges of public hospital those give service to Jimma Zone dwellers. To design appropriate intervention to address quality management implementation gaps of public hospital laboratories. Therefore your honest opinion and genuine participation by responding the questions is highly appreciable and helpful to attain this study objective.

The aim of this study: is to know the level of implementation of QMS in the laboratory, to identify challenges during implementation to give a useful insights and understanding the problem of the hospital and laboratory management. The information you give could help us to find out the level of participation of staff and management, barrier, challenges and possible solutions for the recommendation to improve laboratory QMS.

Risks for participant: the proposed research does not have any drawback on the research participants to any harm, social discrimination, physiological trauma and economical loss.

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

INFORMED CONSENT FORM IN AMHARIC.

ጅም ዩንቨርሲቲ ፣ ህክምና ኢኒስቲቲዩት ፣ ጤና ሳይንስ ፈካሊት

ላቦራቶሪ ትምህርት ክፍል

ይህ ቃለ መጠይቅ የተዘጋጀው በመንግስት ሆስፒታል የላቦራቶሪ አገልግሎት ጥራት አስተዳደር ስርዐት አፈፃፀም እና ተሳትፎውን የሚወስኑ ምክንያቶችን ለማጥናት ነው።

ፈቃድ መጠየቂያ

ዘላለም ተስፋዬ እባላለሁ በጅም ዩንቨርሲቲ ፣ ጤና ኢኒስቲቲዩት ፣ ጤና ሳይንስ ፈካሊት ፣ በላቦራቶሪ ትምህርት ክፍል የሁለተኛ ዲግሪ ተማሪ ነኝ። ይህን ቃለ መጠይቅ ለእርስዎ ያቀረብኩት “**Implementation of laboratory QMS and its challenges in public hospitals in Jimma zone, southwest Ethiopia**” በመንግስት ሆስፒታል ፣ የላቦራቶሪ አገልግሎት ጥራት አስተዳደር ስርዐት አፈፃፀም እና ተሳትፎውን የሚወስኑ ምክንያቶችን ለማጥናት ነው። በሆኑም የእርስዎ ግልጽ እውነተኛ ተሳትፎ የጥናቱን አላማ ለማሳካት ጉልህ ድርሻ አለው። የተሳታፊው ስም ባለመጻፉ ሚስጥራዊነቱ የተጠበቀ ነው። መመለስ የማይፈልጉትን ጥያቄ ያለመመለስ።

እንዲሁም ጥናቱ ላይ ያለመሳተፍ ሙብተዎ በማንኛው ሰዓት የተጠበቀ ነው።

ለመመለስ ፍቃደኛ ነዎት

ሀ. አዎ

ለ. የለም

ለመመለስ ፍቃደኛ ከሆኑ ብቻ ወደሚቀጥ ለው ገጽ ይቀጥሉ። መጠይቁ በእንግልዘኛ የተዘጋጀ ነው።

እናመሰግናለን!

ዘላለም ተስፋዬ

INFORMED CONSENT FORM IN AFAN OROMO

YUUNIVARSIITII JIMMAA, INSTIITUYITHI FAYYAATTI

FAKALTII SAAAYINSII FAYYAA

MUUMMEE BARNOOTA SAAAYINSII LAABORAATOORII

Gaaffiiif deebiin kun kan qophaa'ee Hospitaala mootummaa kutaa laaboraatoorii keessatti kenninsaa tajaajilaa fayyaa qulqullinaa tajaajilaa fi hanqinoota isaa qorachuun kan qophaa'eedha.

Gaaffii Iftooma

An maqaan koo **Zalaalam Tasfaayee**'n jedhama, Yuunivarsiitii Jimmaa, Muummee sayinsii fayyaa Laaboraatooriitti baraata digirii 2ffaa gosa barnoota laaboraatoorii manajimeentiittin baraachaan jira. Yeroo amma kana barnoota koo xumuruuf kan galtee qorannoo naaf ta'u mata duree "**implementation of laboratory QMS and its challenges in public hospitals in Jimma zone, southwest Ethiopia**" jedhuun hospitaaloota mootummaa shan filatamaan keessatti hojjechuuf qophii dursaa xumureen jira kanaaf isiinis deebii gaaffii kana keessatti ka'aan haalan deebisuun galtee firrii kootti akka tataan abdiin qaba. Yeroo deebii kennitaan kan dhugaarratti hunda'eefi gara fulduraatti mana hojii keessaniif galtee qorannoo biroo akka ta'u beekuun kan ta'eefi deebiin deebiftaan martinuu iccitiin kan egamuu ta'u isaa gamanumaan ibsaa qorannoo kana irratti hirmachuu keessanif galatoomaa.

Zalaalam Tasfaayee

Part one: Background information

Assurance of Principal Investigator: I put my signature below to confirm you that I take over the responsibility for the information that you give.

Name of data collector _____ Sign _____ Date _____

Demography

110. Sex
A. Male B. Female
120. Age _____
130. Educational background
A. Certificate C. BSc. Degree
B. Diploma D. MSc. Master and Above
140. Professional level
A. Junior professional D. Chief expert professional
B. Senior professional E. Expert professional
C. Chief professional
150. Type of hospital that you serve?
A. Referral Hospital C. Primary Hospital
B. General Hospital
160. Position in the organization
A. Laboratory head
B. Section/department head
C. Laboratory expert
D. Quality officer
107. Years of experience in laboratory professional
A. 6 Months -2 Year C. 6-10 Years
B. 3-5 Years D. >10 Years

Part two: Information of lab professional about LQMS

The following questions were answered by laboratory professional's personnel that help the principal investigator to identify challenge of the implementation of laboratory QMS and **encircle** the degree of number that provide under the columns view.

