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Assessment of Factors Affecting Quality of Clinical Laboratory Service in Health Facilities at South West Shewa Zone, Oromia, Ethiopia.

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This is to certify that the thesis prepared by TamiratWakuma entitled:

Assessing Factors Affecting Quality of Laboratory Service in South West Shewa zone Health Facilities and submitted in partial fulfillment of the requirements for Master of Science degree in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance specialty track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abbreviations and Acronyms

AFCAD Africa Collaborative Initiative to Advance Diagnostics

ASLM African Society for Laboratory Medicine

CDC Center of Disease Control and Prevention

CLSI Clinical and Laboratory Standards Institute

EPHI Ethiopia Public Health Institute

HR Human resource

ISO International Organization for Standardization

QA Quality Assurance

QMS Quality Management system

SLIPTA Stepwise Laboratory Quality Improvement Process Towards Accreditation

SSA Sub-Saharan Africa

TQM Total Quality Management

WHO World Health Organization

WHO-AFRO World Health Organization Regional Office for Africa's

Abstract

Background: A quality medical laboratory service is an important part of the health care system. Commitment of the health personnel, administration and policy makers contribute to the continuous improvement of diagnosis. In developing countries like Ethiopia, the laboratory quality system remains weak due to several factors. Therefore, assessing the factors affecting quality of medical laboratory service is highly important in order to improve service quality.

Objective: To assess factors affecting the quality of medical laboratory service in South West Shewa Zone Health Facilities, Oromia, Ethiopia, January 2020 to May 2020.

Methods: An institution based cross-sectional study was conducted at South West Shewa Zone Health Facilities from January 2020 to May 2020. A pretested, structured questionnaire and checklist was used to collect the socio-demographic information of the study participants and to assess factors affecting the provision of quality medical laboratory services. Data were checked for completeness, entered, and analyzed using SPSS version 24. The strength of association between the dependent and independent variables was assessed using binary and multiple logistic regression analysis. A p-value < 0.05 was considered statistically significant.

Results: A total of 85 medical laboratory professionals participated in the study. Of these, 68 (80%) were males and 27 (31.8%), were laboratory technologists. Of them 78 (91.8%) were not satisfied with their salary. Thirty-two (37.6%) of the participants reported that their laboratory did not provide quality laboratory service. Lack of Quality Manual, Lack of staff recognition and not conducting Internal Quality control activities were the major factors significantly associated with poor quality laboratory service ($p < 0.05$). High work load was identified as the highest technical factor influenced the provision of quality laboratory services 56.1%, followed by Equipment Failure 20% and from administrative factors shortage of resources was rated highest 39% followed by poor staff commitment 23.4%.

Conclusions: More than One third of the study participants reported that their laboratory did not provide quality laboratory services. Lack of quality manual, not conducting internal quality control activities and Lack of staff recognition are the major factors associated with poor quality of laboratory services. Hence timely intervention of these factors is warranted since a third of the participants believe their laboratory does not provide quality service.

Key words: Medical Laboratory, Quality Management system, Ethiopia

1. Introduction

1.1. Background

Laboratory quality can be defined as accuracy, reliability, and timeliness of the reported test result. 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(1).

Poor quality laboratory service leads to many challenges and it could lead to a serious health problems such as inappropriate action or inaction leading to over treatment, over investigation or mistreatment, lack of treatment or inadequate investigations. Laboratories practicing the principles of quality assurance (QA) generates: relevant, reliable and cost-effective results. Reliable results produced by a laboratory improve the decision making capacity of the clinicians as well as public health physicians and poor quality of laboratory services could adversely affect the credibility of the laboratory(2).

Delivery of high-quality laboratory services is essential in the health-care system both for providing the diagnosis service or clinical decisions and as an objective means to measure and monitor biological markers. Accurate and timely laboratory analyses are critical to identify, track, and limit public health threats which ultimately will reduce rates of preventable morbidity and mortality. Optimal functioning of the public health system to meet these threats is dependent on uniform and high-quality laboratory testing(3).

In order to improve the quality of health laboratory service International Organization for Standardization (ISO-15189) has recommended assessment and monitoring of quality management systems (QMS) in laboratory as quality improvement efforts towards quality laboratory services(4).

In many developing countries laboratories have historically suffered from inadequate infrastructure, limited funding, and lack of skilled personnel. This gap in health laboratory leads to poor access to accurate laboratory services which can result in misdiagnosis. The inability to provide etiological confirmations during disease outbreaks can lead to delays in responding efficiently to outbreaks and difficulties in controlling or eradicating endemic diseases, elevating risk of disease transmission, and fueling economic costs(5).

Though laboratory is the key element of health systems, nevertheless in Sub Saharan Africa, with characteristically huge disease burden, laboratories are among the world's poorly equipped and resourced limited facilities with consequent paucity of laboratory supplies. Poor staff attitude, poor state of infrastructure, difficult work flow due to unstructured floor plan, and interrupted power supply poses challenge to the smooth implementation of quality improvement (QI)(6).

In the majority of less developed countries, laboratory services at the intermediate and peripheral level are limited, poorly managed and lack qualified personnel. This is due to an urban bias in the resources distribution in developing countries. The urban bias applies to both facilities and health manpower and international health policies shifted from the comprehensive primary health care (PHC) approach, to a more selective approach with emphasis on disease-oriented programs(7).

In Ethiopia the problems in the laboratories could be aggravated, particularly at peripheral levels, due to different reasons. These include lack of properly designed laboratory rooms, lack of water and electricity access, shortage of equipment and supplies, absence of effective maintenance and spare parts and lack of follow up and supervision. Though, the problem was aggravated in hospital-based laboratories, shortage of supplies and reagents were reported from all health institutions. Moreover, there is weak quality assurance system practice(8).

The government of Ethiopia has shown commitment for quality improvement in laboratories and on quality laboratory service. But still it is our day to day experience to come across patients and physician's complaint about the quality service they are receiving from laboratories (9).

The Ethiopia Public Health Institute (EPHI) is working with regions, partners, and stakeholders to coordinate efforts on bringing each tier of the network up to the standards. This is done in coordination with the quality program, which were utilized in the context of identifying gaps between the state of laboratories and the national standard(10).

1.2. Statement of problem

Quality systems remain as the fundamental need for today's laboratory patient management. In Public health medical laboratories, the provision of medical health care requires adequate access to satisfactory services from the laboratory(5). Most significant illnesses require laboratory confirmation of the diagnosis and laboratory monitoring of the patient after the diagnosis has been done. The importance of fair services provision in the functioning of health care in medical laboratories in developing countries has been universally recognized and accepted but has not been fully achieved. Total Quality Management(TQM) practices in the laboratories, therefore, would generate relevant, reliable and cost-effective results (2). Quality systems remain the need of the hour for today's laboratory patient management and its key component is in its efficiency and accuracy in analyzing, reporting and documentation of results.

Laboratories have suffered from: inadequate infra-structure, limited funding, and lack of qualified human resources. These deficiencies hinder the performance of laboratory health workers and of public health laboratories. In turn, these challenges hinder governments' ability to manage the spread of drug resistance, respond to disease outbreaks, and scale up critical programs. Lack of access to accurate laboratory services can result in misdiagnosis, which in turn leads to compromised patient care, higher costs, and continual transmission of communicable diseases(11).

In England medical Laboratory staff faces several challenges; poor remuneration, high workforce, more unsocial hours without adequate recovery time, high staff turnaround, poor motivation, job cuts, lack of opportunities for professional growth and development. These challenges can potentially result in increased error rate, job-related stress, reduced productivity, high sickness absences, low morale, sub-optimal laboratory service delivery, job insecurity and poor work-life balance(12).

Reports identified many factors contributing to limited laboratory service quality, including lack of properly designed laboratories, insufficient monitoring of test quality, shortage of equipment and consumables, , poor maintenance systems, and lack of close follow-up, supervision, and government standards for laboratory testing and these negligence in African public health laboratories resulted in poor quality of laboratory services and ultimately the lack of utilization of laboratory results and trust by physicians and other health officials(13).

The inadequate attention to laboratory services in general has led to weak leadership in the health laboratory system. The Ministry of Health (MOH) of Zambia showed that there is inadequate numbers of qualified laboratory personnel and weak Implementation of Quality Management system. There are also inadequate and irregular availability of laboratory reagents and supplies, poor resource allocation toward laboratory service. Lack of training on QMS implementation to provide quality laboratory service ,lack of a well- coordinated laboratory inventory system to manage laboratory reagent ,equipment and other supplies are also among the challenges (14).

In Ethiopia study conducted in Addis Ababa health facilities in (2017)identified that major factors affecting the provision of quality laboratory services as shortage of resources, lack of management supports, poor equipment management system, high workload, lack of competent staff, low staff motivation, ineffective communication system and lack of well-established quality management system(15).

Despite their importance, laboratories are often under- resourced, resulting in inadequate infrastructure, poorly trained personnel, and lack of standardization. In Ethiopia, laboratory services are given little attention until recent years and there is inefficient utilization of the availability of human material resources, patient waiting for time and customer satisfaction and clients' preference regarding the laboratory service. As a result, the accessibility of quality laboratory test results and the quality of available services remains a serious challenge. In addition to this, there is a complaint of a patient and health care providers on the quality of the laboratory test results(8).

In addition to the existence of laboratory quality related problems mentioned above, the magnitude is unknown that the coverage and performance of medical laboratories of health facilities in South west shewa Zone have not been reported so far. Therefore, the aim of this study was to assess the factors associated with quality of laboratory service among laboratories of health facilities in south west shewa zone, Ethiopia.

1.3. Significance of the Study

This study contributes to understand the factors associated with quality of laboratory service since there is very little work in the country and no study in the specified area. The findings also enable the stakeholders of health in the country and regions to have an idea of the baseline factors associated with quality of laboratory services and it fulfills the gap in the data availability which enables the local health offices and other concerned bodies to utilize the data in improving the gap identified by this study.

In addition, the results of this study would provide information to promote evidence-based medicine, with an emphasis on reducing unnecessary wastage of medical resources. This would be a milestone to the improvement of quality life of people in the country as well as cost effective to already constrained resources in the health sector. Moreover it can be aspring board for policy makers and the scientific community for further programmatic andresearch endeavor.

2. Literature review

2.1. Quality of laboratory service

Clinical laboratory services are a critical component of health systems, yet they are often neglected in resource-limited countries. Laboratories play a central role in individual patient diagnosis and care, in disease surveillance and control, and in provision of accurate health data for national planning and resource mobilization. In spite of this, many millions of people, particularly those in rural and under-served areas on the African continent, still do not have access to basic reliable diagnostic laboratory services (16).

The unreliability of laboratory results is cited as one of the major limitations to laboratory support for healthcare in Africa. The utility of laboratory systems in the implementation of the International Health Regulations (IHR) is also greatly dependent on the reliability and quality of laboratory results. However, applicable and cost-effective models for achieving accurate and reliable laboratory results in the low-income African countries have yet to be optimized(17).

The provision of efficient and quality laboratory services requires a critical mass of trained, well-motivated staff, infra-structure and equipment. Study conducted in Kenya show that the environment in which the staff work and the equipment with which they perform their allocated duties make a major contribution to their well-being. It is a great challenge for health facilities to produce results of good quality if you do not have appropriate instruments which are functioning optimally. In order for laboratory to continue to have appropriate equipment, it is necessary to have a management procedure which involves a continuing assessment of need and mechanisms for evaluation and purchase(18).

A national survey conducted in Ethiopia by Hiwot Aet al (2020) on Physicians satisfaction with clinical laboratory service revealed that laboratory services did not have the same quality in all working shifts (day, night, holiday and weekend) and 12.5% of them, were doubtful of the quality of the laboratory services at any time whereas 87.5% of them did not trust the quality of the laboratory services done during the over-time (night, holiday, and weekend).In addition,only 38% of the physicians were satisfied with the interaction they have with laboratory personneland

43% of the participants were satisfied with the timely laboratory expert advisory service and (19).

A study conducted in Gonder, Ethiopia on assessment of quality of medical laboratory services provision and associated factors by Belete Bet.al (2019) revealed that 72 (69.9%) of these participants did not attend laboratory refresher training and 93 (90.3%) of participants were also not satisfied with their salary and lack of quality and adequate equipment , no continuing professional development, non-adherence to standard operating procedures, unavailability of adequate supplies and reagents, no regular internal and external quality assessment activity, no customer service management, no result verification, and laboratory safety were identified as the major factors associated with poor quality laboratory service(20).

A study conducted on factors affecting implementation of laboratory management system in Addis Ababa, Ethiopia by Abay S.et al revealed that lack of enough equipment was reported by 73.4% and for 53.9% the available equipment preventive maintenance was not conducted in the laboratory and about 18.8% the laboratory didn't communicate regularly with upper management and additionally customer satisfaction survey not conducted by 37.5% of the laboratory professionals(21).

Additionally another study conducted in Addis Ababa, Ethiopia by Eyob A. et al (2017) on factors affecting quality of laboratory service also revealed that 36% of the laboratory professionals believed that they do not provide quality of laboratory service as per to the standard(15).

2.2. Administrative Factors Affecting Quality of Laboratory Service

According to World Health Organization report (2017) a situation analysis conducted in the Eastern Mediterranean countries identified serious gaps in laboratory areas such as: organization and management of laboratory services, human resources management, document and record control, procurement and supply chain management, information systems, and laboratory monitoring and evaluation mechanisms. Mechanisms for monitoring and evaluation of laboratory performance are poor or non-existent. In particular, no quality indicators are monitored and no internal audits are conducted in many countries, while poor internal quality control (IQC)

program and lack or partial coverage by external quality assessment schemes is common. Quality system documentation, such as quality manuals, policies and standard operating procedures, where they exist, are rarely reviewed and updated and those gaps affects the laboratory from performing quality service (22).

Study conducted in Nepal by Satyam P. (2017) on the increasing trends in unhealthy practices of Clinical Laboratory Medicine Service concluded that unhealthy competition, weak monitoring system, turning service business into commercial business, use of low quality material, unskilled manpower and weak governing policy are factors affecting quality medical laboratory service in Nepal (23).

A study conducted on the current state of laboratory medicine in sub-Saharan Africa identified five types of gaps that affect quality of laboratory service : physical (equipment and infrastructure); professional (human resources, including training and retention); policy (national and supra-national planning); management (quality, maintenance, and supply chain management); and trust and knowledge gaps (poor communication between clinical and diagnostic personnel)(24).

The study conducted on Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City by Robert W. (2019)concluded that Administrative issues 67% reported a limited budget allocation to the public and faith based hospitals. About 44% reported that they would stop tests when reagents run out of stock, 38% of them wait for maintenance of equipment and stop tests ,and many others and no laboratory had adequate quality management systems in place(25).

According to some recent academic publications the current shortcomings or the major challenge that have impact on quality laboratory service is the physical gaps: on the physical level, there are deficiencies in terms of physical infrastructure, including equipment. These gaps are closely linked to managerial (e.g. having good maintenance plans that prolong the lifespan of equipment and increase sustainability) and professional (e.g. having qualified personnel handling the equipment correctly) challenges(26).

Concerned with human resource management insufficient education and training programs as well as poor career development prospects together lead to poor staff retention (26,27). All of these challenges negatively impact the quality of laboratory results. There is another challenge: physicians may lack trust in these results, rather relying purely on clinical judgment and empirical therapy. The consequence is that the strengthening of laboratory systems may not automatically and immediately translate into improved outcomes. Rather, improved communication between clinicians and laboratories will be required in order to build confidence and improve patient care(24, 27). Adequate human resource (HR) capacity is the backbone of a strong health care system and consumes the majority of resources allocated to health systems.

2.3. Technical Factors Affecting Quality of Laboratory Service

The study conducted on Barriers to Medical Laboratory Diagnostic Service Delivery in Mzuzu City by Robert W. (2019) concluded that laboratory personnel identified several technical barriers that affect quality diagnostic services: 79% of laboratory staff reported shortage of laboratory supplies; work overloads 69%, frequent equipment failure 22%, scarcity of modern equipment 20% and others(25).

A study Conducted in Tanzania by Yahiya D. (2011) revealed that lack of training or retraining and heavy workload as the major constraints to the performance of their laboratories. Additionally 73.0% laboratory personnel reported lack of equipment and/or reagents 7.9% mentioned shortage of working space or facilities, electricity and water as the main constraints Six (9.5%) reported that laboratory personnel were under qualified or incompetent while five (7.9%) mentioned shortage of working space or facilities, electricity and water as the main constraints. Six (9.5%) respondents did not report any constraints(28).

Wertheim and colleagues (2010) analyzed the major challenges of developing effective laboratory capacity as :lack of infrastructure, failure to create and/or implement national laboratory policies, weak procurement and supply systems, lack of standardization and quality standards, lack of equipment maintenance, and the inability to follow manufacturers' recommendations to ensure proper operational capacity of laboratory instruments(29).

Overall, stronger enforcement of national policies and the establishment of a legal authority over laboratory practice are needed in Cambodia. While achievements have been made, several management challenges still exist around enforcing habits of quality assurance such as rejecting inappropriate or poor quality specimens, regularly performing internal quality control, documenting tests and processes, performing corrective action, tracking quality indicators and maintenance of equipment. Only through strong leadership from hospital and laboratory directors will staff address these challenges. However, many laboratory managers and directors have assumed their positions through promotion due to their technical skills or seniority, and thus have not had formal laboratory management training(30).

According to a study conducted at Hawassa specialized hospital by DemissieAssegu et .al (2020) quality of laboratory service were hindered by shortage of supplies and reagents 95%, poor management support 72.5%, high workload 87.5%, missing of laboratory results 70% and lack of equipment 92.5% and about 47.5% laboratory professionals believed that they did not produce quality laboratory results for their patients(31).

Laboratory quality management not only focuses on reliable and accurate results but also concentrates on how to achieve these results through technical and management aspects. Khwanjai W.et al (2012) found laboratory management implementations in the country are not as good as technical skills, which suggests there is more management than technical problems. They showed that there is insufficient laboratory personnel, inadequate maintenance of lab equipment, inconsistent financial support and limited power to negotiate with decision-making physician or there is poor communication between laboratory personnel and physician (32).

The study at a Malawian Referral Hospital by Heiman F et.al (2016) revealed that, many of the challenges that affect quality of service are informational in nature, whether related to communication between medical and laboratory staff or the completeness of test paperwork(33)and additionally there is the inability of the laboratory to conduct key tests due to a lack of reagents or machine malfunction.

Study conducted in Afar ,Ethiopia by Andualem T et al (2018) showed that Majority of health facility laboratories (66.7%) do not perform internal quality control measures like running controls daily, checking each reagent using known positive and negative controls, and lack of result verification and in 66.7% of health facility laboratories, there were a problem of obtaining adequate stock of laboratory reagents and equipment and lack of basic laboratory equipment(34).

The other study conducted in Northern Ethiopia AwiZone by Bogale A et al (2020)on Qualityof Laboratory Malaria Diagnostic Serviceidentified as bottlenecks to the provision of high-quality laboratory services.The identifiedmajor limiting factor affecting the quality of Laboratory servicewerelack of professional development 76.9%, Lack of in-service training 14 (53.8%), excessive work load 12 (46.2%) and lack of appreciation by the management 6 (23.1%) were strongly stated as major limiting factor affecting the quality of Laboratory service(35).