Strongly disagree	Disagree	Partially agree	Agree	Strongly agree
1	2	3	4	5

S.No	Activities	Strongly disagree	Disagree	Partially agree	Agree	Strongly agree
2.01	The laboratory professionals have information of laboratory QMS	1	2	3	4	5
2.02	You are interested and participant on implementing of QMS in laboratory	1	2	3	4	5
2.03	The LQMS is important in the laboratory	1	2	3	4	5
2.04	There are sufficient laboratory personnel in this hospital	1	2	3	4	5
2.05	The laboratory professionals perform the laboratory activities according to the duty roster	1	2	3	4	5
2.06	All laboratory personnel have a job description based on service delivered	1	2	3	4	5
2.07	The laboratory applies national or international standard system (ISO) in laboratory	1	2	3	4	5
2.08	The laboratory has written manual, policies and procedures available in laboratory	1	2	3	4	5
2.09	The laboratory has well organized documentation and recording system in laboratory	1	2	3	4	5
2.10	The laboratory has TAT for all tests.	1	2	3	4	5
2.11	The laboratory has sufficient working equipment's and reagents.	1	2	3	4	5
2.12	The laboratory has a system to	1	2	3	4	5

	customer's complain on the service delivered in the laboratory					
2.13	The hospital management controls and supports the laboratory	1	2	3	4	5
2.14	There is appropriate maintenance system for laboratory equipment	1	2	3	4	5
2.15	The laboratory has comfortable working environment for the professionals	1	2	3	4	5
2.16	There is a consistent power supply in the laboratory	1	2	3	4	5
2.17	How much is your satisfaction in laboratory profession	1	2	3	4	5
2.18	The laboratory professionals adhere to the available SOPs	1	2	3	4	5
2.19	There is high work load in this laboratory	1	2	3	4	5
2.20	Continual improvement activities are being done in the laboratory.	1	2	3	4	5
2.21	The quality review meeting conducted in the laboratory	1	2	3	4	5
2.22	There is a risk analysis and management system in this laboratory	1	2	3	4	5
2.23	There is the clinical audit system in this laboratory	1	2	3	4	5
2.24	There is ICT department delegated for laboratory department who can solve the problem happened in the laboratory	1	2	3	4	5
2.25	If the ICT department is not available there is computerized hospital management information system (HMIS) in the laboratory	1	2	3	4	5

Annex III: Qualitative questionnaires

INFORMED CONSENT FOR KEY INFORMANTS

My name is **Zelalem Tesfaye**, I am Postgraduate Student in Clinical Laboratory Management at, School of Medical Laboratory Science, Faculty of Health Sciences, Institute of Health, Jimma University. I prepare this questionnaires to assess the implementation of laboratory QMS and its challenges in public hospitals in Jimma Zone. The purpose of this study is to get information on the implementation of QMS and its implementation challenges of public hospital those give service to Jimma Zone dwellers. To design appropriate intervention to address quality management implementation gaps of public hospital laboratories. Therefore, your honest opinion and genuine participation by responding the questions is highly appreciation and helpful to attain this study objective.

Part three: Demography of the key informants

301. Sex

1. Male

2. Female

302. Age _____

303. Educational background

1. Diploma

3. Medical doctor (MD)

2. 1st Degree

4. 2nd Degree (Masters)

304. Type of hospital that you serve/Lead?

1. Referral Hospital

3. Primary Hospital

2. General Hospital

305. Professional level

1. Junior professional/Manager

3. Chief professional/Manager

2. Senior professional/Manager

4. Expert professional/Manager

306. Position in the organization

1. CEO

5. Quality officer

2. Hospital Manager

6. Budget head

3. Lab Department head

7. Purchaser head

4. Safety officer

307. Years of experience in the hospital

1. <1 Year

3. 5-7 Years

5. >11 Years

2. 1-4 Years

4. 8-10 Years

Part four: Interview questions for quality committee/key informants guide questionnaires

401. How do you see the implementation of QMS in the hospital?

402. How do you see the participation of laboratory professionals in QMS in the hospital?

403. What are the challenges facing in the implementation of QMS in the hospital?

404. What is your knowledge and readiness of clinical management team to sustain QMS in their laboratories?

APPROVAL SHEET

School of Graduate Studies, Faculty of Health Science

Institute of Health, Jimma University

MSc Thesis Submission form

Name of Student: **Zelalem Tesfaye**

Program of Study: **CLINICAL LABORATORY MANAGEMENT**

Title: **“Implementation of Laboratory QMS and Its Challenges in Jimma Zone Public Hospitals Laboratories”**

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: _____ 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: Dr. Tesfaye Kassa (PhD, Assoc. professor) Signature _____ Date _____

Mr. Mitiku Bajiro (MSc, Ass. professor) Signature _____ Date _____

Mr. Daniel Emana (MSc, Ass. Professor) Signature _____ Date _____

Examiner (internal): _____ Signature _____ Date _____

Examiner (external): _____ Signature _____ Date _____

Department Head: _____ Signature _____ Date _____

Decision/suggestion of department graduate council (IRS)

Chairperson of DGC Name _____ Signature _____ Date _____

Chairperson of IRS Name _____ Signature _____ Date _____