The other study conducted in Addis Ababa, Ethiopia show that most of the laboratory professionals 87.8% were not satisfied with their salary and 83.6% respondents indicated that there was no system for staff recognition, and 62.4% of the laboratory professionals did not attend any task specific training and 60.1% continuing education program. A total of 70.4% of the laboratory professionals reported they had high workload while 58.7% of the respondents indicated a shortage of human resources in their laboratories. In addition, 51.6% of the laboratory professionals did not have job descriptions for the task assigned. Concerning communication, the laboratory professionals indicated that there were no systems to communicate with laboratory staff, upper management, and clinicians with respondents 59.2%, 56.3% and 35.2% respectively Laboratory documentation (documents and records) system were not practiced as per standard by 45 (21.1%) the laboratory professionals. One hundred twenty-one (56.8%) laboratory professionals also indicated that customer services management system was poor in their respective laboratories(15).

Hence, this study will focus on assessment of factors associated with quality of laboratory service in south west shewa zone health facilities. The status of factors associated quality of laboratory service in the study area was not studied therefore assessing those factors associated with quality of laboratories will have a lot of significance which includes: indicates gaps on

knowledge of laboratory professionals about laboratory quality management system, it will show the status of laboratory quality management practice and gives guidance for policy makers to strengthen the laboratory as well as health system at large. The findings will also enable the stakeholders of health in the country and regions to have an idea of the baseline factors associated with quality of laboratory service.

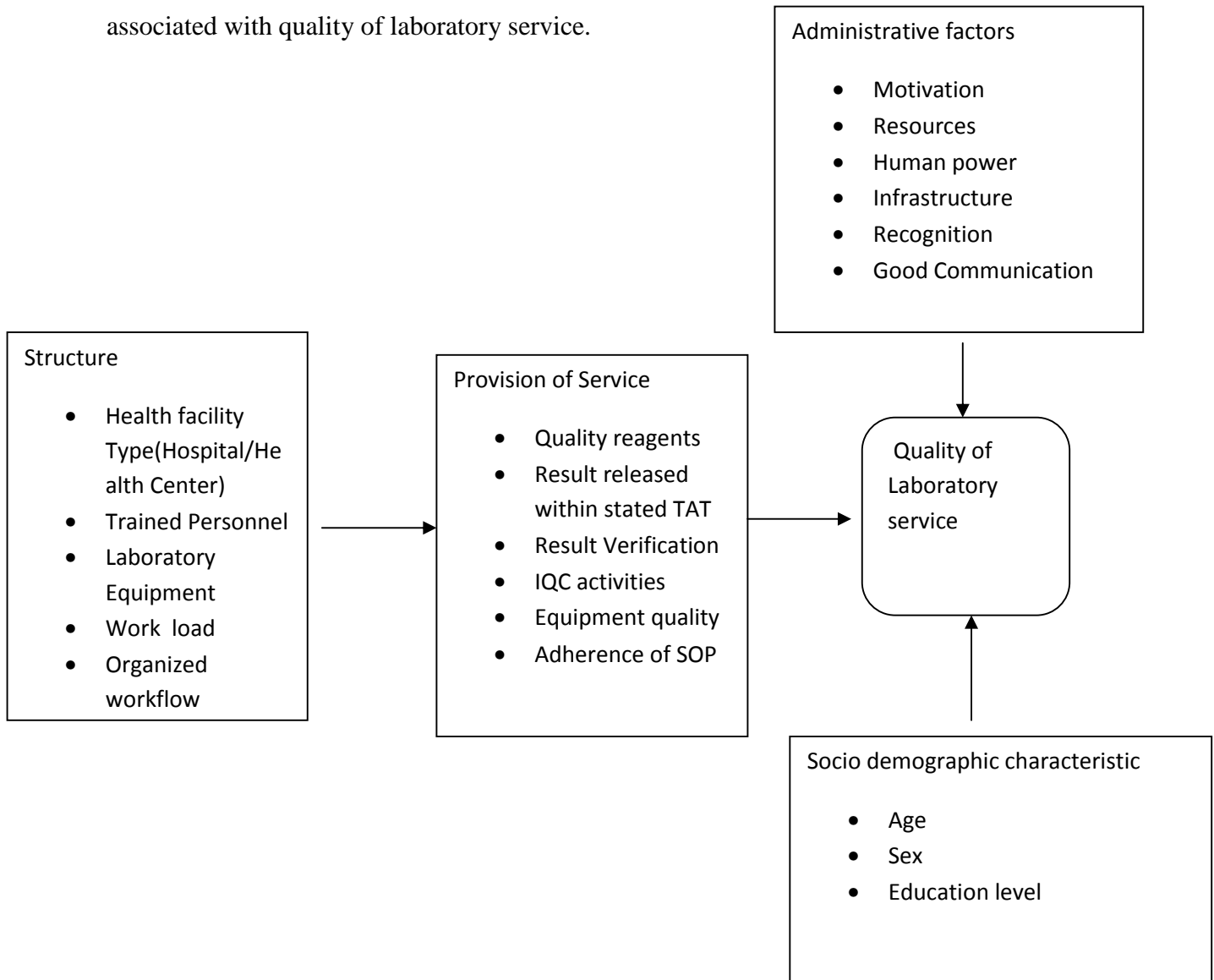


Figure 1: Conceptual framework to identify factors affecting quality of laboratory service among health facilities at south west shewa zone, 2020.

3. Objectives

3.1. General Objective

The aim of this study is to identify factors affecting quality of clinical laboratory service in health facilities at South West Shewa Zone, Ethiopia, January 2020 to May 2020.

3.2. Specific objectives

- To identify technical factors affecting quality of laboratory service in health facilities at South West Shewa Zone, Ethiopia, January 2020 to May 2020.
- To identify Administrative factors affecting quality of laboratory service in health facilities at South West Shewa Zone, Ethiopia, January 2020 to May 2020.

4. Method and materials

4.1. Study area

This study was conducted in South West Shewa Zone Health Facilities, on Laboratory staff .South-west shewa zone, which is part of Oromia Regional National state, which is located in the western central part of Ethiopia and at the same time it is located at the central part of Oromia Region. South West Shewa zone is bounded by Finfine Special zone and east Shewa zone in the North and north East, Gurage zone of SNNP Region in the West and West shewa zone in the North and West, with the total population of (1,275,281) according to population estimation of 2007 (36). It covers total area of 5812.4Km²,the geographical coordinates of south west shewa zone is approximately with elevation variation of 1550-3380 meters above sea level; temperature range of 10-30°and average annual rainfall of 1200mm³.

In South west Shoa zone there are 54 Health Center, 1 nongovernmental hospital and 4 governmental hospitals and totally 59 health institutions and there are ninety nine (99) laboratory personnel in the zone. In this study 5 hospitals 35 health centers were participated(37).

4.2. Study design and period

A facility based cross-sectional study design was conducted from January 2020 to May 2020.

4.3. Population

4.3.1. Source population

The source populations were all Laboratory professionals working in health facilities at south west Shewa zone

4.3.2. Study population

The Study populations were Laboratory professionals fulfilling the eligibility criteria and willing to participate from selected health facilities at South West Shewa zone

4.4. Inclusion and Exclusion criteria

4.4.1. Inclusion criteria

Laboratory personnel who worked at least three months in the health facility

4.4.2. Exclusion criteria

Laboratory personnel's who were on annual leave during the study period.

Laboratory personnel's who were not volunteer to participate in the study.

4.5. Study Variables

4.5.1. Dependent variables

- ❖ Quality of laboratory service

4.5.2. Independent variables

- Sex
- Age
- Educational level
- Working experience
- Health facility type
- Position in the laboratory
- Training
- Workload
- Motivation
- Availability of Laboratory reagents
- Availability of Laboratory Equipments
- Equipment Preventive Maintenance

4.5.3. Sample size and sampling technique

Medical laboratory professionals which fully fill the inclusion criteria from health facilities at South West Shewa zone were included in this study and the sample size of the study participant was 85.

Qualitative part

The qualitative data was collected by using key informant interview; unstructured interview guide questionnaire and fifteen health professionals were participated in the qualitative study. The sample size was determined based on information saturation.

4.5.4. Data collection procedure

Quantitative part

Structured questionnaire and observation check list was used for data collection. Interview was applied in order to collect the data from medical laboratory professionals. It was categorized into four parts: socio-demographic part, Knowledge laboratory personnel, Quality assurance practices of laboratory and factors associated with quality laboratory service. The data was collected by trained data collectors. Principal Investigator was involved in over-all controlling activities of data collections and assisting data collectors during the process of data collection.

Qualitative part

The qualitative data was collected from purposely selected health professionals of health facility and collected by using key informant interview, unstructured interview guide questionnaire. Data were gathered from health professionals of five hospitals and five health centers and the interviewees were physician, health officers and health facility administrator based on information saturation.

4.6. Data Management and Quality Assurance

To assure data quality, the questionnaire was pretested on Wolete health center and Dalati health center in Sebeta town before actual data collection. Based on the pretest; questions were revised and edited. During actual data collection, training was given to the data collectors. Completeness of data collected was checked every day by the principal investigator. Every day collected data was reviewed and checked for completeness and consistency of the response and the principal investigator supervise the data collection process.

4.7. Data analysis and interpretation

Data were checked for completeness, entered, and analyzed using SPSS version 24. First, descriptive statistics was computed for most of the study variables. Frequency distribution tables and graphs were used to describe the findings. Variables with p-values <0.2 in bi-variant analyses, were included in the multivariate logistic regression. To determine the presence of associations between dependent variable provision of quality laboratory service and the independent variables: socio demography variables, education background, work experience, motivation, communication, training, workload and quality assurance practices, multivariate logistic regressions were employed. Adjusted Odds Ratios with 95% confidence interval and P-values less than 0.05 were considered as statistically significant. The qualitative data was edited and compiled then thematic analysis was done.

4.8. Ethical considerations

Ethical clearance was obtained from Addis Ababa University, College of Health Sciences, Department of Medical Laboratory Sciences Department Research and Ethics Committee (DREC). Letter of permission was obtained from South West Shewa zonal health office. Informed oral consent was taken from each participant prior to interview. All information obtained from the study participants was kept strictly confidential.

4.9. Dissemination of results

The final report will be presented for Department of Medical Laboratory Sciences of Addis Ababa University. The report will also be disseminated to South West Shewa zonal health office, Oromia regional health bureau and for the study centers. Efforts will be made to present the results on scientific Conferences and for publication in Reputable Journals.

4.10. Operational definitions

- Provision of quality laboratory services: Is the ability of a laboratory service to satisfy stated or implied needs of a specific customer or fulfills requirements(38)and this will be determined as perceived by medical laboratory professional's trends.
- Technical factors: the technical aspects of the laboratory service like IQC activities,TAT,result verificationthis will be identified bymedical laboratory professionals perception.
- Administrative factors: the administrative Issues affecting quality of laboratory service and this will be identified as perceived by medical laboratory professional's trends.

5. Results

Findings from this research are presented in this part through five sets of interconnected aspects: the first part is the socio demographic profile of the respondents. Second, the descriptive finding of the study, the third part contains findings of Administrative factors, the fourth part contains findings of technical Factors and finally finding of bi-variant regression and multivariate logistic regression of major variables with quality of laboratory service.

5.1. Socio-demographic characteristics of study participants

In this study a total of 85 laboratory professionals were participated from 5 Hospitals and 35 health centers in South west shewa Zone health facilities. About 80% (68/85) of participants were male, the median age of the participants were 25 years. Sixty six (77.6%) of respondents were between 20-30 years old. Fifty nine (69.4%) of respondents were from health centers, 28 (33.0%) were Medical Laboratory Technologist (Bachelor Degree) and Fifty Seven (67.0%) were Medical Laboratory Technicians (Diploma) and 44 (51.8%) of respondents had >5 yrs work experience in the health facilities. One safety officer and 4 quality officers were part of the study (Table 1).

Table 1: Socio-demographic Characteristics of Laboratory professionals in South West Shewa Zone health facilities, Weliso, Oromia, Ethiopia, 2020.

Age		Frequency	Percent
	20-30	66	77.6
	31-40	14	16.5
	41-50	4	4.7
	51-60	1	1.2
	Total	85	100.0
Sex			
	Male	68	80.0
	Female	17	20.0
	Total	85	100.0
Health facility type			
	Hospital	26	30.6
	Health center	59	69.4
	Total	85	100.0
Educational status			
	Diploma	57	67.0
	Degree	28	33.0
	Total	85	100.0
Service year			
	<2 years	30	35.3
	2-5 years	11	12.9
	>5 years	44	51.8
	Total	85	100.0
Responsibility			
	Laboratory bench work	68	80.0
	Safety Officer	1	1.2
	Quality officer	4	4.7
	Dept head	12	14.1
	Total	85	100.0

5.2. Laboratory Quality Management Activities

In this study 78 (91.8%) of the laboratory professionals were not satisfied with their salary and 44 (51.8%) disclosed that there is no quality manual. About 62 (72.9%) of the laboratory professionals did not attend any task specific training and 62 (72.9%) of respondents did not get opportunity of continuing education program and 52 (61.2%) respondents indicated that there was no system for staff recognition.

Additionally 49 (57.6%) of the laboratory professionals claimed that they had high workload while 30 (35.3%) of the laboratory professionals had fair work load. Moreover, 47 (55.3%) of the respondents indicated a shortage of human resources in their laboratories. In addition 41 (48.2%) of the laboratory professionals did not have job descriptions for the task assigned. Concerning to communication, the laboratory professionals indicated that there were no systems to communicate with laboratory staff, upper management, and clinicians with respondents 20 (23.5%), 29 (34.1%) and 50 (58.8%) respectively (Table 2).

Regarding to laboratory equipments high proportion of the participants 54 (63.5%) of the laboratory professionals claimed that there was shortage of equipments in their laboratory and 31 (36.5%) of the participants reported shortage of reagents (Table 2).

Table 2a: Laboratory Quality Management Activities reported by Laboratory Professionals working in South West Shewa zone health facilities, Weliso, Oromia, Ethiopia, 2020.

Knowledge about quality management system		Frequency	Percent
	Yes	66	77.7
	No	19	22.3
	Total	85	100.0
Quality Manual			
	Yes	41	48.2
	No	44	51.8
	Total	85	100.0
Communication Among Laboratory Staff			
	Yes	65	76.5
	No	20	23.5
	Total	85	100.0
Laboratory Communication with physician			
	Yes	56	65.9
	No	29	34.1
	Total	85	100.0
Laboratory Communication with upper Management			
	Yes	35	41.2
	No	50	58.8
	Total	85	100.0
Satisfaction with salary			
	Yes	7	8.2
	No	78	91.8
	Total	85	100.0
System for Employee Recognition			
	Yes	33	38.8
	No	52	61.2
	Total	85	100.0
Opportunity of Continuing Education			
	Yes	23	27.1
	No	62	72.9
	Total	85	100.0

Table 2b: Laboratory Quality Management Activities reported by Laboratory Professionals working in South West Shewa zone health facilities, Weliso, Oromia, Ethiopia, 2020.

Laboratory personnel Attending of Laboratory Refreshment Training		Frequency	Percent
	Yes	23	27.1
	No	62	72.9
	Total	85	100.0
Having Written Job Description for Assigned Task			
	Yes	44	51.8
	No	41	48.2
	Total	85	100.0
Enough and Quality Supplies and Reagents			
	Yes	54	63.5
	No	31	36.5
	Total	85	100.0
Adequate and Quality Equipment's in the Laboratory			
	Yes	31	36.5
	No	54	63.5
	Total	85	100.0
Patient Satisfaction Survey Conducted			
	Yes	30	35.3
	No	55	64.7
	Total	85	100.0
Enough Number of Staff for Laboratory Service			
	Yes	38	44.7
	No	47	55.3
	Total	85	100.0
Laboratory Work Load			
	High	49	57.6
	Fair	30	35.3
	Low	6	7.1
	Total	85	100.0

5.3. Quality assurance practices and provision of quality laboratory service

According to this study from all participants only 53 (62.4%) of the participants believed that they provide quality laboratory service and the rest 32 (37.6%) of them mentioned that they do not provide quality laboratory service according to the standard as shown in Table 3.

Regarding to quality assurance practice and provision of laboratory service, findings from this study revealed that 31(36.5%) of the respondents indicated that there was supplies and reagents interruption and 36 (42.6%) laboratory professionals did not perform equipment preventive maintenance as per instruction. Additionally, internal quality control (IQC) was not conducted as stated by more than 34.1% while 9.4% not regular and complete. Of the respondents only 25(29.4%) of the laboratory professionals verify laboratory results, is shown in Table 3.

Additionally 34 (40%) of respondents claimed that laboratory results were not released within pre-defined turnaround time and 50 (58.8%) laboratory professionals also indicated that customer services management system was poor in their respective laboratories

Three (3.5%) laboratory professionals did not monitor laboratory safety practices and 9 (10.6%) the professionals also did not use personal protective equipment (PPE) is shown in [Table 3](#).

As regard to laboratory services, 32 (37.6%) laboratory professionals believed that their laboratories did not provide quality of laboratory services as per the standards as displayed in Table 3. In addition to this, 56 (65.8%) of professionals reported that there were frequently laboratory service interruption in their respective laboratories due to several reasons.

Table 3a: Laboratory Provision Activities Reported by Laboratory Professionals working in South West Shewa zone health facilities ,Weliso, Oromia, Ethiopia,2020.

Adherence to the Standard Operating Procedures		Frequency	Percent
	Yes	71	83.5
	No	12	16.5
	Total	85	100.0
Performing Equipment Preventive Maintenance			
	Regularly and completely	38	44.7
	Irregular	11	12.9
	No	36	42.4
	Total	85	100.0
Utilization of Personnel Protective Equipment			
	Yes	76	89.4
	No	9	10.6
	Total	85	100.0
Habit of Applying Laboratory Safety Practice			
	Yes	82	96.4
	No	3	3.5
	Total	85	100.0
Standard test request and Reporting Format			
	Yes	71	83.5
	No	14	16.5
	Total	85	100.0
Provision of Uninterrupted Diagnostic Service			
	Yes	29	34.1
	No	56	65.9
	Total	85	100.0
Customer Service Management			
	Yes	35	41.2
	No	50	58.8
	Total	85	100.0
Laboratory Result Reported Within Turn Around Time			
	Yes	51	60.0
	No	34	40.0
	Total	85	100.0

Table 3b: Laboratory Provision Activities Reported by Laboratory Professionals working in South West Shewa zone health facilities, Weliso, Oromia, Ethiopia, 2020.

Laboratory Result Verification			
	Yes	25	29.4
	No	60	70.6
	Total	85	100.0
Participation on EQA activities			
	Yes	70	82.4
	No	15	17.6
	Total	85	100.0
Performing Internal Quality Control Activities			
	Completely and regularly	48	56.5
	Incomplete and irregular	8	9.4
	Not performed	29	34.1
	Total	85	100.0
Setting Biological Reference Range for Each Tests			
	Yes	42	49.4
	No	43	50.6
	Total	85	100.0
Setting Criteria for Accepting and Rejecting Samples			
	Yes	39	45.9
	No	46	54.1
	Total	85	100.0
Laboratory class Enough Room with Mini store			
	Yes	51	60.0
	No	34	40.0
	Total	85	100.0
Provision of Quality Laboratory service			
	Yes	53	62.4
	No	32	37.6
	Total	85	100.0

5.4. Factors affecting provision of quality laboratory services

5.4.1. Technical Factor

Regarding to technical factors that affecting the quality assurance practice and provision of laboratory service, this study revealed that high workload, equipment failure and skill gap on quality assurance practice were the major technical factors affecting the quality assurance practices and provision of laboratory services (Table 4).

Table 4 Technical Factors Affecting quality of laboratory service activities reported by laboratory professional working in south west Shewa zone health facilities, Weliso, oromia, Ethiopia, 2020.

Variables*	Equipment Failure	lack of refreshing training	High work Load	Poor equipment quality	Skill gap
The reason for Equipment Preventive Maintenance not Performed (n=31)	2 (6.3%)	4 (13%)	21 (67.7%)		4 (13%)
The reason for interrupted Diagnostic Service (n=25)	14 (56%)	2 (8%)	-	3 (12%)	6 (24%)
The reason for no adherences to the Standard Operating Procedures (n=13)	-	-	3 (23%)	-	10 (67%)
The reason for no Customer Service Management (n=17)	-	2 (11.8%)	15 (88.2%)	-	-
The reason for laboratory result not reported within Turn Around Time (n=27)	10 (37%)	-	17 (63%)	-	-
The reason for no laboratory result Verification (n=25)	-	-	22 (88%)	-	3 (12%)
The reason for No IQC activities Conducted(n=18)	-	3 (16.7%)	13 (72.2%)	-	2 (11.1%)

*Variables selected from Table 3 with “No” or “Partial” answers for quality assurance activities and Quality Laboratory service provision

In this study concerning to technical factors that affecting the provision of quality laboratory services, high work load was rated highest factor influenced the provision of quality laboratory services to a great extent by 56% and the second and third highest ranked factors were Equipment failure and skill gap on quality assurance practice and rated 32.2% and 10.8% respectively, is shown in Figure 2.

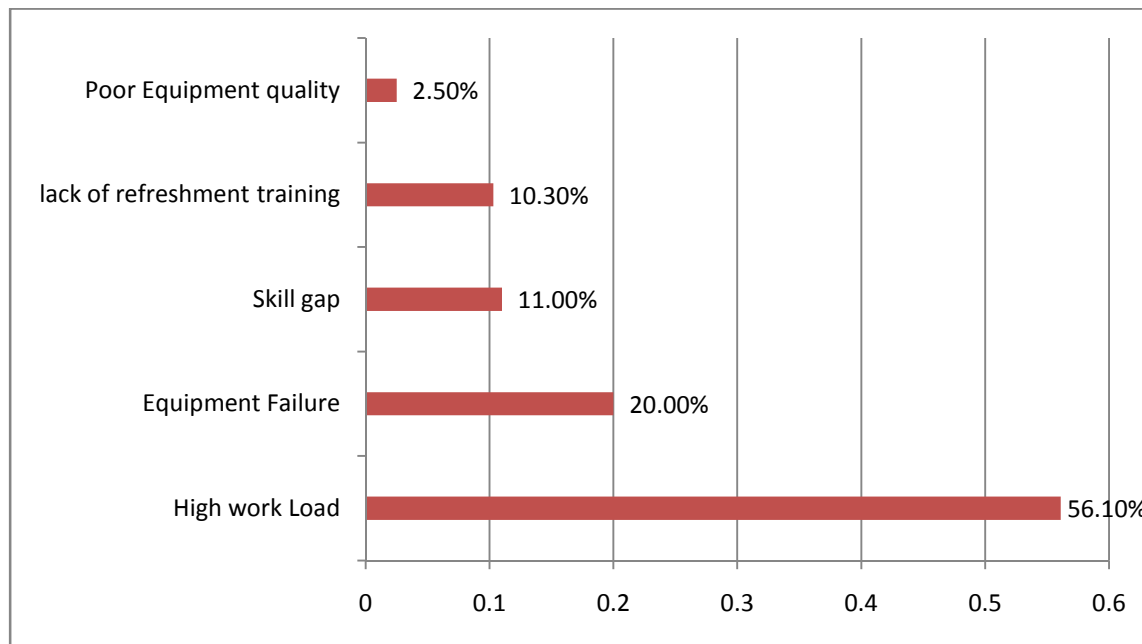


Figure 2

Technical Factors affecting the provision of quality laboratory service in South West Shewa Zone health facilities, Weliso, oromia, Ethiopia, 2020.

5.3.2. Administrative factors

Shortage of resource, poor staff commitment, poor management supports and Shortage of human resource were the major administrative factors identified and affect the quality assurance practice at the laboratories as shown in Table 5.

Table 5 Administrative Factors Affecting Laboratory service provision activities reported by Laboratory Professionals working in South West Shewa Zone health facilities, Weliso, Oromia, Ethiopia, 2020.

Variables*	Administrative factors				
	Shortage of Resource	Poor Commitment	Inadequate number of laboratory staff	Scarcity of Equipment	Poor Management Support
The reason for No Adherences to the Standard Operating Procedures (n=22)	8 (36.3%)	2 (9)	-	6 (27.3%)	6 (27.3%)
The reason for Equipment Preventive Maintenance not conducted n=47	10 (21.28%)	19 (40.43%)	20 (42.5%)	-	2 (4.26%)
The reason for No Utilization of Personnel Protective Equipment n=9	6 (66.7%)		-	-	3 (33.3%)
The reason for not Applying Laboratory Safety Practice n=6	4 (66.7%)		-	-	2 (33.3%)
The reason for no Standard test request and Reporting Format (n=18)	10 (55.5%)		-	-	8 (44.5%)
The reason for interrupted Diagnostic Service (n=60)	38 (63.3%)	4 (6.7%)	3 (5%)	11 (18.3%)	4 (6.7%)
The reason for no Customer Service Management (n=40)	20 (50%)	5 (12.5%)	-	-	15 (37.5%)
The reason for no Laboratory Result Verification (n=37)	6 (16.3%)	16 (43.2%)	15 (40.5%)	-	-
The reason for Laboratory Result not Reported Within TAT (n=11)	-	9 (81.8%)	2 (18.2%)		
The reason for Internal Quality Control Activities not conducted (n=37)	8 (21.6%)	16 (43.2%)	9 (24.3%)	-	2 (5.4%)

Regarding to Administrative factors that affecting the provision of quality laboratory services, this study identified that shortage of resources was rated highest factor influenced the provision of quality laboratory services to a great extent by 39 % and the second and third highest ranked factors were Poor staff commitment and inadequate number of laboratory staff and rated 23.4% and 16.7% respectively, is shown in Figure 3.

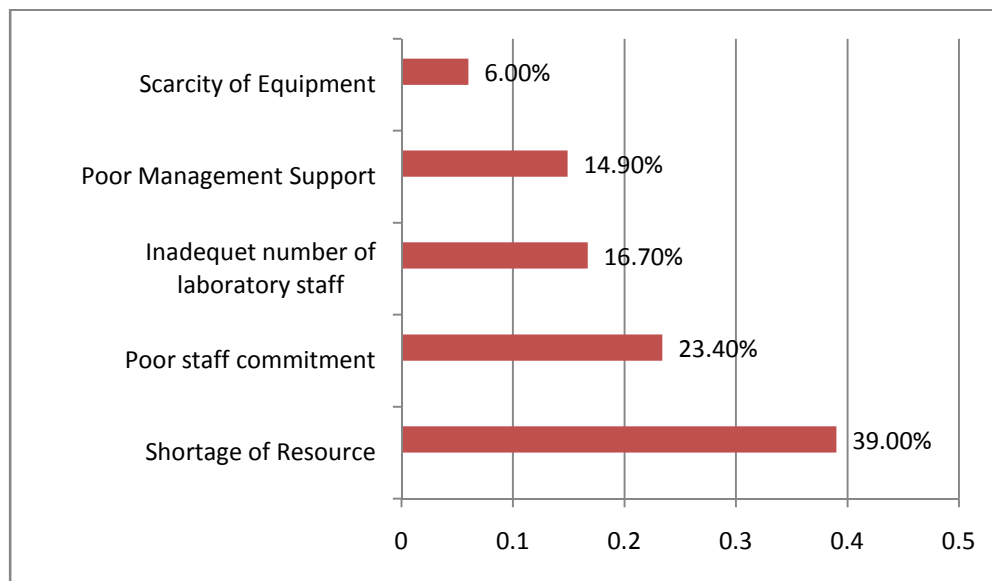


Figure 3
Administrative factors affecting the provision of quality laboratory service in South West Shewa Zone health facilities, Weliso, oromia, Ethiopia, 2020.

5.5. Result of binary and multivariate regression

Poor quality service was reported by 32 (37.6%) of the participants as shown above. The impacts of selected independent variables on quality of laboratory service were investigated using bi-variant logistic regression. Variables with p-values <0.2 in bi-variant analyses, were included in the multivariate logistic regression to determine the presence of associations between dependent variable provision of quality laboratory service and the independent variables

Finally the multivariate logistic regressions which take the effect of confounding variables into account were applied. All explanatory variables with $P < 0.20$ in bi-variant analyses were included in the logistic regression and two explanatory variables were significantly associated with quality of laboratory services.

Accordingly, provision of quality laboratory services was significantly associated with Conducting Internal Quality Control activities (AOR= 0.44, 95% CI=0.026, 0.78), System for Employee recognition (AOR= 6.02, 95% CI=1.14, 31.96) and Having Quality Manual (AOR= 2.27, 95%CI= 1.01, 14.81).

Laboratory professionals who do not have the habit of using quality manual were found to be 2.27 times more likely to provide poor quality laboratory services when compared with those who have quality manual (AOR= 2.27, 95%CI= 1.01, 14.81) as shown in [Table 6](#).

Table 6a: Logistic regression analysis showing the association between provision of quality laboratory service and independent variables in South West Shewa Zone Health facilities, Weliso, Oromia, Ethiopia, 2020.

Variables		Lab Quality Service		Crude odds ratio (95 % CI)	P. value	Adjusted odds ratio (95 % CI)	P. value
Educational status		Yes	No				
	Diploma	30	27	1		1	
	Degree	23	5	0.24 (0.81,0.72)**	0.008	0.242(0.31, 1.91)	0.177
Service year							
	<2 years	13	17	1		1	
	2-5 years	9	2	0.172 (0.04, 0.92)	0.15	0.98(0.08, 11.62)	0.99
	>5 years	31	13	0.32(0.12, 0.85)	0.11	0.48(0.06, 3.44)	0.46
knowledge about Quality Management System							
	Yes	46	20	0.23 (0.7, 0.64) **	0.004	0.8 (0.011, 1.56)	0.012
	No	7	12	1		1	
Quality Manual in the laboratory							
	Yes	29	12	1		1	
	No	24	20	2.01(0.82, 4.94)	0.12	2.27(1.018, 14.81)*	0.029
Laboratory Communication among Laboratory Staff							
	Yes	45	20	0.29 (0.10, 0.83)*	0.018	0.12 (0.016, 1.91)	0.041
	No	8	12	1		1	
Laboratory Communication with Management							
	Yes	25	10	1		1	
	No	28	22	1.96 (0.78, 4.94)	0.122	1.32 (0.29, 6.28)	0.72
System for Employee Recognition							
	Yes	27	6	1		1	
	No	26	26	4.5 (1.59,12.71)**	0.001	6.02 (1.14, 31.96)*	0.034
Adequate and quality Supplies and Reagents							
	Yes	39	15	0.39 (0.15, 0.98)*	0.04	0.22(0.036, 0.90)	0.053
	No	14	17	1		1	

Table 6b: Logistic regression analysis showing the association between provision of quality laboratory service and independent variables in South West Shewa Zone Health facilities, Weliso, Oromia, Ethiopia, 2020.

		Lab Quality Service		Crude odds ratio (95 % CI)	P. value	Adjusted odds ratio (95 % CI)	P. value
		Yes	No				
Adherence to the Standard Operating Procedure							
	Yes	48	23	0.31(0.92, 1.06)	0.053	2.618 (0.05, 1.01)	0.426
	No	5	9	1		1	
Performing Equipment Preventive Maintenance							
	Completely and regularly	30	8	1		1	
	Incomplete and irregular	7	4	2.14 (0.50, 9.18)*	0.032	1.1 (0.40, 29.9)	0.852
	No	16	20	4.68 (1.69, 12.99)	0.014	5.82 (0.35, 48.42)	0.276
Provision of uninterrupted Diagnostic Service							
	Yes	21	8	1		1	
	No	32	24	1.96 (0.74, 5.2)	0.16	0.44 (0.04, 4.61)	0.492
Laboratory result reported within Turn Around Time							
	Yes	36	15	0.51 (0.21, 1.26)	0.14	1.94 (0.34, 11.07)	0.456
	No	17	17	1		1	
Laboratory Result Verification							
	Yes	20	5	1		1	
	No	33	27	2.42 (0.84, 6.91)	0.094	0.99 (0.16, 5.71)	0.991
Internal Quality Control Activities							
	Completely and regularly	34	14	0.26(0.99, 0.69)*	0.006	0.44 (.026,0.78)*	0.025
	Incomplete and irregular	6	2	0.23 (0.40, 1.37)*	0.022	0.43 (0.001, 1.889)	0.991
	No conduct IQC	13	16	1		1	

* The odds ratio indicated that there was significant association between provision of quality laboratory service and independent variables ($p = 0.01-0.05$), ** Strong statistical significance association ($p = 0.001-0.01$).

5.5. Observational Assessment Result

To maintain and support the evaluation of quantitative data, the study area facility laboratories were assessed by observational checklist during data collection moment. The assessment covered by this observational checklist was reviewing of documents and records in the laboratory room.

Based on the observational assessments, out of 40 assessed laboratories six (15%) of them did not participate at External quality assurance activities (EQA) and proficiency testing (PT) for the last one year.

Regarding to patient management system only three (7.5%) of the laboratories had compliance handling system within the laboratory that enables patients to give feedback or present complains.

Additionally most of the laboratories (85%) had reference value for most tests on the report and the test request form found in all laboratories included patient identification, name or other unique identifier of person legally authored to request included.

From assessed health facility laboratories 2 (5%) of them did not have access of pipe water and electricity and only 15(37.5%) laboratories have laboratory room with mini store. On the other hand majority of the health facility laboratories have standard operating procedure (SOP) for majority of the tests and only 5(12.5%) laboratories did not have any SOPs in the laboratories.

From observed laboratories 10(25%) of them did not conduct and document equipment preventive maintenance for the last one year and similarly majority of health facility laboratories (52.5%) assessed did not perform and document internal quality control (IQC) measures like running controls daily, checking each reagent using known positive and negative controls, and counter check test reports with another colleague before dispatch.

5.6. Result of the key informant interview

To fortify the quantitative study part data were gathered from health professionals of five hospitals and five health centers. Interviews were open-ended in nature and primarily focused on quality of laboratory service and factors affecting quality of laboratory service. The interviewees were Laboratory head, physician, health officers and health facility administrator and they were three female and twelve male, had 2-20 years of work experiences, had 25 - 45 years of age range and had educational level from first degree to specialist at different departments.

Quality of Laboratory Service

Majority of the participants 11(73%) mentioned that their health facility laboratory provide quality service and 4(27%) of the participants mentioned that their health facility laboratory did not provide quality service (Figure 4).

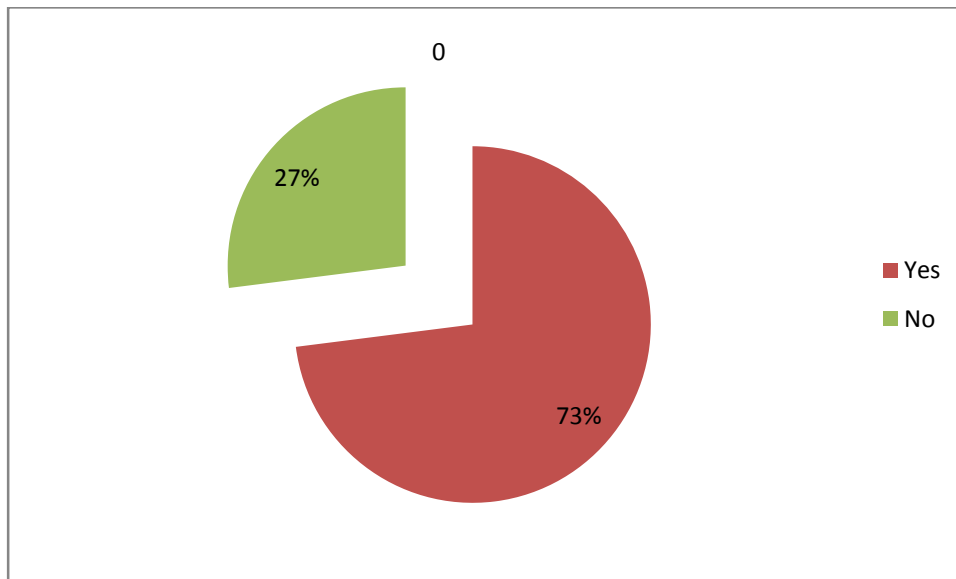


Figure 4
Provision of quality laboratory service in South West Shewa Zone health facilities reported by health professionals, Weliso, oromia, Ethiopia, 2020.

R1 from primary hospital said “the quality of laboratory service of our health facility is not good and the laboratory staff had bad name and their job was weak but now the laboratory staff number has increased and their work improved”.

R2 said that: “We have many limitations in the diagnosis of many diseases here, and this determines the quality of laboratory service and treatment and service we provide to our patients.

Factors affecting quality of laboratory service

Most of the participants 13(86.7%) mentioned that Lack of reagents had always been a major problem that affect laboratory service provision and additionally, majority of the participants mentioned that poor communication system between laboratories and other health professionals, lack of motivation and recognition, lack of commitment of health facility directors in supporting laboratory personnel’s to provide quality service and to improve their capacity based the standard of health facility and frequently equipment failure were the other factors that affect quality of laboratory service is shown in figure 5.

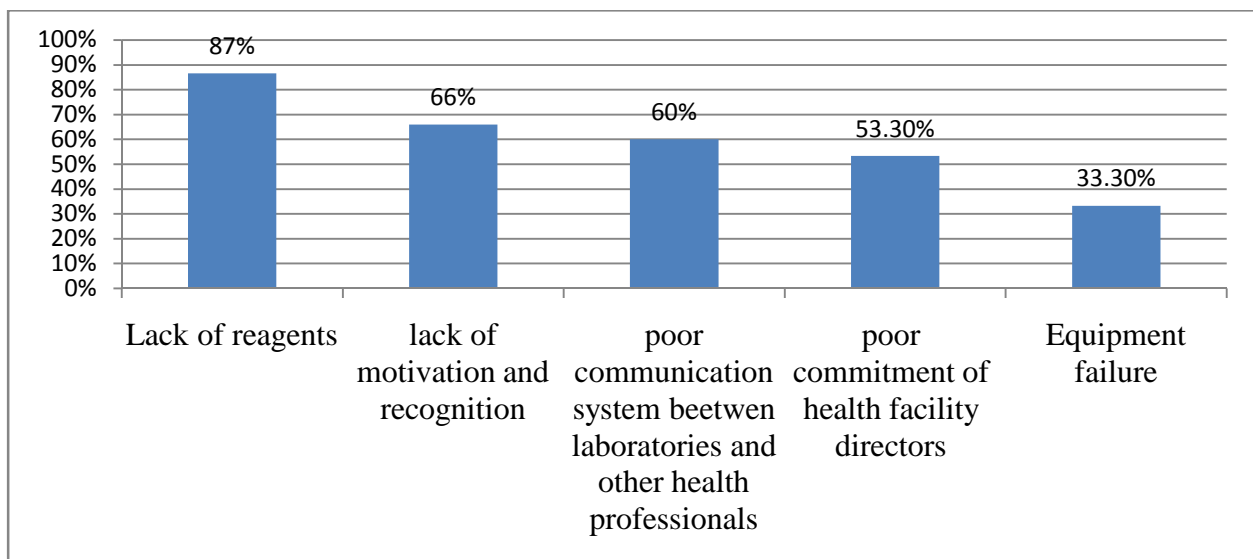


Figure 5
Factors affecting Quality of Laboratory service based on Qualitative study in South West Shewa Zone health facilities reported by health professionals, Weliso, oromia, Ethiopia, 2020.

R3 said that “there are many factors which can determine the Quality of Laboratory service in this Hospital, but above all the main factor which affects quality of laboratory service is frequently were shortage of reagents”

Communication

Communication is the major tool and a better way for efficient working and solving the gaps in a team work institutions. Regarding this issue most of the respondents 9(60%) explained that ‘unavailability of formal communication system which enables specified responsible body. In addition, most of the participants noted that communication and positive interactions between laboratory workers and clinicians are crucial but there is no managerial support, formalized system or motivation to maintain regular meetings or contact between clinicians and laboratory staff.

R4. said that ”Poor communication between physician and laboratory Staff further causes compliances on laboratories when the physician request a large number of tests , unaware of the high work load of the frequently under staffed laboratory.”

R5.From hospital said that “there is no communication between laboratory and health facility administration, even they don’t ask their demands quickly and the response from the management is also sometimes not fast.”

R6 from health center said that” due to poor management system of the health facility there is no communication between laboratory and other health professionals and laboratory with health facility administration”.

Motivation and Recognition

Finally Majority of the participants 10(66.7%) agreed that there was no system of motivating staffs in their institution. However it is well understood that motivation could be brought with simple letter recognition.

R7 Said that “Even if motivation and recognition are good for quality service provision it is not habited in our health facility and there were no system for staff recognition”.

Additionally all the participants had the same opinion on the improper time usage and they believed that delivering laboratory reports on time is one of the good measures of quality service. Majority of the participants Mentioned that most of the compliance of the patients were related turnaround time for routine tests.

6. DISCUSSION

In this study regarding to quality assurance practice and provision of laboratory service, findings from this study revealed that 54(63.5%) of the respondents indicated that there was supplies and reagents interruption and 36 (42.6%) laboratory professionals did not perform equipment preventive maintenance as per instruction. Additionally, internal quality control (IQC) was not conducted as stated by more than 34.1% while 9.4% not regular and complete and of the respondents only 25(29.4%) of the laboratory professionals verify laboratory results.

In this study findings showed that the majority of laboratory professionals work without job descriptions, continuing education and training. However Schneidman M, et al 2014 revealed that education, training and motivation are major factors for implementation of quality system (5) and non-trained professionals can be costly to the laboratory system due to inaccurate test results. In addition to this, among participants 91.8% of the professionals were not satisfied with their salary and there were poor staff recognition system, as well as poor communication system with management, physician and among laboratory staffs. However, the study done in Kenya by Ojwang P. et al revealed that the provision of efficient and quality laboratory services requires a critical mass of trained and well-motivated staff (24).

According to this study 32 (37.6 %) laboratory professionals believed that their laboratories did not provide quality of laboratory services as per the standards. This finding is slightly higher than the study conducted in Addis Ababa health facilities by Eyob A et al. (15) who reported that 34.5% of laboratory professionals believed that their laboratories did not provide quality laboratory results. Additionally the result of this qualitative study also shows that 4(27%) of them mentioned that there is poor quality service in their institutions which is concordant with quantitative study.

Turnaround time (TAT) is one of the most noticeable signs of laboratory service and is often used as a key performance indicator of laboratory performance. In this study, about 40% of the participants believe that TAT was not followed for most laboratory tests performed and they do not report the laboratory result within a stated turnaround time. Lower than this finding was reported from Addis Abeba 32.9% (15) of laboratory results were claimed not to be released

within predefined turnaround time. This difference may be due to the difference in human resource, workload, and workflow arrangement difference in the study institutions. Therefore, the laboratory, in consultation with the users, should establish turnaround times for each of its examinations that reflect clinical needs and periodically evaluate monitoring TAT is the ideal choice of activity to illustrate the laboratory's commitment to providing a high quality service.

This study also found out that result verification and reporting system, quality control activities, equipment preventive maintenance, customer management and adherences and usage of SOP were not implemented as per the standards. But International Organization for Standardization (ISO-15189) revealed that implementation of laboratory standards helps laboratories to demonstrate a well-functioning quality management system, technical competence, and customer-focused services that contribute to health care services (4). So poor quality management system directly affects the provision of quality laboratory services as well as patients and health care services at large.

According to this study the results indicated that 63.5% of laboratory professionals reported that there was scarcity of laboratory equipment in their laboratories and 36 (42.6%) laboratory professionals did not perform equipment preventive maintenance as per instruction. This finding was similar to that of Brown JA (24) who indicated that laboratory medicine in sub-Saharan Africa is characterized by an acute shortage of modern equipment and it is slightly lower than the study conducted in Afar, Ethiopia by Andualem T et al (2018) showed whose results were 66.7% of the participant respond that there is no enough equipment in their laboratories (34) and also lower than the study conducted on factors affecting implementation of laboratory management system in Addis Ababa, Ethiopia by Abay S. et al revealed who that lack of enough equipment was reported by 73.4% (21) laboratory professionals. This difference may be due to the difference in health facility status and sample size.

Finding from this study also shows 72.9% of the participants reported lack of professional development, high work load 57.6% and 80% of the participants reported lack of refreshment training and similarly study conducted in Awizone, Ethiopia (35) shows that lack of professional development was reported by 76.9% and followed by excessive work load 12 (46.2%), Lack of in-service training 14 (53.8%) and lack of appreciation by the management 6 (23.1%).

Finding from this study also shows internal quality Controls (IQC) were not conducted as reported by 34.1% and External Quality Assurance (EQA) were not conducted as per the standards. But Masanza MM and his colleagues showed that external quality assurance(EQA) is critical and applicable models for achieving accurate and reliable laboratory services(17). It is very important to maintain EQA and IQC for reliable, quick and dependable results. This will help the clinicians to come to a correct diagnosis and treat the patient early.

Besides this, regarding to technical factors that Affect quality of laboratory service this study discovered that high workload, equipment failure and lack of knowledge were the major technical factors that affecting the quality assurance practices and provision of laboratory services and rated by 56.1%, 20% and 11% respectively. Similarly, the African Field Epidemiology Network (AFENET) study showed that: laboratory equipment maintenance and calibration is one of the key components of improving the quality of laboratory services. Additionally, quality equipment is essential to produce the valid and reliable laboratory results needed to inform decision-making in outbreak situations(25)Furthermore, another study done in Zambia by Misuzu et al revealed that lack of equipment maintenance, shortage of reagents and supplies, poor laboratory management and lack of follow-up were identified as factors(15, 25) .

Additionally, the study also revealed that provision of quality laboratory services had statistically significant association with Conducting Internal Quality Control activities regularly, Having Quality Manual and system for employ recognition. This clearly indicates that there existed a negative relationship between factors affecting quality laboratory service and provision of quality laboratory service.

Laboratories who have good practices of regular and complete Internal Quality Control activities were much better laboratory quality service provider than laboratories which doesn't conduct Internal Quality Control Activities 0.44 (0.026, 0.78) , Similarly a study conducted in Gonder, Ethiopia by Belete B et al revealed that not conducting internal quality control regularly were identified as the major factors affecting quality of laboratory service(20).

Laboratory professionals with lack of recognition system were found to be 6.02 times more likely to provide poor quality laboratory services when compared with those who have recognition in their health facilities. Similarly, the study done in Kenya by Ojwang P. et al revealed that lack of motivation and lack recognition affects quality of laboratory service (18).

A study conducted in Tanzania explained that factors that influenced laboratories' readiness for quality improvement were shortage of staff, lack of knowledge, shortage of resource and poor staff commitment(28). This report is concordant with the finding of current study which identified the shortage of resource, poor staff commitment and poor management supports as the major administrative factors that affect the quality assurance practice at the laboratories. Similarly the study done in Addis Ababa by Abera et al. revealed that lack of resource, poor management system and shortage of staff were the major factors affecting laboratory services(15).

In general the major findings from this study were technical factors associated with high work load, equipment failure, and skill gap about quality management system. Administrative factors such as shortage of reagents and resource, human resource, infrastructure problem, and poor commitment. These are challenges facing laboratory systems in resource-poor settings like Ethiopia. Together, these factors compromise the provision of quality laboratory services and quality health care services delivery as well as public health provision. So improving laboratory quality systems requires commitment at all levels, financial support, and strong support and follows up from the health system leaders, and competent and motivated laboratory staff.

7. Strength and Limitation of this study

7.1. Strength of the study

The study used mixed study design to support and strengthen the quantitative finding.

7.2. Limitation of the study

This paper is built on the laboratory professional perceptions on the quality of service and the quality of the laboratory service is not measured, which may bear a certain level of subjectivity.

8. CONCLUSION

In conclusion, the aim of this study was to identify the factors affecting the quality of laboratory service delivery. Most of the laboratories did not have: Quality manual, system for staff recognition, and continuing education/training program and more than one third of the study participants reported that their laboratory did not provide quality laboratory services

Additionally in this study high number of the participants disclosed that there is no quality manual in their laboratory and majority of the participants did not satisfied with their salary and also lack of training and lack of opportunity of education were reported by the participants.

The finding also revealed that conducting internal quality control activities regularly, lack of Quality Manual and Lack of staff recognition had a significant association with provision of quality laboratory service in south west shewa health facilities.

9. Recommendation

- To hospitals and health centers found in South West Shewa Zone
 - Analysis is needed on human resource management of medical laboratories; staff motivation and recognition and continuous training incentives.
 - There is need for a government and stakeholders to be supporting and strengthening laboratory quality system since it is an essential component of health care system.
 - Proper regulation of laboratory services through activities such as setting and supervising laboratory standards and standardizing and regulating in-service training will help improve morale and the quality of services.
 - Setting strategies for formal and regular communication between laboratory professionals and other health professionals.
 - As laboratory services is an essential component of the health care system, laboratory capacity building and quality management system implementation will enable to provide quality and reliable services for disease treatment and prevention. Therefore, government and stakeholders should understand and address the factors affecting the provision quality laboratory service and they should work together for strengthening quality of laboratory service.

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Annex I: Information Sheet

Code _____

Title of the project: Assessment of Factors Affecting Quality of laboratory service in South west shewa zone, Ethiopia

Name of Principal Investigator: TamiratWakuma

Organization: Addis Ababa University

This information sheet was prepared for Medical laboratory professionals who will be involved in project entitled above. I will tell them about the whole processes that have been undertaken in the study and requesting them to participate voluntarily.

Introduction:

This is to invite you to participate in a study conducted by TamiratWakuma, MSc student at Addis Ababa University, College of Health Science, and Department of Medical Laboratory Science. I am conducting a research on Factors affecting quality of laboratory service. I am going to give you information to be part of this research. Please read or understand the following information and ask any doubt you have. However, you are not obligated to participate and you can refuse to answer any questions or withdraw from the interview at any time. You will still be able to receive the services if you do not want to participate. If you are interested to being part of this study, you have to sign on the consent form.

Procedure: - This questionnaire will take about 15 minutes of your time and your honest answer to these questions will help me to identify factors affecting quality of laboratory service and will enable to design better mechanism to improve provision of quality service.

Benefit: - This study will help you and your organization to identify factors affecting quality of laboratory in your institution

Risk: -There is no risk to you from answering the questions.

Payment: - There is no payment to you for being part of the study.

Confidentiality: - All information collected during this study will be kept private and will only be known by the investigators

Annex II: Consent form

Participant Agreement

I have read the information above, or it has been read to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. I voluntarily consent that I would participate in this study and am a participant in this study and understand that I have the right to withdraw from the study at any time.

Participant name _____ signature _____

Date, _____, _____, _____ (dd/mm/yy)

Name of investigator _____ Signature _____ Date _____

You can contact the principal investigator for any questions about any part of the research study by the following address.

TamiratWakuma

Cell phone: +251913648182

EMAIL:twakuma10@gmail.com

Thank You for Your Cooperation

Annex III: Questionnaire

Part I Socio demographic Data

Dear participant, the following questions are targeted to differentiate your Socio Demographic characteristics Please tick the best proper choice of answer code

S.N	Socio demographic Data	Participant Code-----
1.	Age: -----	
2.	Sex:	1 Male 2 Female
3.	Health Facility Type	1. Hospital 2. Health Center
4.	Qualification of medical laboratory professional	1. First Degree 2.Diploma 3. Certificate 4.Masters
5.	Service year of medical laboratory professional	1.<2 years 2. 2-5 years 3. >5 years
6.	Responsibility	1. Staff 2. Safety officer 3. Quality officer 3. Dept Head

Part II Laboratory management activity

S.N	Laboratory management activity	1. Yes	2. No
7.	Do you have Knowledge about laboratory quality system essentials?		
8.	Does your laboratory have an appropriate quality policy?		
9.	Is there communication among laboratory staff on service provision?		
10.	Do you communicate with physicians Of your institution about result /laboratory service?		
11.	Does the laboratory have communication tool with upper Management regularly or at any time regarding personnel, facility and other operational needs?		
12.	Are you satisfied with your current salary?		
13.	Is there System for employee's recognition in your institution?(certificate or incentives)		
14.	Is there opportunity to Attend continuing education program?		
15.	Do you attend laboratory refreshment training? If yes list the training you received.....		
16.	Do you have written Job descriptions for assigned task?		
17.	Do you have adequate and quality supplies & reagents?		
18.	Do you have adequate and quality equipment in laboratory?		
19.	Do you conduct Patient satisfaction survey on laboratory service? If yes.....		
20.	Is there Adequate number of staff for laboratory services?		
21.	How you see Laboratory workload in your facility?	High <input type="checkbox"/>	Fair <input type="checkbox"/> Low <input type="checkbox"/>

PART III Quality assurance practices and provision of laboratory services

S.N		Dear participants, the following questions are target to see your Quality Assurance practice and provision of laboratory service				
		1.Y es	2.parti al	3.No	If no/partial what is/are the factors /Reasons	
					Technical factors	Administra tive factors
22.	Are standard operating procedures for laboratory procedures available in this Laboratory?					
23.	Do you perform Equipment calibration & maintenance?					
24.	Do you have the habit of Utilization of personal protective equipment?					
25.	Do you have the habit of applying Laboratory safety practices?					
26.	Does the laboratory have standard printed test requests and reporting forms?					
27.	Do you Provide un interrupted diagnostic services for all requested tests?					
28.	Do you perform laboratory quality improvement activities					
29.	DO you report laboratory result within statted TAT?					
30.						

	Is there applicable Customer services management					
31.	Do you achieved acceptable PT/EQA results on the two most recent PT challenges?					
32.	Do you Countercheck test reports with another colleague before dispatch? Laboratory result verification					
33.	Are test requests checked with test results and technically verified by an authorized person, thereby assuring the accuracy and completion of all tests?					
34.	Is there an IQC process in place to verify the accuracy of results on each batch that is analyzed?					
35.	Do you perform, document and review the IQC prior to release of results?					
36.	Is there improvement measure and follow-ups to fill the gaps from quality indicators monitoring?(EQA/IQC)					
37.	Does the report indicate and document biological reference ranges for each test?					
38.	Does your Laboratory develop and monitor TAT					
39.	Are the date and time of specimen collection, receipt of specimen and release of report indicated on the laboratory report format?					
40.	Do you periodically evaluate your performance to meet the established turnaround time?					

41.	Do you believe that your laboratories provide quality of laboratory services					
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Part IV Facility Observation Checklist

Facility name _____ Date: _____

S.N	Facility Observation Checklist	1.Yes	2.partial	3.No	Remark
1.	Is there a system or procedure for document & record control and retention?				
2.	Does the laboratory have an appropriate quality policy?				
3.	Are SOP for laboratory procedures available in your laboratory				
4.	Is there developed and monitored Laboratory TAT document?				
5.	Is the IQC performed, documented and reviewed prior to release of results?				
6.	Does the facility lab take part in external quality assurance (EQA) program?				
7.	Do you achieved acceptable PT/EQA results on the two most recent PT challenges?				
8.	Is there improvement measure and follow-ups to fill the gaps from quality indicators monitoring?(EQA/IQC)				
9.	Is routine preventive maintenance performed on all equipment and recorded according to SOPs?				
10.	Is there Organized and implemented Work flow in the laboratory?				
11.	Has the laboratory provided uninterrupted testing services, with no disruptions due to stock outs in the last six month				

12.	Is there developed Criteria for acceptance or rejection of samples.				
13.	Does the laboratory have an appropriate quality policy?				
14.	Do you have documented policies in place to ensure that quality management system documents are understood and implemented?				
15.	Are there documented standard operating procedures (SOP) for tests performed				
16.	Is there a system or procedure for document & record control and retention?				
17.	Are documents & records properly maintained (including an up-to-date Master List) and easily accessible?				
18.	Is there any documented internal audit about customer satisfaction and feedback filled by physicians?				
19.	Is there developed and monitored Laboratory TAT document?				
20.	Does the facility have adequate equipment in laboratory? Check inventory data				
21.	Is equipment installed and placed as specified in the operators' manuals and Uniquely labeled or marked?				
22.	Is current equipment inventory data available on all equipment in the Laboratory?				
23.	Is routine preventive maintenance performed on all equipment and recorded according to SOPs?				
24.	Has the laboratory provided uninterrupted testing services, with no disruptions due to equipment failure in the last year?				
25.	Has the laboratory provided uninterrupted testing services, with no disruptions due to Electric failure?				
26.	Is your laboratory class enough and conducive to perform test (enough room with mini store)				
27.	Is there Organized and implemented Work flow in the				

	laboratory?				
28.	Are inventory records complete and accurate, with minimum and maximum stock levels denoted?				
29.	Are stock counts routinely performed and documented?				
30.	Are all reagents/test kits in use (and in Stock) currently within the manufacturer assigned expiry dates. Check.....				
31.	Is there a tool for regularly evaluating client satisfaction and is the feedback received effectively utilized to improve services? Check document.....				

Part V In-Depth Interview Questions

Deep interview questionnaire for laboratory Quality assessment among health professionals

1. How do you see your health facility laboratory service?
2. How do you explain the quality of laboratory services in health facility?
3. What are the Factors affecting quality of laboratory service?
4. How do you explain the management support for laboratory service?
5. Whom do you think that the responsible body for quality of laboratory service

Annex VI: Declaration

Title of Project: Assessing Factors Affecting Quality of Laboratory Service in South West Shoa Zone Health Facilities, Oromia, Ethiopia

I, the undersigned, declare that this MSc research project is my original work. It has not been presented for a degree in any other University. False statements could be cause for invalidating this research project and may lead to other administrative or legal action.

M.Sc. candidate: **TamiratWakuma (B.Sc.)**

Signature: _____

Date of submission: _____

This Thesis has been submitted with our approval as advisors.

Advisor: **FatumaHassen (MPH, PhD candidate)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: **HabtamuMolla (MSc, PhD candidate)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

Advisor: **Aster Tsegaye (MSc, PhD)**

Signature: _____

Date: _____

Place: Addis Ababa, Ethiopia.

